

Clinical Policy Committee

MINUTES

Wednesday 18 May 2022 – 9.30 am to 12.30 pm

Via Microsoft Teams

Present:

Dr Glen Allaway (Chair)	Voting Member	NHS Devon CCG
Dr Andrew Craig	Voting Member	NHS Devon CCG
Richard Croker	Deputy Director for Medicines Optimisation	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 Paul Melling	Voting Member	NHS Devon CCG
Chris Roome	Head of Clinical Effectiveness	NHS Devon CCG
Mark Taylor	Lay Public Member	
Dr Emily Youngman	Consultant in Public Health Medicine	Devon County Council

Guests:

Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Nic Perrem	Healthcare Evidence Reviewer	NHS Devon CCG
Dr Chris Price	Consultant Neurologist	RD&E

Observer:

Dr Laura Faulkner	GPST4 Leadership and Education Trainee	DRSS/Kingskerswell and Ipplepen Health Centre
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In attendance:

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

Note:

On 1st April 2022 the Royal Devon and Exeter NHS Foundation Trust (RD&E) and Northern Devon Healthcare NHS Trust (NDHT) formally merged to become Royal Devon University Healthcare NHS Foundation Trust.

1. Welcome and announcements

Apologies

Dr Kay Brennan	Voting Member	NHS Devon CCG
Dr Claire Hooper	Voting Member	NHS Devon CCG
Dr Tawfique Daneshmend	Secondary Care Clinician	RD&E
Dr Simon Jones	Voting Member	NHS Devon CCG
Lorraine Webber	Associate Director of Commissioning (Community Services)	NHS Devon CCG
Mac Merrett	Lay Public Member	

Confirmation of voting members and Declarations of interest

The seven voting members present were identified.

Dr Kay Brennan had delegated voting to Richard Croker

Dr Claire Hooper had delegated voting to Chris Roome

Dr Simon Jones had delegated voting to Paul Foster

Richard Croker left the meeting after the discussion of agenda Item 4. Sodium Oxybate and pitolisant: review of policies for use in narcolepsy (with or without cataplexy) following publication of NICE TA758 (solriamfetol for treating excessive daytime sleepiness caused by narcolepsy).

Declarations of Interest were collected and reported. All Declarations of Interest are reported in the minutes. As a result of declaring the interest detailed below the committee agreed that Chris Roome should participate in discussions but not vote on agenda item 4 – Sodium Oxybate and Sodium oxybate and pitolisant: review of policies for use in narcolepsy (with or without cataplexy) following publication of NICE TA758 (solriamfetol for treating excessive daytime sleepiness caused by narcolepsy).

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Tirbanibulin (Kylisyri®) for actinic keratosis Alternative treatments: 5-Fluorouracil 5% cream (Efudix®) Imiquimod 5% cream (Aldara®) Methyl-5-aminolevulinate cream (Metvix®) with Photodynamic therapy (PDT) Fluorouracil (.05%) with salicylic acid 100mg/g (10%) cutaneous solution (Actikerall®)	Almirall Limited Mylan Meda Pharmaceuticals Galderma (U.K) Ltd Almirall Limited

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
<p>Sodium oxybate and pitolisant: review of policies for use in narcolepsy (with or without cataplexy) following publication of NICE TA758 (solriamfetol for treating excessive daytime sleepiness caused by narcolepsy)</p> <p>Solriamfetol (Sunosi®)</p> <p>Pitolisant (Wakix®)</p> <p>Sodium oxybate (Xyrem®)</p>	<p>Jazz Pharmaceuticals</p> <p>Bioprojet UK Limited</p> <p>UCB Pharma Limited</p>

Name of Attendee	Role	Declaration
Chris Roome	Head of Clinical Effectiveness. Delegate voting member	Co-author of a research paper on the cost effectiveness of sodium oxybate in the treatment of narcolepsy and cataplexy, and which is referenced for methods in the NICE evidence review: Lanting L, Roome C, Lang L, et al. Sodium oxybate for narcolepsy with cataplexy - A cost-effective analysis. Journal of Neuroinfectious Diseases 2014;5:2.

Notification of Any Other Business

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

2. Minutes of the meeting held on 15th September 2021 and matter/actions arising

The minutes of the meeting held on Wednesday 15th September 2021 were approved.

Summary of actions		
	Action	Lead
21/05	<p>Policy for chronic rhinosinusitis - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p>This policy has completed the CCG governance and approval processes and is expected to be published shortly, pending DRSS confirming whether there are any referral implications requiring advanced notice.</p> <p>A difference in two-week wait criteria in this policy and the DRSS policy has been noted. Work is being undertaken with the GP lead to resolve this.</p> <p><u>18th May 2022</u></p> <p>This is part of the Evidence Based Interventions (EBI) List 2. A discussion with DRSS regarding the 2 week wait criteria is planned for July.</p>	Chris Roome
21/07	<p>Removal of Kidney Stones - Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p>Claire Hooper reported that there had been a delay in progressing this policy. Claire will take this through the Commissioning Committee via e-mail.</p> <p><u>18th May 2022</u></p> <p>The policy was published on 20th October 2021.</p>	
21/13	<p>Fidaxomicin for Clostridium difficile Infection - Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p><u>18th May 2022</u></p> <p>The policy was published on 9th December 2021.</p>	
21/14	<p>Policy for Assessment and Removal of Benign Skin and Subcutaneous Lesions – governance update - agree wording for the communication of the governance update to the policy for Assessment and Removal of Benign Skin and Subcutaneous Lesions and forward to the Clinical Effectiveness Team.</p> <p><u>18th May 2022</u></p> <p>The policy was published on 4th January 2022.</p>	

21/15	<p>Policy for Assessment and Removal of Benign Skin and Subcutaneous Lesions – governance update – Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p><u>18th May 2022</u></p> <p>The policy was published on 4th January 2022.</p>	
21/16	<p>Policy for Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of uterine fibroids – revised indication Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p><u>18th May 2022</u></p> <p>This policy was published on 11th November 2021.</p>	

3. Tirbanibulin for actinic keratosis

Actinic keratoses (AK), are lesions of the skin which occur in areas which have sustained sun damage. Classically these lesions are viewed as pre-cancerous, however some AK have the capacity to develop into invasive squamous cell carcinomas when left untreated. AK is a very common condition which is more common in men, and in individuals with lighter skin tones, particularly those who are prone to sun burn. Due to the high prevalence and potential risk of the condition it is often treated early in primary care.

Treatment of AK is broadly broken down into two approaches. An individual lesion may be targeted with a focussed topical agent, cryotherapy or minor surgery. When a small area of keratosis with field change is present, a range of topical agents may be applied dependent upon the severity of the condition.

Tirbanibulin (Klisyri®) is a topical agent used to treat low grade AK with field change of the face or scalp. The product first received its marketing authorisation in August 2021. Tirbanibulin ointment is applied once daily, for 5 days.

In January 2022 an application was received from Dr Toby Chave, a Consultant Dermatologist at University Hospital Plymouth, which requested that tirbanibulin was added to the formulary, allowing the products routine use in Devon. The rationale for this request was that tirbanibulin offers an alternative treatment option to other regularly used topical agents. It was noted that tirbanibulin had a shorter treatment course time and also that it may be better tolerated than comparators. A suggestion was also made that if tirbanibulin was used in place of other agents a cost saving may be made. Nic Perrem, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper.

At present the only product available in Devon to treat low grade AK is the 5% formulation of 5-fluorouracil cream (Efudix®), commonly referred to as 5-FU, which is listed in the Devon formulary as a first line (green) treatment option. A range of other treatments are available, but these require initiation in secondary care. Previously in Devon, the topical agent ingenol mebutate (Picato®) was available as a first line (green) treatment option. However, in February 2020 the licence for this product was withdrawn following safety concerns raised by the MHRA. The withdrawal of ingenol mebutate led to 5-FU being the only first line green option available for this condition.

5-FU is a well-known product, and one which practitioners in primary care will have good knowledge and experience of. For the treatment of AK 5-FU is applied daily for a treatment course lasting up to 4 weeks. The nature of the treatment means that localised skin reactions when using 5-FU are common.

At present due to the novel nature of the agent, the national guidelines available from both the British Association of Dermatologists and the Primary Care Dermatology Society do not consider the use of Tirbanibulin. NICE has not reviewed its use, however both the Scottish Medical Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG) have approved the use of Tirbanibulin as a treatment option for AK within their localities.

The Clinical Effectiveness team had conducted a full literature search which identified one article reporting the findings of two identical Randomised Controlled Trials (RCTs) comparing tirbanibulin to a vehicle placebo control. The pooled results of each study report that 49% of patients in the Tirbanibulin group demonstrated a complete clearance of AK in the treatment zone at 8 weeks. This was 41 percentage points greater than the rate observed in the control arm. Within both studies those patients who demonstrated complete clearance at 8 weeks were followed up at one year. If longer term efficacy data is applied to a hypothetical cohort of 100 patients a substantial majority are likely to require a secondary treatment. The licencing conditions for tirbanibulin currently do not allow for this meaning that these patients would require treatment using another agent.

No direct comparative evidence is currently available to compare the efficacy of tirbanibulin with other topical agents used to treat AK. However, a network meta-analysis (Heppt et al, 2022) was also identified. This allowed for an indirect comparison of topical agents by calculating their odds ratios for complete clearance compared to that of topical placebo. The results of this analysis suggest that the agent with the largest odds of causing a complete clearance of actinic keratosis at initial follow up is the 5% formulation of 5-FU. The 4% formulation of 5-FU and imiquimod 5% cream (Aldara®) also have a higher point estimate than that of tirbanibulin. The point estimate for Tirbanibulin is similar to that of the now withdrawn Ingenol Mebutate. However, the credible limits present alongside these point estimates are very wide, meaning there is overlap across all of the treatment options which creates a large amount of uncertainty in this analysis.

Direct evidence of the side effect profile for tirbanibulin from phase 3 clinical trials is only available in paper by Blauvelt and colleagues. The rate of severe adverse events from tirbanibulin is extremely low and in line with that observed in the control group. The most common adverse event observed in those that received tirbanibulin was a localised skin reaction which were all reported to be either easily managed or spontaneously resolved. The application was suggestive that the rate and severity of skin reactions from tirbanibulin may be lower than that of 5-FU. No direct comparative data is available to assess this claim.

Both the SMC and the AWMSG were presented with a cost-utility analysis undertaken by the company. The SMC analysis described tirbanibulin as cost saving. The AWMSG found tirbanibulin to be a cost-effective treatment option. However, the Clinical Effectiveness Team noted that the setting of care for tirbanibulin and comparators may not represent local practice. The Clinical Effectiveness Team also noted the level of uncertainty in the efficacy data used. The incremental cost differences and change in quality-of-life scores projected from this modelling are very small and interpretation of the ratio measure required contextualisation. As there was such a high degree of uncertainty the Clinical Effectiveness team completed further exploratory economic modelling. The aim of this work was to explore the incremental cost differences in using tirbanibulin or 5-FU and to also assess the difference in QOL whilst patients are receiving each treatment.

The output of the model was suggestive that during treatment the average difference in QOL for a patient receiving either treatment does not differ meaningfully. Thus, the more important focus

may be the incremental cost difference between treatments. In the base case it was found that Tirbanibulin is a cheaper treatment option however all scenario analysis favoured 5-FU. As an explanation for the base case, it is likely that this analysis overestimates the cost to manage local skin reactions as secondary care visits are assumed. In scenarios when this was controlled for 5-FU it became the cheaper option. Further to the treatment-state model a cost-consequence analysis was performed. This analysis was completed as on face value tirbanibulin has a higher acquisition cost and so if efficacy and tolerability were the same the additional expenditure would not lead to any benefits gained. As such the Clinical Effectiveness Team considered a range of scenarios which allowed exploration of how difference in efficacy and tolerability would alter this outcome. This modelling included a range of scenarios. Initially it was assumed the efficacy of tirbanibulin and 5-FU would be the same, but that tirbanibulin had improved tolerability, in this analysis tirbanibulin was a more expensive treatment option, incurring additional costs of around £2000 when a hypothetical cohort of 100 patients are treated. However, 12% fewer skin reactions requiring medical management occurred when tirbanibulin was used which led to less follow up GP appointments being required. In a second scenario where 5-FU had a greater efficacy than tirbanibulin, but tolerability was greater with tirbanibulin, tirbanibulin was again the more expensive treatment option. This analysis demonstrated that the number of skin reactions was likely higher when 5-FU was used but overall, the number of medical appointments would be less. This result was driven by the fact that the treatment failure rate of tirbanibulin was higher resulting in a greater need for follow up care.

Cost comparisons with 5-FU suggest that tirbanibulin is a more expensive treatment option. A treatment course of tirbanibulin is priced at £59, a very similar figure to the average cost per item of ingenol mebutate dispensed in 2019 (£61.66), thus if prescribing of tirbanibulin simply replaced ingenol, it would be expected that similar costs are incurred. In 2019, 3691 prescriptions were issued in Devon for ingenol. Ingenol was withdrawn during the Covid pandemic during which time 5FU was the only formulary recommended option and costs of prescribing for AK fell. However, it is acknowledged that prescribing patterns seen during this time are likely anomalous. A budget impact analysis completed by the Clinical Effectiveness Team which considers historical prescribing data suggests that if tirbanibulin was to be used to manage actinic keratosis in Devon an increase in costs over than seen in 2020/2021 with an upper limit of £70,000 per annum may occur if tirbanibulin replaces 5FU.

In conclusion, the evidence of clinical effectiveness available for Tirbanibulin is limited to 2 identical RCTs. This data shows that Tirbanibulin is an efficacious treatment option when compared to placebo. Indirect evidence of clinical effectiveness derived from a network meta-analysis suggests that 5-FU likely has a greater potential to achieve complete clearance of actinic keratosis at initial follow up. However, there is a large amount of uncertainty in that data set. Locally completed economic modelling suggests that costs will increase if Tirbanibulin is used in place of 5-FU to treat mild to moderate AK with field change. At present the situation in Devon is that 5-FU is the only treatment option for this indication. Tirbanibulin may offer a safe and effective alternative treatment option, albeit one with increased costs. The application to use Tirbanibulin has been well received in the feedback from other local specialists.

The Clinical Policy Committee discussed issues pertinent to the routine commissioning of Tirbanibulin for the treatment of actinic keratosis, including:

- Feedback from specialists is generally positive. Comments received noted the shorter treatment course, that tirbanibulin is likely well tolerated and, it was suggested, costs lower.
- It was suggested that there may be pressure for GPs not to refer AK to secondary care as the GP will be expected to have done an initial treatment with 5-FU. If more evidence was available tirbanibulin could be a preferable option due to short course length and tolerability, this would reduce pressure on GPs.
- Diagnosis can be uncertain. If 5-FU has failed the GP may consider that the patient might have a Squamous Cell Carcinoma (SCC) and a GP would likely refer in this scenario.

- A head-to-head trial of 5-FU and tirbanibulin would be useful.
- The committee questioned whether 14% clearance at one year is good enough. It was noted that it is not always clear if a previous lesion has returned or if the patient has developed a new lesion.
- A GP present suggested that experience has shown that the majority of AKs return after treatment with 5-FU. Patients treated with 5-FU can be retreated after 12 months. Retreatment with Tirbanibulin is not approved.

The Committee voted unanimously in favour of recommending the routine commissioning of Tirbanibulin.

The Committee recommended that the FIG consider tirbanibulin initially as a second line (blue) treatment for actinic keratosis where there has been a reaction to treatment with 5-FU.

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

The Committee thanked Nic Perrem for an excellent piece of work in producing the meeting papers and presenting on Tirbanibulin for actinic keratosis.

4. Sodium oxybate and pitolisant: review of policies for use in narcolepsy (with or without cataplexy) following publication of NICE TA758 (solriamfetol for treating excessive daytime sleepiness caused by narcolepsy)

The CCG has existing policies for the commissioning of sodium oxybate (Xyrem®) for use in narcolepsy with cataplexy, and for pitolisant (Wakix®) for use in narcolepsy with or without cataplexy. The sodium oxybate policy has been in place since July 2017 when it was developed following NHS England forming a commissioning position on its use in children. Commissioning in adults is the responsibility of the CCG and the existing Devon policy effectively applies the same criteria to adults. The commissioning policy for pitolisant was published in August 2020 following an application from a narcolepsy specialist. The position is that pitolisant can be used in patients meeting criteria for sodium oxybate. There is no NICE guidance on either of these drugs.

NICE TA758 was published in January 2022 and covers solriamfetol (Sunosi®) for the management of excessive daytime sleepiness caused by narcolepsy. The publication of this technology appraisal (TA) has implications for two existing policies for narcolepsy drugs. Nic Perrem, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper. Dr Chris Price, Consultant Neurologist, RD&E joined the meeting for the discussion.

Narcolepsy is a chronic sleep disorder. The primary symptoms of the condition are excessive daytime sleepiness (EDS) and periods of an involuntary loss in muscle tone, which is known as cataplexy. Sufferers may also experience disturbed night-time sleep, hallucinations when transitioning between sleep and wakefulness, and sleep paralysis. Modelling completed by the Clinical Effectiveness team suggests that there are around 184-523 adults currently living with the disorder in Devon, with 7-13 new diagnoses made annually.

In January 2022, NICE published TA758 – solriamfetol for EDS caused by narcolepsy. This TA recommends the use of solriamfetol as a third line treatment option for EDS. The criteria set by NICE for eligibility is that individuals have been unable to control their EDS following first line treatment with modafinil and second line treatment with either dexamfetamine or methylphenidate.

In Devon, two commissioning policies currently exist for drugs which manage the symptoms of narcolepsy, these are sodium oxybate and pitolisant. Sodium oxybate is a drug which can manage both EDS and cataplexy, uniquely sodium oxybate can also assist those with narcolepsy by improving night-time sleep. Pitolisant can also help to manage EDS and cataplexy. Solriamfetol is only able to manage EDS, meaning that if a patient also has cataplexy, they would require a secondary drug to manage this symptom when prescribed solriamfetol.

The existing commissioning policy for sodium oxybate was published in July 2017. Prior to this time, the CCG had a policy that sodium oxybate was not routinely commissioned in Devon. However, NHS England released a policy for the use of the drug in children. As CCGs are the responsible commissioner for the drug in adults a local policy was developed to allow for continuation of treatment in those receiving the drug as a child as they move into adulthood, also to ensure a level of equity, the policy adopted the criteria specified by NHS England to allow for the commencement of treatment in adults. The policy for pitolisant was published in August 2020. This states that an individual eligible for sodium oxybate would also be eligible for pitolisant. The full policies for both drugs were included in the meeting papers.

At present no direct evidence comparing EDS specific outcomes between solriamfetol, sodium oxybate, and pitolisant is available. For the NICE assessment of solriamfetol the company produced a network meta-analysis (NMA) which suggested no significant difference in outcomes between the three treatments. The data from this NMA is not publicly available so could not be reviewed. The economic analysis undertaken by NICE found that when compared to pitolisant, solriamfetol was associated with a high south-west quadrant incremental cost effectiveness ratio (ICER), meaning that solriamfetol was marginally less effective but created a financial saving over pitolisant. Solriamfetol dominated sodium oxybate, meaning it was a cheaper and more effective treatment option for EDS. However, feedback from local specialist suggests that this finding should be viewed with some caution. Sodium oxybate improves nocturnal sleep and solriamfetol does not. As this was not captured in the data informing the economic model the result may be non-representative of patients currently receiving sodium oxybate in local clinical settings. NICE acknowledge that their model may not capture all the benefits of treatment of narcolepsy.

To further understand the local cost implications the Clinical Effectiveness team completed a cost-comparison analysis. This compared the costs to prescribe all three drugs. The Clinical Effectiveness team found that even when solriamfetol was prescribed with a secondary drug to manage cataplexy at the highest dose available it was a cheaper treatment option than either pitolisant or sodium oxybate when they were prescribed at their lowest possible dose.

As NICE TA758 is mandatory, solriamfetol for the management of EDS was added as a third line treatment option to the Devon Formulary in March 2022. The inclusion of solriamfetol as a third line treatment option for EDS has implications for the existing commissioning policy for sodium oxybate. In turn this also impacts the policy for pitolisant.

The existing criteria for an adult to initiate to treatment with sodium oxybate is that they should have failed first line treatment for EDS using methylphenidate and second treatment using either dexamfetamine, lisdexamfetamine, modafinil or atomoxetine. They should also have failed first- and second-line treatment for cataplexy using venlafaxine, clomipramine or other selective serotonin reuptake inhibitors (SSRIs).

The committee were asked to consider an update to the existing policy for sodium oxybate to include the following key changes:

Firstly, the first line treatment option for EDS should change from methylphenidate to modafinil. This change should occur as feedback from the regional narcolepsy expert has confirmed that modafinil is used as a first line treatment option in adults. This change would also bring the Devon commissioning policy in line with the pathway used by NICE.

Secondly, it is proposed that solriamfetol becomes a third line treatment option for EDS. The wording of the policy would therefore change to state that eligibility for sodium oxybate would require patients to have failed management with three lines of treatment for EDS and two lines of treatment for cataplexy.

Other proposed changes in the wording of the policy try to remove such a direct link to the NHS England policy and make the sodium oxybate policy more specific to adults in Devon. These changes do not alter the eligibility criteria or the pathway but attempt to provide clarity and make the policy more relevant to the local population.

The committee's attention was drawn to feedback received from local specialists who have raised some concerns regarding how the proposed change to the existing sodium oxybate policy may create a more restrictive pathway for patients to receive the drug.

The Committee discussed the proposed update:

- Written comments submitted by specialists were noted.
- Dr Chris Price outlined that his experience of using sodium oxybate was similar to that of other neurology specialists in tertiary sleep service centres. Most refractory narcolepsy patients seen in tertiary care are managed using sodium oxybate. He detailed that as specialists had less experience of using both pitolisant and solriamfetol the real-world outcomes were less understood. He also confirmed that only a few patients with narcolepsy have uncontrolled symptoms requiring their management in specialist sleep centres, as such the cost implications for which of these drugs to be used a preferred option are likely to be small. Dr Price also confirmed that the proposed changes to the policy wording were reasonable.
- It was noted that patients experience different symptoms/circumstances and need different treatments. Prescribing data was discussed for Devon which indicated that seven patients were currently receiving sodium oxybate, whilst no patients were receiving pitolisant. All prescriptions are initiated from secondary care, however it was noted that there is shared care for sodium oxybate.
- The relevance of NICE using the same modelling methods as had been used in the research paper on the cost effectiveness of sodium oxybate in the treatment of narcolepsy and cataplexy on the outputs generated was noted. The lack of head-to-head trials with suitable quality of life measures was noted.

The committee were asked to cast their votes. Chris Roome had declared an interest and did not vote.

The six committee members who voted, voted unanimously in favour of accepting the pathway changes for sodium oxybate, making the recommended first line treatment for EDS Modafinil.

The six committee members who voted, voted four to two against including Solriamfetol in the commissioning policy for sodium oxybate for narcolepsy with cataplexy in adults. This will enable clinicians to have more flexibility in providing the best treatment for their patients.

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

It was suggested that this topic would be useful for discussion at a future Clinical Policy Committee members development day.

The Committee thanked Nic Perrem for an excellent piece of work producing the meeting papers and presenting on sodium oxybate for narcolepsy with cataplexy in adults

5. Update from NICE Planning Advisory Group (NPAG)

The committee received a report of the work undertaken by NPAG. Four meetings of the group had taken place since the CPC meeting held on 15th September 2021.

Tuesday 5th October 2021

Twenty-three NICE publications were considered at the NPAG meeting on 5th October 2021. These were:

- Two CCG commissioned Technology Appraisals
- Seven NHS England commissioned Technology Appraisals
- Two Clinical Guidelines
- Three NICE Guidelines
- Five Interventional Procedures Guidelines
- One Diagnostic Guideline
- Three Medical Technology Guidelines

Tuesday 14th December 2021

Twenty-eight NICE publications were considered at the NPAG meeting on 14th December 2021. These were:

- Two CCG commissioned Technology Appraisals
- Thirteen NHS England commissioned Technology Appraisals
- One Highly Specialised Technology
- Two NICE Guidelines
- Nine Interventional Procedures Guidelines
- Two Medical Technology Guidelines

The group also received a report of the forthcoming MedTech Funding Mandate 2022-23.

Tuesday 1st February 2022

Twenty-five NICE publications were considered at the NPAG meeting on 1st February 2022. These were:

- Two CCG commissioned Technology Appraisals
- Nine NHS England commissioned Technology Appraisals
- Four NICE Guidelines
- Three Medical Technology Guidelines
- One Diagnostic Guideline
- Six Interventional Procedures Guidelines

Tuesday 29th March 2022

Thirty NICE publications were considered at the NPAG meeting on 29th March 2022. These were:

- Six CCG commissioned Technology Appraisals

- Eight NHS England commissioned Technology Appraisals
- One Highly Specialised Technologies.
- Two Clinical Guidelines
- Three NICE Guidelines
- Seven Interventional Procedures Guidelines
- One Diagnostic Guideline
- Two Medical Technology Guidelines

The group also received the MedTech Funding Mandate Policy 2022/23 and a report on the NHS Digital Innovation Scorecard.

6. 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 14th October 2021.

The Clinical Policy Engagement Panel had considered two items:

- Fidaxomicin for the treatment of *Clostridioides difficile* infection.
- Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of uterine fibroids

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

7. Update on Evidence Based Interventions (EBI) programme list

The committee received a verbal update on the EBI programme.

The programme is led by the Academy of Medical Royal Colleges along with NHS England, NHS Improvement, NHS Commissioners and the National Institute for Health and Care Excellence. It was noted that:

- EBI List 3 is due to be published in late May 2022, following a consultation period which ran between January – March 2022.
- Members of the Clinical Effectiveness team have attended some the consultation engagement events and submitted feedback on the proposals.
- NHS resources do not appear to have been considered.
- Some areas in which the CCG has policies are included in the programme and may need to be reviewed.
- Specialist Clinicians have noted some concerns.

8. Transition to the Devon Integrated Care System and future committee arrangements from 1st July 2022

The Committee received an update on the transition to the Devon Integrated Care System (ICS) and future committee arrangements.

The ICS for Devon is due to be established on 1st July 2022 as a partnership of health and care organisations coming together to plan and deliver joined up services and to improve the health of

people who live and work in Devon. Within this, NHS Devon Integrated Care Board (ICB) will become the statutory organisation, responsible for specific functions and for ensuring that the organisation meets its statutory commissioning duties.

Discussions have been ongoing to set out the proposed structure and processes for clinical policy making for the system in preparation for the transfer:

- to ensure the ICB fulfils its statutory function as a commissioning organisation and discharges its responsibilities for making local decisions about the funding of medicines and treatments in the NHS.
- to build on the existing CCG arrangements for clinical policy making, which provide strong governance and assurance that a high-quality process has been followed, with robust evaluation, engagement, visibility, and documented record keeping, to withstand scrutiny and potential legal challenge.

These proposals have been developed following discussions with the Clinical Chair and the Clinical Cabinet. They have been refined following feedback from discussions with the NHS Devon Executive Team and the Chair of the ICSD and have now been approved.

The Draft Terms of Reference (TOR) were circulated with the meeting papers. It was noted that since the papers were circulated a couple of aspects of this have changed or are to be confirmed. These were highlighted to the committee. A final version will be shared with the committee.

Key points:

- It has been agreed that the Clinical Policy Committee process will be replicated within the governance structure of the ICB for Devon.
- The new committee will be known as the 'Clinical Policy Recommendation Committee' to provide clarity on its function and output.
- Existing membership of the Clinical Policy Committee is retained to sit on the new Committee.
- The TOR now refers to registered 'clinical' professionals (rather than specifically medical) to reflect a changing context in the legislation which refers to clinical leadership and sets out an aspiration to include a wider range of professionals. The wording of the TOR permits a wider group membership, potentially including both medical and non-medical clinical colleagues. Individuals will however need to satisfy the competencies required to fulfil the functions of the role described in the TOR.
- Chief Executives have been contacted to facilitate additional secondary care advisory members who may be drawn from across all secondary care providers who are part of the Devon ICS, and could include any clinical speciality (both medical and non-medical) – a call for Expressions of Interest has been put out.
- Secondary care advisory member nominations will be considered through a process involving the ICS Medical Director, the Committee Chair and Head of Clinical Effectiveness to ensure members possess the skills to fulfil the responsibilities and functions required as set out in the TOR.
- It has been agreed that the clinical policy making process will continue to be supported by a lay member led Clinical Policy Engagement and Consultation Panel.
- Membership of the Clinical Policy Engagement and Consultation Panel is an expectation of the ICB non-executive director for citizen and community involvement.
- Clinical policy recommendations will be ratified by an appropriate body under delegation from the ICB Executive Committee (expected to be the Executive Strategy and Transformation Group) to become the commissioning policy for NHS Devon ICB.

- Existing CCG clinical commissioning policies will be grandfathered across to the ICB from the date of its establishment on 1st July 2022.

The first meeting of the new committee under the ICB will occur as previously scheduled on Wednesday 20th July.

The committee discussed issues pertinent to the Transition to the Devon Integrated Care System:

- There will be no significant changes, the meeting scheduled for July 2022 should feel much like previous CPC meetings with additional secondary care members.

ACTION: Rebecca Owen to share the final version of the Clinical Policy Recommendation Committee Terms of Reference with the committee.

9. Any other business

Format of Future meetings

It was agreed that the Clinical Effectiveness Governance Manager will undertake a survey of members preferences for the format of future meetings.

ACTION: Rebecca Owen to undertake survey of members preferences for the format of future meetings.

Summary of actions		
	Action	Lead
21/05	<p>Policy for chronic rhinosinusitis - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p>This policy has completed the CCG governance and approval processes and is expected to be published shortly, pending DRSS confirming whether there are any referral implications requiring advanced notice.</p> <p>A difference in two-week wait criteria in this policy and the DRSS policy has been noted. Work is being undertaken with the GP lead to resolve this.</p> <p><u>18th May 2022</u></p> <p>This is part of the Evidence Based Interventions (EBI) List 2. A discussion with DRSS regarding the 2 week wait criteria is planned for July.</p>	Chris Roome
22/01	Tirbanibulin for actinic keratosis: Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Owen
22/02	Sodium oxybate and pitolisant: review of policies for use in narcolepsy (with or without cataplexy) following publication of NICE TA758 (solriamfetol for treating excessive daytime sleepiness caused by narcolepsy: Policy recommendation and QEIA to be prepared and subsequently processed to final CCG approval and communication.	Rebecca Owen
22/03	Transition to the Devon Integrated Care System and future committee arrangements from 1 July 2022: Share final version of the Clinical Policy Recommendation Committee Terms of Reference with the committee.	Rebecca Owen
22/04	Any other Business – Format of Future Meetings – Undertake survey of members preferences for the format of future meetings.	Rebecca Owen