Clinical Policy Recommendation Committee Minutes

Wednesday 26th June 2024, 09.30-11.30
via Microsoft Teams

Present:

Name	Job Title	Organisation
Dr Glen Allaway	Chair	NHS Devon
Dr Kay Brennan	Voting Member	NHS Devon
Dr Andrew Craig	Voting Member	NHS Devon
Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon
Dr Lucy Harris	Voting Member	NHS Devon
Dr Claire Hooper	Voting Member	NHS Devon
Barbara Jones	Head of Contracting	NHS Devon
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NHS Devon
Mark Taylor	Lay Public Member	
Dr Ben Titford	Voting Member	NHS Devon
Sara Wright	Head of Nursing and Quality	NHS Devon

Guests:

Dr Patrick English	Consultant Physician	UHP NHS Trust
Matt Howard	Clinical Evidence Manager	NHS Devon
Peter Kelly	Diabetes Nurse Consultant	UHP NHS Trust
Nic Perrem	Healthcare Evidence Reviewer	NHS Devon
Dr Christopher Redford	Consultant Diabetologist	T&SD NHS FT
Amy Rice	Clinical Effectiveness Pharmacist – Commissioning Projects Lead	NHS Devon
Dr Neil Walker	Consultant Physician	RDUH NHS FT
Dr Roderick Warren	Consultant Physician	RDUH NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon
Rebecca Owen	Clinical Effectiveness Governance Manager	NHS Devon

1. Welcome and announcements

Apologies:

Name	Job Title	Organisation
Paul Foster	Director of Pharmacy	T&SD NHS FT
John Trevains	Deputy Chief Nursing Officer	NHS Devon
Dr Emily Youngman	Public Health Representative	Devon County Council

Confirmation of voting members and Declarations of interest

The five voting members present were identified.

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
Continuous glucose monitoring in diabetes	Manufacturers of glucose monitoring systems for diabetes, such as Abbott, Dexcom, Gluco Rx, Medtronic, Medtrum Ltd, Senseonics Inc, Ypsomed Ltd *(list not exhaustive)*
Guanfacine (Intuniv®) **for attention deficit hyperactivity disorder (ADHD) in adults** Alternative treatments: **Dexamfetamine** **Lisdexamfetamine** (Elvanse®, Elvanse Adult®) **Methylphenidate** **Atomoxetine**	Takeda UK Ltd Various manufacturers Takeda UK Ltd Various manufacturers Various manufacturers Would benefit from private provision of ADHD services
Myringotomy (with or without grommet insertion) and adjuvant adenoidectomy in children under 12 years with otitis media with effusion	Would benefit from private provision of myringotomy/grommets or alternative treatments for otitis media

Name of Attendee	Role	Declaration
Richard Croker	Deputy Director for Medicines Optimisation	Declared an indirect non-financial personal interest
Patrick English	Consultant Physician	1. Received educational support from Abbott who gave educational grant to our R&D team for a team member to attend the ATTD conference in Italy in February 2024 and this was used by me to facilitate my attendance covering flights and conference costs 2. I have been used as a consultant by Roche as they are developing a new CGM product for the market. I will be paid for this time and for future meetings to discuss current features/improvements on the device-this device is not yet available for use. Agreement is that I will give no more of 10 hours time at £250 per hour.
Peter Kelly	Diabetes Nurse Consultant	In receipt of lecture fees in the last year - Provided education for Abbott
Amy Rice	Clinical Effectiveness Pharmacist - Commissioning Projects Lead	Declared an indirect non-financial personal interest

Notification of Any Other Business

No other items of business were noted.

2. Minutes of the meeting held on 17th April 2024 and matters/actions arising

The minutes of the meeting held on 17th April 2024 were approved.

Summary of actions			
	Action	**Lead**	**Status**
24/01	Tonsillectomy for quinsy – amend draft commissioning policy to clarify the definition of 'recurrent'.		Complete

24/02	Tonsillectomy for quinsy – policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 26th June 2024 The final outstanding approval (for the QEIA) has now been received and the updated policy will be published shortly.	Rebecca Owen	Pending
24/03	Review of commissioning policy for radiofrequency ablation for Barrett's oesophagus - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 26th June 2024 The final outstanding approval (for the QEIA) has now been received and the retirement of this policy will be actioned shortly.	Rebecca Owen	Pending
24/04	Review of commissioning policies for drug treatments for diabetes: Alogliptin for type 2 diabetes - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 26th June 2024 The final outstanding approval (for the QEIA) has now been received and the retirement of this policy will be actioned shortly.	Rebecca Owen	Pending
24/05	Review of commissioning policies for drug treatment for diabetes: Insulin degludec for type 1 diabetes - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 26th June 2024 The final outstanding approval (for the QEIA) has now been received and the retirement of this policy will be actioned shortly.	Rebecca Owen	Pending
24/06	Clinical Policy Recommendation Committee Annual Report 2023/24 to be submitted within the ICB for information and assurance. 26th June 2024 This will be submitted to the ICB for information and assurance alongside the CPEC Annual Report. The Clinical Effectiveness Team will plan internal onward reporting in line with changes in the organisation, i.e. the appointment of a new Chief Medical Officer.	Rebecca Owen	Pending

The Chair explained how items 3, 4 and 5 would be presented, discussed and, in the case of item 5, voted on. The Clinical Effectiveness Team present papers for each of the items. Items 3 and 4 were brought to the committee for noting only. Dr Patrick English, Consultant Physician and Peter Kelly, Diabetes Nurse Consultant from UHP NHS Trust, Dr Christopher Redford, Consultant Diabetologist from T&SD NHS FT, Dr Roderick Warren Consultant Physician and Dr Neil Walker Consultant Physician from RDUH NHS FT were present for discussion of these three items.

3. Implications of NICE TA943 and NG18 on the existing NHS Devon commissioning policy for continuous glucose monitoring in diabetes

Nic Perrem, Healthcare Evidence Reviewer, presented an overview paper.

Continuous glucose monitors (CGMs) are small wearable devices which measure glucose levels in the users interstitial fluid. These devices do this using a small sensor which is placed just under the skin. The information captured is then wirelessly transmitted to a reader device. There are two forms of CGM, these are intermittently scanned devices which require the user to actively take a measurement by bringing their reader into close proximity of their sensor and real time devices which do not require an active reading to be taken meaning that the sensor automatically passes the users glucose level to the reader in real time. Both forms of CGM are available on the NHS via prescription issued by a patient's GP. There are also some real time CGM devices which are only available from specialist secondary care diabetes teams. These systems must be procured directly by Trusts following standard secondary care procurement processes. Secondary care procured real time CGM systems provide a greater range of functions to users, however these systems are more costly than GP prescribable real time CGMs.

In December 2022 NHS Devon published a commissioning policy for CGM in diabetes. The policy was developed in line with best practice principles for the provision of these devices published in NICE guidelines NG17, NG18 and NG28 which cover the management of diabetes in children, young people and adults. To ensure best use of NHS resources access criteria were agreed in the policy which allow for access to secondary care procured real time CGM systems in those patients deemed to have the greatest clinical need.

All patients living with type 1 diabetes require treatment with insulin. Insulin is either provided via injection or may be delivered via a small wearable insulin pump.

Hybrid closed loop systems are comprised of an insulin pump, a CGM, and software which allows for integration between the two. These systems allow for insulin delivery to be automated to information received from the users CGM device.

In December 2022, NICE published TA943 which covers hybrid closed loop systems for type 1 diabetes. One of the patient groups for which the NHS Devon commissioning policy allows provision of a secondary care procured CGM system is now covered by TA943 meaning that the access criteria stated within NHS Devon's existing policy are superseded by the NICE TA and therefore will be removed.

In May 2023, NICE published an update to NG18 which covers management of type 1 and type 2 diabetes in children and young people. As a part of this update a new recommendation was made that a real time CGM should be offered to some children and young people living with type 2 diabetes. This group is not covered in the NHS Devon policy.

The publication of NICE TA943 and the update to NG18 have implications for the existing CGM commissioning policy. These implications are considered under agenda items 4 and 5.

4. TA943: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

Rebecca Owen, Clinical Effectiveness Governance Manager presented a paper.

The committee received a presentation on TA943: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes for information only in line with NHS Devon's governance requirements.

NICE technology appraisals (TA) carry a statutory duty for ICBs to fund them in line with the recommendations made by NICE. Each TA will detail an implementation period after which the ICB is required to fund the technology. For most TA's this period is 3-months, however for fast-track TAs the implementation may be set at 30 days.

TA943 which covers hybrid closed loop systems in diabetes recommends the use of this technology in 3 patient groups, these are:

- Children and young people with type 1 diabetes
- Women, trans men, and non-binary individuals who are pregnant, or planning a pregnancy and
- People with type 1 diabetes who despite use of a CGM, or insulin pump are unable to achieve a HbA1c of 7.5% or lower.

The TA also states that hybrid closed loop systems should only be used when delivered in line with the NHS England implementation plan and when procured at the NICE defined cost-effective price agreed with NHS Supply chain.

The implementation period set for TA943 is five years. This implementation period is longer than usual as NHS England submitted a funding variation request to NICE, which was accepted. The rationale behind this decision was that the cost for roll out of these systems is large, and that system capacity constraints would not make it practicable to immediately roll out hybrid closed loop systems to all individuals covered by the TA.

To support the roll out of TA943 NHS England has published an implementation plan. This plan highlights 3 priority groups for hybrid closed loop roll out among patients with type 1 diabetes. These groups are:

- Children and young people.
- Pregnant individuals, or those planning a pregnancy.
- Current insulin pump users who meet the TA criteria.

The current local CGM commissioning policy makes provision for insulin pump users who have been deemed to benefit from integration between the pump and a CGM to have access to a secondary care procured CGM system. This group is now covered for access to a CGM which is interoperable with an insulin pump due to the eligibility criteria set in TA943. This patient group is also identified as one of NHS England's priority groups for hybrid closed loop role out.

Where a TA exists for a technology, the ICB has a statutory duty to fund this in line with the TA recommendations.

As such the existing local CGM commissioning policy will be amended as follows:

Under the text which defines access to a secondary care procured CGM system, group 3, defined as "Patients who receive insulin via a pump and who have been deemed likely to benefit from integration between CGM and pump by members of the specialist secondary care diabetes team"

will be removed from the CGM policy. Patient group 4 will be renumbered as patient group 3. No other changes relating to the implications of TA943 on the existing CGM policy will occur at this time.

5. NG18: Diabetes (type 1 and type 2) in children and young people

Nic Perrem, Healthcare Evidence Reviewer, presented a paper.

NG18 covers the management of diabetes in children and young people. An update to this guideline was published in May 2023. This update recommends that children and young people living with type 2 diabetes should be offered a real time CGM if:

- They have a need, condition, or disability (including mental health need, learning disability or cognitive impairment) that means they cannot self-monitor their own blood glucose.
  or
- They would otherwise need to self-monitor blood glucose 8 or more times daily.
  or
- They have recurrent or severe hypoglycaemia.

A recommendation was also made that a real time CGM may be considered in children and young people living with type 2 diabetes who are insulin treated.

The existing NHS Devon commissioning policy for CGM which was published in December 2022 does not make provision for these devices in this group as the guidance in NG18 at that time did not include this recommendation. The updated NICE guidance was published following a range of stakeholder feedback received by NICE in consultation for the planned update to NG18 which aimed to review the use of medicines in children and young people living with diabetes. The NICE committee decided to update the guidance relating to CGM use in children and young people living with type 2 diabetes as they deemed that this group of individuals commonly suffer from a range of other health issues, such as autism spectrum disorder, learning disabilities, mental health disorders, and childhood obesity. NICE identified that children and young people with type 2 diabetes also experience a range of health inequalities, and that the non-provision of CGM for this group could further worsen health outcomes.

NHS Devon has a statutory duty placed upon it by the Health and Care Act 2022 to reduce health inequalities with respect to the outcomes achieved for the population of Devon due to the provision of health services. The ICB also has a key strategic mission set out within its joint forward plan to improve health outcomes and reduce health inequalities particularly in individuals living with mental illness, learning disabilities, and/or autism.

A budget impact assessment has been undertaken to understand the likely impact of a change in the CGM commissioning policy to include this patient group in line with the updated NICE guidance.

Data from the national paediatric diabetes audit identifies the likely number of children and young people living with type 2 diabetes in Devon. If all these patients were to be provided with a real time CGM system the total annual spend on these devices for this group would be between £11,489 and £26,000 annually. It is likely that these patients are currently using finger prick blood testing for glucose monitoring at present. This would not be required if they transitioned to use a CGM, meaning that the current costs for finger prick testing can be offset against the increased costs of CGM use. Previous modelling undertaken by the Clinical Effectiveness Team suggested that the average patient with diabetes in Devon would undertake 4.6 finger prick tests daily, this equates to an annual cost of £295.15 per patient. When offset against the total population costs

the Clinical Effectiveness team assume that the uplift in glucose monitoring costs for this patient group would be between £8,012 to £22,163 per year.

The Clinical Effectiveness team have received one piece of feedback from specialists relating to this proposed change to the policy. This was from a consultant physician in diabetes and endocrinology based at RDUH. It highlighted that there is some discordance between the criteria used by NICE for children and young people with type 2 diabetes and that used for adults with the same form of diabetes. The specialist queried how decisions relating to continuation when a child transition into adult services should be made. The Clinical Effectiveness team agreed with the feedback and suggestions received. As such continuation criteria have been included in the proposed policy amendments.

A discussion took place the main points raised included:

- Specialists present raised a number of issues relating to the implementation of TA943. These discussions included:
  - Due to the funding constraints of the NHS England 5-year roll out plan the number of patients in Devon who could receive a hybrid closed loop system in the first year of the implementation period would be limited. Specialists suggested that this would account for only a small percentage of children.
  - Of concern to specialists present was the provision of HCL to patients with Type 1 diabetes who are pregnant. Specialists stated that the provision of an insulin pump is common practice in this population. The existing policy allowed for provision of a hospital procured rtCGM in individuals who had been deemed to benefit from integration between their pump and CGM. Specialist felt that when this is removed (as per agenda item 4) the ability of these individuals to form a closed loop between the CGM device for which they would still be funded and the pump they have would be impeded.
  - It was confirmed that agenda point 4 was an item for committee information only and that the ICB will provide funding for hybrid closed loop technologies in line with TA943 and NHS England's implementation plan.
  - Specialists raised issues around the number of patients who would be going to trusts to access hybrid closed loop systems and suggested that not having funding in place early would result in serious capacity implications which would result in an insurmountable backlog of patients building up in the final year of the implementation period. This could result in the ICB not keeping up with its statutory responsibilities. As a minimum all currently eligible children and young people need to be seen early.
  - A committee member asked whether in terms of health inequalities pregnancy is a temporary protected characteristic. It was noted that it is.
  - It was noted that funding for CGM and hybrid closed loop technologies was creating operational issues for the specialist diabetes teams. A specialist form UHP reported how insufficient funding was being made available resulting in difficult conversations with their finance team resulting in the need to write a business case. In the specialist's opinion, this is a very difficult situation because CGM is transformative for the mental health of patients.
  - Specialists also reported that patients' expectations are that they can now be provided with a hybrid closed loop system, meaning that specialist teams are having to have difficult conversations with patients to explain that this technology is not widely available.
  - The Clinical Effectiveness team stated that hybrid closed loop systems would be commissioned in line with the recommendations made in NICE TA943, and implementation would be delivered in line with plans published by NHS England. It was confirmed that the NHS England rebate for this technology is yet to be put in place, and that when this is available the hybrid closed loop delivery group would be working with providers to ensure optimisation of delivery. It was also confirmed that the ICB has a statutory duty to fund hybrid closed loop systems in line with TA943 which has a 5-year implementation period from December 2023.
  - It was noted that whilst the ICB recognises the challenges faced by providers in the delivery of this technology, commissioning and implementation of these devices will not be able to

occur at a more accelerated pace, or in a wider patient population than that recommended by NHS England in the national implementation plans referred to in the NICE guidance. The ICB is in segment four of the NHS Oversight Framework (NOF4) and the health system of Devon is overspent. NHS England therefore holds considerable control over the ICBs current spend. NICE has included a five-year implementation period for TA943. After that time routine commissioning of hybrid closed loop technologies must occur in line with the recommendations made by NICE. The ICB will be fully compliant with this statutory obligation. Delivery of this technology within the 5-year implementation period will be guided by NHS England's delivery plan. At such time as it is made available additional funding from NHS England will be used to optimise the delivery of this technology within Devon.

- It was noted that FreeStyle Libre 2+ is on the Clinical Effectiveness Team's work plan and the team would like to expedite this for review by the Formulary interface Group as soon as possible. The team can also look at Dexcom ONE+, and if required Freestyle Libre 3. Specialists noted that the benefit of FreeStyle Libre 2+ is that it can be linked to a pump without extra cost. Freestyle Libre 2+ gives real-time CGM with less cost, it saves £200 per month. Specialists suggested it be made GP prescribable.

- The chair noted that whilst the above conversation raised many valid points it was not directly linked to the item under discussion, and that a vote regarding agenda point 5 would take place.

The committee voted unanimously in favour or recommending acceptance of the updated commissioning policy for continuous glucose monitoring in diabetes following consideration of the implications of NG18: Diabetes (type 1 and type 2) in children and young people.

ACTION: Policy Recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.

6. Guanfacine for attention deficit hyperactivity disorder (ADHD) in adults

Within NHS Devon, guanfacine is routinely commissioned for the management of ADHD in children and adolescents, but there is no commissioning position for its use in adults. This scenario has resulted in queries on the management of patients initiated on guanfacine whilst under child and adolescent services who later transition to adult services when they turn 18. As such, a commissioning position is required for the use of this drug in adult patients. To ensure equitable access to treatment, the Clinical Effectiveness Team has undertaken a review which also includes the routine commissioning of new initiations of guanfacine in adults with ADHD, i.e., those who have not received this treatment whilst under CAMHs. For consistency with the commissioning policy for children and adolescents, this application considers guanfacine as a fourth line treatment option for patients who have failed to respond to, or failed to tolerate, stimulant drugs and atomoxetine.

Amy Rice, Clinical Effectives Pharmacist (commissioning projects lead) presented a paper.

Within the UK, guanfacine is only licensed for people aged 6 to 17 years of age. The SmPC specifically states that "the safety and efficacy of guanfacine in adults and the elderly with ADHD has not been established. Therefore, guanfacine should not be used in this group". In addition, the BNF and Maudsley Prescribing Guidelines do not include the unlicensed use of guanfacine as a recognised treatment option for ADHD in adults.

NICE guideline NG87 states that guanfacine should not be offered to adults without advice from a tertiary ADHD service. This recommendation was made because guanfacine is not licensed for adults and, at the time of their review, there was no evidence supporting its use in this population.

Evidence for the efficacy of guanfacine in adult ADHD is extremely limited. One 10-week RCT conducted in Japan reports significantly greater improvements in ADHD symptom scores compared to placebo. A single arm extension study also reported significant improvements in ADHD symptom scores following continued long-term use. A crossover study reports that guanfacine had significantly lower ADHD symptom scores versus placebo for some, but not all outcomes, however the short duration of two weeks limits the clinical relevance of these findings; furthermore, the small sample size means this study is likely to be underpowered. The only other published placebo-controlled study reports no significant difference in the change in ADHD symptom scores for guanfacine versus placebo, however the relevance of this study is limited as interventions were given as supplements to existing stimulant therapy, which is outside of the scope of this application. Direct comparisons to other ADHD drugs are limited to findings from the small cross-over study, which reported no significant difference in ADHD symptom scores for guanfacine versus dexamfetamine. Indirect comparisons to other ADHD drugs are reported in a network meta-analysis, which estimated no significant difference in the change in ADHD symptom scores between guanfacine, and each of the ADHD drugs methylphenidate, mixed amphetamine salts, and atomoxetine. The reliability of these findings are however unclear, as data used to represent guanfacine within the network was taken from the study which only evaluated guanfacine as a supplementary treatment given alongside stimulant drugs. As such, there is no evidence that guanfacine has superior efficacy over other established, licensed ADHD drugs, and there is no evidence to suggest that guanfacine would be effective in patients who have failed to respond to existing options.

The cost-effectiveness of guanfacine for adults with ADHD is unknown, as no published studies have been identified. Average treatment costs are higher than currently available, licensed options. The budget impact of routinely commissioning guanfacine in adults with ADHD is difficult to estimate, due to uncertainty in the degree of uptake of guanfacine, but if 30% of patients currently prescribed non-stimulant medication switched to guanfacine, this would result in an increase in average total costs of approximately £5,000 per annum. Regardless of the level of uptake, any switch in prescribing practice from atomoxetine, methylphenidate, or lisdexamfetamine, will (on average) lead to an increase in drug expenditure.

Feedback received from specialists acknowledges that evidence to support the unlicensed use of guanfacine in adult ADHD is weak. Specialists from Devon Partnership Trust do not feel that there would be a need to initiate treatment in adults. They feel that guanfacine should be available for patients initiated on treatment as a child, however in each case they would still consider whether a switch to a licensed alternative was appropriate. Specialists from Livewell Southwest also see a need for guanfacine to be available for patients transitioning to adult services from CAMHS, but additionally felt that it could be clinically indicated for initiation in adults with ADHD not responding to, or not tolerating, stimulants or atomoxetine, despite the recommendations of NICE guideline NG87 and the limited evidence base.

The committee considered issues pertinent to the routine commissioning of guanfacine for adults with ADHD, including:

- Patients transitioning from childhood to adulthood and how removing the option of guanfacine for them may impact their lives.
- The need for an equitable policy between those who have and have not received guanfacine in childhood.
- The lack of evidence for the effectiveness of guanfacine in adults. It was suggested that the number of patients requiring guanfacine once they reach adulthood it likely to be low as they are often able to tolerate licensed treatments they could not when they were younger.
- That adult patients with exceptional circumstances who require guanfacine may be able to access the drug via the Individual Funding Request Panel. It was noted that applications for treatment through the Individual Funding Request Panel create additional work for clinicians. However, if guanfacine were to be routinely commissioned for adults there is a risk that it

would not be limited to those exceptional cases, which are too difficult to define within a commissioning policy.
- It was noted that good planning is needed for patients coming into Devon from other counties. However, it is unclear what can be done about this.

The committee voted unanimously in favour of not recommending the routine commissioning of guanfacine in adults with ADHD.

ACTION: Policy Recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.

7. Myringotomy (with or without grommet insertion) and adjuvant adenoidectomy in children under 12 years with otitis media with effusion

Within NHS Devon, the routine commissioning of grommet insertion and adjuvant adenoidectomy for otitis media with effusion (OME) in children under 12 years is subject to a commissioning policy which was last reviewed in 2020. Current commissioning criteria reflect the recommendations of NICE guideline CG60. In August 2023, this guideline was superseded by NICE guideline NG233 in which recommendations on the use of surgery for OME are less restrictive, as such there is a need to review this aspect of the commissioning policy.

Amy Rice, Clinical Effectiveness Pharmacist (commissioning projects lead) presented a paper.

NG233 differs from the current NHS Devon commissioning policy in three key areas. Firstly, NG233 recommends treatment is considered for those with persistent hearing loss greater than 20 decibels. At present surgery is routinely commissioned for those with persistent hearing loss greater than 25 decibels, unless the impact of hearing loss on a child's developmental, social, or educational status is judged to be significant. Secondly, NG233 recommends surgery for unilateral OME where hearing difficulties impact on daily living or communication. At present, surgery is not routinely commissioned for this patient cohort. Thirdly, NG233 recommends adjuvant adenoidectomy for all children undergoing grommet insertion. At present, adjuvant adenoidectomy is only routinely commissioned where there is adenoidal hypertrophy that is associated with persistent or frequent nasal obstruction, or the child is undergoing reinsertion of grommets for recurrent or persistent OME.

In terms of grommet insertion, changes to commissioning criteria are proposed to lower the hearing level threshold to 20 decibels, effectively commissioning treatment for all children with minor OME related hearing loss, and to routinely commission treatment for children with persistent unilateral OME with hearing loss that significantly impacts the child's developmental, social, or educational status. These changes are in line with the recommendations of NG233.

Whilst the evidence review conducted by NICE did not identify any studies reporting outcomes specifically for these two patient cohorts, studies which enrolled patients with all degrees of hearing loss and both unilateral and bilateral OME reported significantly lower hearing levels (i.e., better hearing outcomes), for grommet insertion versus no treatment. The cost-utility analysis conducted by NICE also indicated that, compared to no treatment, grommet insertion for the overall OME population was cost-effective at a willingness to pay threshold of £30,000 per QALY gain.

The proposed change to hearing levels is not expected to affect local activity however commissioning surgery for unilateral OME is expected to result in an increase in grommet insertion procedures within NHS Devon. A budget impact analysis estimates that this change to commissioning criteria could result in an additional 42 procedures per annum with an increase in annual costs of approximately £40,000 per annum.

In terms of adjuvant adenoidectomy, no changes to commissioning criteria are proposed. This is not in line with NG233 which recommends that adenoidectomy is offered to all children undergoing grommet insertion.

Consultation with local specialists identified that extending the provision of adenoidectomy would lead to increased costs and impact surgical capacity with longer procedure times. In addition, they felt that adenoidectomy should only be offered where children had enlarged adenoids causing nasal obstruction, or where children were undergoing grommet reinsertion, i.e., in line with the existing commissioning criteria for NHS Devon.

A budget impact analysis estimates that, adopting the recommendations of NG233 could lead to 134 additional adenoidectomies per annum, equating to an increase in annual costs of approximately £172,000. Some specialists suggested that wider use of adenoidectomy could result in lower rates of repeat surgery for recurrent or persistent OME however an additional budget impact analysis estimates that savings from reductions in repeat surgeries would be insufficient to outweigh the increase in costs associated with the wider use of adenoidectomy, and overall expenditure could still increase by approximately £110,000 per annum.

Within the evidence review conducted by NICE, one study did report significantly lower hearing levels (i.e., better hearing outcomes) for grommet insertion with adenoidectomy versus grommet insertion alone. However, in an additional study that adopted a similar follow up period, differences in hearing levels were not significant. The cost-utility analysis conducted by NICE showed that, compared to no treatment, grommet insertion with adenoidectomy for the overall OME population was cost-effective at a willingness to pay threshold of £30,000 per QALY gain however NICE concluded that minimal differences in ICERs meant that it was not possible to determine whether, compared to no treatment, grommet insertion with adenoidectomy or grommet insertion alone was more likely to be cost-effective.

The balance of uncertainties favours only offering adjuvant adenoidectomy under the limited circumstances as described in the existing NHS Devon commissioning policy. This position is supported by local specialists.

In addition to the previously mentioned changes to commissioning criteria, two additional changes to the policy wording are proposed. Firstly, clarification of the watchful waiting period; the proposed update reflects existing practice in NHS Devon and is aligned with the recommendations of NICE guideline NG233. And secondly, the removal of good practice guidance for children with Down's syndrome and cleft palate. These points were previously included in the policy because they were cited in NICE guidance, but they are not included in NG233. Whilst these points are still valid, they do not impose more restrictive commissioning criteria; their removal is proposed to keep the policy concise and directed to commissioning criteria only.

The committee considered issues pertinent to the proposed updates to the ICB's commissioning policy for Myringotomy (with or without grommet insertion) and adjuvant adenoidectomy in children under 12 years with otitis media with effusion, including that:

- For grommet insertion, NICE has made a slight relaxation in their recommendations due to acknowledgement of the impact that persistent hearing loss can have on some children.
- The proposed commissioning criteria for adjuvant adenoidectomy would not be in line with NICE. The rationale provided by NICE for their change in recommendations was discussed. Whilst cost-effectiveness forms part of the decision process for NICE, it is up to the ICB to consider the impact of recommendations to the local health economy. In this scenario, the balance of uncertainties between efficacy evidence, cost-effectiveness, and impact to the local health economy favours only offering adjuvant adenoidectomy in line with the criteria proposed

in the policy. This position is also supported by local specialists with whom there has been extensive consultation.

- At present, patients who are suitable for grommet insertion (under the existing commissioning policy criteria) face long waiting lists and are being offered hearing aids as an interim measure. Due to the economic impact (patients are effectively receiving two treatments, hearing aids are more expensive than grommet insertion), this issue is to be discussed at the forthcoming demand management meeting however it was acknowledged that a change in commissioning position that impacts surgical capacity (such as extending the use of adjuvant adenoidectomy) would impact this further.
- The Clinical Effectiveness Team will consider whether to keep good practice guidance on educational and behavioural strategies during watchful waiting periods. This does not affect commissioning criteria within the policy.

ACTION: Clinical Effectiveness Team to consider whether to keep good practice guidance on educational and behavioural strategies during watchful waiting periods.

The committee voted unanimously in favour of recommending the updated commissioning policy for myringotomy (with or without grommet insertion) and retention of the existing policy criteria for adjuvant adenoidectomy in children under 12 years with otitis media with effusion.

ACTION: Policy Recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.

8. Update from NICE Planning Advisory Group (NPAG)

The committee received an update from the NPAG meetings held on March and May 2024.

Across the two meetings the group considered:

- Five ICB commissioned TAs
- 16 NHS England commissioned TAs
- One Highly Specialised Technology
- Eleven Clinical Guidelines
- Eight NICE guidelines
- Two Diagnostic guidelines
- 13 Interventional procedures guidelines
- One Medical Technologies Guideline
- Two Health Technology Evaluations

9. Update from Clinical Policy Engagement and Consultation Panel (CPEC)

The committee received an update from the Clinical Policy Engagement and Consultation Panel meeting which took place at Aperture House, Exeter on Thursday 9th May 2024.

An update on the action was provided in respect of sharing the panels discussion and question regarding cost recovery from the private sector with the finance team. It was noted that this has been raised with the finance team who advised that there was no mechanism to recoup costs from private providers where the NHS has incurred these as a result of its duty of care to support patients in medical need following complications from cosmetic surgery. The panel expressed their surprise at this and asked that this be escalated, via the finance team, to a national forum. The panel remain concerned at the potential for this to be a growing area.

The Clinical Policy and Engagement Panel (CPEC) considered four items:

- Tonsillectomy for quinsy
- Radiofrequency ablation for Barrett's oesophagus
- Alogliptin for type 2 diabetes
- Insulin degludec for use in patients with type 1 diabetes

The panel saw no reason for further engagement or consultation actions on any of the items discussed.

10. Clinical Policy Engagement and Consultation Panel Annual Report 2023-24

The Committee received the Clinical Policy Engagement and Consultation Panel (CPEC) Annual report. This provides an account of the activity and governance of the Clinical Policy Engagement and Consultation Panel in 2023-24.

The panel continues to support the ICB in determining the need for any further engagement or formal public consultation on recommendations made by the Clinical Policy Recommendation Committee. This process is prior to a final decision being taken by the ICB on any clinical policy recommendations.

The wider public interest issues are considered to determine the need for any further engagement or formal public consultation on clinical policy recommendations.

In year, three panel meetings were held considering seven clinical policy recommendations.

Of note, when the Panel considered the proposed update to the ICB policy for Breast Implant Removal and Replacement they raised some concerns about the future costs the NHS will incur resulting from its duty of care to support patients in medical need including complications from cosmetic surgery which is becoming more normalised across society. In the case of breast implants this work had highlighted that breast implants have a finite lifespan and will therefore nearly always fail at some point.

Although the NHS will only fund removal, not replacement, of implants where the original procedure was undertaken privately it was questioned whether the NHS has any ability to recoup costs from private providers. There was concern about the increasing pressures on an already challenged NHS in terms of supporting patients to address medical issues following private cosmetic treatment. It was suggested that this concern and the question relating to cost recovery from the private sector could be raised with the ICB finance team.

Feedback received emphasised that the approach of the Clinical Policy Recommendation Committee was the best (in having clear and medically appropriate criteria) as there was no mechanism for recovery of costs from private sector providers where the NHS had to step in and provide a subsequent procedure.

The Clinical Policy Committee accepted the CPEC annual report for information and assurance.

ACTION: Clinical Policy Engagement and Consultation Panel Annual Report for 2023-24 to be submitted within the ICB for information and assurance.

11. Any other business

There was no other business to report.

Summary of actions			
	Action	**Lead**	**Status**
24/02	Tonsillectomy for quinsy – policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. <u>26th June 2024</u> The final outstanding approval (for the QEIA) has now been received and the updated policy will be published shortly.	Rebecca Owen	Pending
24/03	Review of commissioning policy for radiofrequency ablation for Barrett's oesophagus - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. <u>26th June 2024</u> The final outstanding approval (for the QEIA) has now been received and the retirement of this policy will be actioned shortly.	Rebecca Owen	Pending
24/04	Review of commissioning policies for drug treatments for diabetes: Alogliptin for type 2 diabetes - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. <u>26th June 2024</u> The final outstanding approval (for the QEIA) has now been received and the retirement of this policy will be actioned shortly.	Rebecca Owen	Pending
24/05	Review of commissioning policies for drug treatment for diabetes: Insulin degludec for type 1 diabetes - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. <u>26th June 2024</u> The final outstanding approval (for the QEIA) has now been received and the retirement of this policy will be actioned shortly.	Rebecca Owen	Pending

24/06	Clinical Policy Recommendation Committee Annual Report 2023/24 to be submitted within the ICB for information and assurance. <u>26th June 2024</u> This will be submitted to the ICB for information and assurance alongside the CPEC Annual Report. The Clinical Effectiveness Team will plan internal onward reporting in line with changes in the organisation, i.e. the appointment of a new Chief Medical Officer.	Rebecca Owen	Pending
24/07	NG18: Diabetes (type 1 and type 2) in children and young people: impact on policy for continuous glucose monitoring in diabetes - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
24/08	Guanfacine for attention deficit hyperactivity disorder (ADHD) in adults - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
24/09	Myringotomy (with or without grommet insertion) and adjuvant adenoidectomy in children under 12 years with otitis media with effusion - consider whether to keep good practice guidance on educational and behavioural strategies during watchful waiting periods.	Chris Roome	Pending
24/10	Myringotomy (with or without grommet insertion) and adjuvant adenoidectomy in children under 12 years with otitis media with effusion - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
24/11	Clinical Policy Engagement and Consultation Panel Annual Report 2023-24 to be submitted within the ICB for information and assurance.	Rebecca Owen	Pending