

Clinical Policy Recommendation Committee Minutes

Wednesday 2nd July 2025
Microsoft Teams

Present:

Name	Job Title	Organisation
Dr Glen Allaway	Chair	NHS Devon
Richard Croker	Chief Pharmacist – Primary Care	NHS Devon
Dr Lucy Harris	Voting Member	NHS Devon
Dr Claire Hooper	Voting Member	NHS Devon
Dr Felicity Knott	Voting Member	NHS Devon
Mac Merrett	Lay Public Member	
Chris Roome	Deputy Director - Clinical Effectiveness	NHS Devon
Mark Taylor	Lay Public Member	
Ben Titford	Voting Member	NHS Devon

Guests:

Matt Howard	Senior Clinical Effectiveness Pharmacist	NHS Devon
Chris Sullivan	Deputy Chief Pharmacist	DPT
Dr Keith Gilhooly	Consultant	DPT
Amanda Gulbransen	Lead Pharmacist	Children and Family Health Devon

Observers:

Louise Whitehead	Senior Clinical Evidence Review Specialist	NHS Devon
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In attendance:

Fiona Dyroff	Senior Clinical Effectiveness Governance Support Officer	NHS Devon
Rebecca Owen	Clinical Effectiveness Governance and Individual Funding Request (IFR) Panel Manager	NHS Devon

1. Welcome and announcements

Attendees were welcomed to the meeting.

Apologies:

Name	Job Title	Organisation
Dr Kay Brennan	Voting Member	NHS Devon
Dr Andrew Craig	Voting Member	NHS Devon
Barbara Jones	Deputy Director Contracting	NHS Devon

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 Andrew Craig had delegated voting to Chris Roome

There were no declarations of interest to report.

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Metformin for the management of antipsychotic induced weight gain (various branded and generic) Alternative treatments: Other weight loss treatments including GLP-1 agonists, e.g. tirzepatide (Mounjaro), liraglutide (Saxenda) and semaglutide (Wegovy)	Various manufacturers Eli Lilly and Company Limited, Novo Nordisk Limited, and others
Bevacizumab (Lytenava) for the first line treatment of wet age related macular degeneration Alternative treatments: Specials formulations of Avastin for use in the eye Ranibizumab (Lucentis) Ranibizumab biosimilar products Aflibercept (Eylea) Aflibercept biosimilar products Brolucizumab (Beovu) Faricimab (Vabysmo)	Outlook Therapeutics Ltd Various specials manufacturers utilising Avastin made by Roche Products Novartis Pharmaceuticals UK Ltd Teva UK Limited (Ongavia), Samsung Bioepis UK Limited (Byooviz), Orion Pharma (UK) Limited (Rimmyrah), Genus Pharmaceuticals (Ximluci) Bayer plc Teva (Ahzantive) Novartis Pharmaceuticals UK Ltd Roche Products Limited
Fluticasone furoate and vilanterol trifenate combination inhaler (Relvar Ellipta) for chronic obstructive pulmonary disease and for asthma	GlaxoSmithKline UK

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Alternative treatments: Any other ICS + LABA combination inhalers	Various manufacturers including Chiesi Limited, Lupin Healthcare (UK) Ltd, Orion Pharma (UK) Limited, AstraZeneca UK limited, Teva Pharma B.V., Sandoz Limited, Zentiva (<i>asthma only</i>)

Notification of Any Other Business

No other items of business were noted.

2. Minutes of the meeting held on Wednesday 13 November 2024 and matters/actions arising

The minutes of the meeting held on Wednesday 13 November 2024 were approved subject to one amendment:

- Claire Hooper noted that she had not been at the previous meeting but wanted to add that attendance at CPRC is included in her Job Plan.

This will be added as a post meeting note to the minutes of the meeting held on 13 November 2024 under item 6 Attendance Review.

It was also noted that with regard to commissioning representation, the Clinical Effectiveness Team routinely contact commissioning managers for relevant items.

Summary of actions			
	Action	Lead	Status
24/06	Clinical Policy Recommendation Committee Annual Report 2023/24 to be submitted within the ICB for information and assurance.		Complete
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. <u>4th September 2024</u> Policy and QEIA going through the governance process for sign off. <u>13th November 2024</u> As above.	Rebecca Owen	Pending
24/09	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.		Complete

24/10	Clinical Policy Engagement and Consultation Panel Annual Report 2023-24 to be submitted within the ICB for information and assurance.		Complete
24/11	Opicapone for Parkinson' disease – policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		Complete
24/13	Ferric Maltol (Feraccru®) for iron deficiency anaemia in inflammatory bowel disease - Policy Recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		Complete
24/14	Dymista® (Azelastine hydrochloride and fluticasone propionate) nasal spray for allergic rhinitis - Policy Recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		Complete
24/15	Clindamycin 1%/Tretinoin 0.025% w/w gel (Treclin®) for the topical treatment of acne vulgaris - Policy to be retired.		Complete
24/16	Attendance Review - Terms of Reference to be updated in line with the discussion.		Complete
24/17	Attendance Review - Recruitment of members for agreed roles to be pursued.		Complete

3. Metformin for the management of antipsychotic induced weight gain

Matt Howard, Senior Clinical Effectiveness Pharmacist presented a paper. Dr Keith Gilhooly, Consultant and Chris Sullivan, Deputy Chief Pharmacist, Devon Partnership Trust and Amanda Gulbransen Lead Pharmacist, Children and Family Health Devon attended the meeting for discussion of this item.

An application was received from specialists at Devon Partnership Trust (DPT), supported by Livewell Southwest for the use of metformin for the prevention of antipsychotic induced weight gain (AIWG).

According to NHS England, people living with severe mental illness (SMI) face one of the greatest health equality gaps in England; their life expectancy is 15–20 years shorter than that for the general population (largely due to preventable physical illnesses). Adults living with SMI have an almost five times increased risk of dying prematurely compared to those living without SMI. Antipsychotics increase life expectancy; however, they commonly cause weight gain.

Obesity and overweight are known to be associated with adverse health outcomes, including increased risks of type 2 diabetes, hypertension, ischaemic heart disease, stroke, and some cancers. Overweight and obesity are also associated with sleep apnoea, joint pain, urinary incontinence, impaired fertility, depression, anxiety, and functional limitations that can severely impair health and quality of life.

Concerns regarding AIWG may also lead some patients to avoid starting, or stop taking, antipsychotic medication. Interventions to reduce AIWG may help improve adherence and overall treatment outcomes.

In line with a recently published guideline (Carolan et al, 2024), it was proposed that eligible patients for treatment with metformin would include: those prescribed olanzapine or clozapine, those prescribed quetiapine, paliperidone or risperidone with at least one specified risk factor / co-morbidity, and any patient prescribed an antipsychotic who experiences greater than 3% weight gain at any time in the first year of treatment.

Metformin is not licensed for prevention of AIWG; it is an established oral medicine that is widely used in the management of type 2 diabetes mellitus in adults and children. It may also be used for the prevention of type 2 diabetes and the management of polycystic ovary syndrome. Metformin has a well-documented adverse effect profile and is generally well tolerated.

NICE has published clinical guidelines on psychosis and schizophrenia in children and young people (2013) and in adults (2014). Both recognise the potential for AIWG but do not make specific recommendations for its management. In 2023, NICE planned to update these guidelines following a surveillance review that identified new evidence suggesting a benefit from metformin versus placebo in attenuating AIWG. However, having reviewed their guidelines portfolio to identify topics that will add the most value to the health and care system, NICE subsequently decided not to proceed with the update.

There is no guidance from All Wales Medicines Strategy Group (AWMSG) or the Scottish Medicines Consortium (SMC) in respect of metformin for AIWG.

The Scottish Intercollegiate Guidelines Network (SIGN), the British Association for Psychopharmacology, and The Maudsley Prescribing Guidelines in Psychiatry all recommend metformin for the prevention of AIWG.

The Clinical Effectiveness Team identified four ICBs that appear to support the use of metformin for antipsychotic induced weight gain.

The evidence base for metformin for AIWG includes many meta-analyses of data from a limited number of short term RCTs of mixed quality. The RCTs include adults and children across a range of ethnicities, although trials conducted predominantly in European populations are lacking. In the studies, metformin was used for either prevention or treatment of weight gain. Three recent meta-analyses were considered in detail; the participant characteristics, antipsychotic, and metformin dose varied between included studies.

Peng et al published a systematic review with meta-analyses of data from double-blind, placebo controlled RCTs. Up to 20 studies, provided data for up to 1,070 patients for analysis. Meta-analysis found a statistically significant difference in favour of metformin for mean bodyweight and mean BMI. Consistent results were seen across a range of subgroup analyses including adults only, children and young people only, treatment naïve, study duration and metformin dose.

Yu et al published a systematic review with meta-analyses of data from double-blind, placebo controlled RCTs, with a focus on prevention of weight gain. The authors only included RCTs in adults who were commenced on metformin within seven days of starting a new antipsychotic. Although both groups put on weight, the authors reported statistically significant differences in favour of metformin for mean change in bodyweight and BMI (up to 12 studies, 907 participants). Subgroup analyses for antipsychotic naïve patients, and for those switching antipsychotics at the time of metformin initiation found bodyweight and BMI were statistically significantly lower in the metformin group. A sensitivity analysis including only studies judged to be of high quality was also consistent. However meta-analysis of waist circumference data found no significant difference between groups.

A Cochrane review (Agarwal et al) assessed a range of pharmacological interventions for the prevention of antipsychotic induced weight gain; it included meta-analysis of data from five studies (227 participants) of metformin. The results were broadly consistent with those already discussed, finding statistically significant differences in body weight and BMI, but not waist circumference.

All three meta-analyses have similar limitations; duration of treatment is limited (3-6 months) and although some included studies were in Western populations, none were conducted in Europe.

Sixteen other meta-analyses published between 2010 and 2022 were reviewed, all produced results that are broadly consistent.

Overall, there is consistent, but low certainty evidence that metformin reduces antipsychotic induced weight gain by approx. 3kg body weight compared to placebo at 3-6 months. There is uncertainty whether the results are generalizable to a UK population, or whether metformin is effective in the longer term. Results for measures of central adiposity and assessments of other metabolic parameters such as lipids and measures of glycaemic control were mixed and of unclear clinical relevance.

Longer term observational data are available, including a two-year retrospective cohort study in a UK primary care population. Although limited by confounding factors and inherent sources of bias, these suggest metformin is associated with a small but statistically significant reduction in antipsychotic associated weight gain.

There are no published cost-effectiveness analyses of metformin for the prevention or treatment of AIWG. Economic evaluations of weight loss interventions by NICE recognise that long term data are lacking. Their models assumed weight lost is gradually regained over 2 to 10 years. NICE has previously indicated that at a population level, an intervention would be cost-effective if it cost less than £100 to £500 per person (one-off cost) and prevented at least 1kg weight gain. Metformin is estimated to have a very low annual cost (around £29 per patient), which might be below the threshold considered to be cost effective, even if it results in only relatively small attenuation of antipsychotic associated weight gain, however this is uncertain.

Under the applicants' proposal, metformin would be offered to patients only when initiating or switching antipsychotics (estimated to be a maximum of 600 patients per year). The additional annual costs in Devon are estimated to be no more than approximately. £17,000 per year. This would likely result in an increasing cohort of patients i.e. up to 600 additional patients would be initiated on metformin every year..

A discussion took place. The main points of the discussion included:

- the risk of weight gain discourages people from adhering to antipsychotic medication. Weight gain can impact quality of life and physical health,
- the amount of reduction in weight gain, the expected health benefits of this and how long the reduction in weight gain lasts,
- the opinion of specialists present was that metformin is useful in reducing weight gain in patients treated with antipsychotics where lifestyle and diet changes have not been effective. However, it was noted that it did not always work, in which case treatment with metformin is discontinued,
- a suggestion that some newer antipsychotics may not cause weight gain. A specialist present noted that significant weight gain has been seen with aripiprazole in children and young people who appear to be more at risk of experiencing adverse drug reactions, even at lower doses,

- where dose titration would take place. The specialists present explained that they would expect to prescribe metformin until the patient is established on the target dose, after which GPs would be asked to continue prescribing metformin.

The committee voted unanimously in favour of recommending that metformin is routinely commissioned for the prevention of antipsychotic induced weight gain.

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

4. Commissioning policy for bevacizumab for the first line treatment of wet age related macular degeneration

NHS Devon has a long standing policy for bevacizumab for the first line treatment of neovascular (wet) age related macular degeneration (AMD) which has been in place since 2013.

At the time this was developed, bevacizumab was acknowledged to be a closely related drug to ranibizumab but one which was not licensed for use in wet AMD. The policy supported bevacizumab being offered as an alternative to the first line use of ranibizumab for patients meeting the criteria in National Institute for Health and Care Excellence (NICE) Technology Appraisal (TA) 155.

Since then, a number of licensed drug treatments for wet AMD have been recommended by NICE for use under various Technology Appraisal guidance. Besides ranibizumab (TA155), these now include aflibercept (TA294) and faricimab (TA800).

In December 2024 NICE published further Technology Appraisal guidance (TA1022) which recommends the use of bevacizumab gamma as a treatment option for the same population. Bevacizumab gamma is an ophthalmic formulation of bevacizumab, indicated in adults for treatment of wet AMD.

Given the change in available treatment options for this condition since the original policy was developed and the fact that these are recommended by mandatory NICE Technology Appraisal guidance, which the ICB has statutory responsibilities to fund, the existing policy has now been superseded and will be retired accordingly.

The Clinical Policy Recommendation Committee acknowledged that this commissioning policy has now been superseded by NICE Technology Appraisal guidance and will be retired accordingly.

ACTION: Policy to be retired.

5. Commissioning policies for Fluticasone furoate and vilanterol trifenatate combination inhaler (Relvar Ellipta) for chronic obstructive pulmonary disease (COPD) and asthma

As part of routine management of NHS Devon clinical commissioning policies it has been identified that Chronic obstructive pulmonary disease (COPD) and asthma are therapeutic areas which have evolved since the existing policy positions for the use of Relvar Ellipta were formed in 2016 and 2018, respectively.

Relvar Ellipta is a combination dry-powder inhaler containing both an inhaled corticosteroid (ICS), fluticasone furoate, and a long-acting beta₂-agonist (LABA) vilanterol trifenate.

COPD

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) published a report in 2024 which includes a number of changes to the management of COPD.

Prompted by the publication of this report, the Devon Formulary Interface Group discussed and agreed an update to formulary guidance for the management of COPD in September 2024.

This includes a move away from the use of ICS/LABA combination inhalers for patients without features of asthma. Further formulary guidance was subsequently developed and agreed on the management of patients currently using an ICS/LABA combination inhaler for COPD, based on advice on this subject in the GOLD report.

Asthma

In November 2024 a collaborative guideline (NG245) on Asthma was published, having been developed by the British Thoracic Society, NICE and Scottish Intercollegiate Guidelines Network (SIGN).

There is now a recognised move towards anti-inflammatory reliever (AIR) therapy and maintenance and reliever therapy (MART) for asthma.

AIR therapy is treatment with a reliever inhaler that contains a combination of an inhaled corticosteroid and formoterol. When this is used in response to symptoms without regular maintenance therapy it is called as-needed AIR therapy.

MART is a form of combined ICS plus formoterol treatment in which a single inhaler containing ICS and formoterol is used for daily maintenance therapy and the relief of symptoms as needed. Relvar Ellipta is not licensed for either MART or AIR therapy; the LABA component is vilanterol. In November 2024, the only product licensed for as-needed AIR therapy contained budesonide/formoterol. With the changes to clinical guidance in this area there may be a reduction in the market share of Relvar Ellipta compared to other treatment options.

As a result of review of the existing policies in light of the changing context outlined, it was proposed to now retire these policies as national guidance in these therapeutic areas has evolved since the original policy positions were agreed.

The Devon Formulary will continue to support guidance for prescribers, including the continuation of treatment for patients who are stable, whilst being responsive to further changes to support the making of rational treatment choices in Devon.

The Committee unanimously supported the retirement of the commissioning policies for fluticasone furoate and vilanterol trifenate combination inhaler (Relvar Ellipta) for COPD and asthma.

ACTION: Policy Recommendations and EQIAs to be prepared and subsequently progressed to final ICB approval and communication.

6. Commissioning policy for Botulinum Toxin for urinary incontinence due to detrusor overactivity

As part of routine management of clinical commissioning policies it has been identified that the policy rationale requires updating for the existing NHS Devon clinical commissioning policy for Botulinum Toxin for urinary incontinence due to detrusor overactivity, for governance purposes.

This is as a result of the publication of NICE Technology Appraisal guidance TA999 on Vibegron for treating symptoms of overactive bladder syndrome.

The policy rationale states that bladder wall injection of botulinum toxin should only be used in patients refractory to conservative management and drug treatments (including a trial of anticholinergic medication and mirabegron if appropriate).

With the publication of NICE TA999 NICE has said that vibegron works in a similar way to mirabegron. The appraisal evaluation looked at vibegron for the same people who would be offered mirabegron.

A minor addition to the policy rationale was proposed to acknowledge that that vibegron is now recommended by NICE as an alternative treatment to mirabegron, to bring this policy up to date for governance purposes. It does not alter the reasons for the original policy decision, which remains current.

The Clinical Policy Recommendation Committee supported the update to this commissioning policy for governance purposes to reflect latest NICE guidance.

ACTION: Updated policy to be published.

7. Update from NICE Planning Advisory Group (NPAG)

The committee received an update from the NICE Planning Advisory Group.

In total 82 NICE publications were considered at the meetings held on October 2024, December 2024 and February 2025.

Across the three meetings the group considered:

- Thirteen ICB commissioned Technology Appraisals
- 30 NHS England commissioned Technology Appraisals
- 19 Clinical Guidelines
- One Social Care Guideline
- Six Health Technology Evaluations
- Nine Interventional Procedures Guidance
- Four Diagnostic Guidelines

The meeting scheduled for April 2025 had been stood down due to a light agenda. A virtual process had taken place between 25th March and 8th April 2025. This will be reported on at the next CPRC meeting.

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

The committee received an update from the Clinical Policy Engagement and Consultation Panel which took place on 5th December 2024.

The Clinical Policy and Engagement Panel considered two items:

- Ferric Maltol (Feraccru) for iron deficiency in anaemia in inflammatory bowel disease.
- Dymista (Azelastine hydrochloride and fluticasone propionate) nasal spray for allergic rhinitis.

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

9. Clinical Policy Recommendation Committee Annual Report 2024-5 and updated Terms of Reference

Through the Clinical Policy Recommendation Committee the ICB discharges its responsibilities for making local decisions about the funding of medicines and treatments in the NHS, making recommendations for ratification on whether specific treatments represent good value, appropriate, evidence-based choices for adoption into primary care treatment plans via the Formulary and clinical management pathways. This is following discussion of the clinical effectiveness, cost effectiveness and budgetary impact issues.

The annual report gives an account of the activity and governance of the Committee in 2024-25.

During the year four meetings were convened. These considered evidence assessments resulting in 12 new or updated commissioning policy recommendations.

Two meetings were unfortunately stood down during the early part of 2025 due to very limited evidence reviewer capacity in the team pending the conclusion of recruitment processes. A recruitment process has now taken place, and Louise Whitehead has joined the Clinical Effectiveness Team as a Senior Clinical Evidence Review Specialist.

The items considered at the meetings held resulted from a range of inputs, including updated NICE guidance, Academy of Medical Royal Colleges (AoMRC) Evidence Based Interventions guidance, acknowledged changes in clinical practice, and requests from local clinicians for the use of specific treatments to be considered for patients in Devon.

There was also the agreement to retire four commissioning policies following review conducted as part of the routine management of clinical policies. Routine review processes ensure that clinical policies are kept up to date and there is clarity on their ongoing need and relevance to the local health system.

The Committee continues to be supported by two lay public advisory members, to ensure the public interest of the local population is represented in discussion and decision making.

The lay members also sit on the Clinical Policy Engagement and Consultation Panel which continues to support the committee and the ICB by providing a separate opportunity to reflect on the recommendations and consider the public interest issues, to determine the need for any further engagement or formal consultation to be carried out. This occurs prior to a final decision being taken by the ICB.

All policy recommendations also have an Equality and Quality Impact Assessment (EQIA) undertaken as an integral step in the process of policy formation. There have been some changes to the impact assessment process during the year following the ICB review and revision of its processes for EQIA. The secretariat has engaged with the training sessions held in the early part of 2025 and had further discussion with the relevant team to understand the implications of the new process, which uses the Datix system, in relation to clinical policy recommendations to ensure continuity of processes.

In year a number of changes to the committee membership have taken place. In April and November 2024 the group welcomed Dr Ben Titford and Dr Felicity Knott, respectively, to fulfil clinical voting member vacancies on the Committee.

In terms of advisory members, the Committee welcomed John Trevains, the ICB's new Deputy Chief Nursing Officer in April 2024, replacing Susan Masters who stepped down from the Committee in December 2023. However with John's recent departure from the ICB confirmation is now awaited in respect of his replacement on the Committee for future meetings.

Paul Foster, Clinical Director of Pharmacy and Prescribing, resigned from the Committee in November 2024 noting that his attendance had been limited, to enable one of the other trust Chief Pharmacists to replace him.

An attendance review was undertaken in line with good governance principles, to ensure the Terms of Reference remain fit for purpose, and to support mitigation of any risks to the resilience and quoracy of the Committee and therefore its ability to fulfil its functions on behalf of the ICB.

Although progress has been made in filling clinical voting member vacancies on the Committee, challenges remain in filling secondary care clinician advisory member roles on the Committee despite previous escalation. Obtaining secondary care representation is not an isolated challenge to this Committee but has also been escalated as a concern for the Devon Formulary Interface Group.

The Terms of Reference have been updated following the review and were included in the meeting pack.

The Committee received and accepted the annual report, which will subsequently be submitted within the ICB for information and assurance.

ACTION: Clinical Policy Recommendation Committee Annual Report 2024-25 to be submitted within the ICB for information and assurance.

10. Any other business

There was no other business to report.

Summary of actions			
	Action	Lead	Status
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. <u>4th September 2024</u> Policy and QEIA going through the governance process for sign off. <u>13th November 2024</u> As above.	Rebecca Owen	Pending
25/01	Metformin for the management of antipsychotic induced weight gain - policy recommendation and EQIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
25/02	Commissioning policy for bevacizumab for the first line treatment of wet age-related macular degeneration to be retired.	Rebecca Owen	Pending
25/03	Commissioning policies for Fluticasone furoate and vilanterol trifenatate combination inhaler (Relvar Ellipta) for COPD and asthma - policy recommendations and EQIAs to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
25/04	Commissioning policy for Botulinum Toxin for urinary incontinence due to detrusor overactivity to be updated for governance purposes.	Rebecca Owen	Pending
25/05	Clinical Policy Recommendation Committee Annual Report 2024-25 to be submitted within the ICB for information and assurance.	Rebecca Owen	Pending