Clinical Policy Recommendation Committee Minutes

Wednesday 6th September 2023
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
Dr Lucy Harris	Voting Member	NHS Devon
Dr Claire Hooper	Voting Member	NHS Devon
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NHS Devon
Mark Taylor	Lay Public Member	
Dr Emily Youngman	Consultant in Public Health Medicine	Devon County Council

Guests:

Matt Howard	Clinical Evidence Manager	NHS Devon
Amy Rice	Clinical Effectiveness Pharmacist – Commissioning Projects Lead	NHS Devon

Observers:

Sam Trethewey	Speciality Registrar on placement with Public Health Devon	Devon County Council
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon

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	Clinical Director of Pharmacy and Prescribing	T&SD
Barbara Jones	Head of Contracting	NHS Devon
Susan Masters	Deputy Chief Nursing Officer	NHS Devon

Dr Paul Melling	Voting Member	NHS Devon

Confirmation of voting members and Declarations of interest

The five voting members present were identified.

Dr Paul Melling had delegated voting to Chris Roome.

There were no Declarations of Interest to report.

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Breast Implant Removal and Replacement	Providers of private breast implant removal and replacement
Penile circumcision	Providers of private penile circumcision

Notification of Any Other Business

The committee were asked if there were any items of any other business to note.

2. Minutes of the meeting held on 28th June 2023 and matters/actions arising

The minutes of the meeting held on 28th June 2023 were approved.

Summary of actions			
	Action	**Lead**	**Status**
23/01	High Intensity Focussed Ultrasound for recurrent prostate cancer – Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		This policy was published and communicated on 29th August. Action complete.
23/02	Cryotherapy for recurrent prostate cancer – Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		This policy was published and communicated on 29th August. Action complete.

23/03	Focal hyperidrosis – Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 06/09/2023 The policy has been approved by the ICB and is pending confirmation from DRSS colleagues of any referral implications before publication and communication.	Rebecca Owen	Pending
23/04	Clinical Policy Recommendation Committee Annual Report 2022-23 to be submitted to the Strategy and Transformation SLT on behalf of NHS Devon ICB for information and assurance, and the risk posed by ongoing membership challenges to be escalated. 28/06/23 This action is progressing within the context of changes to organisational structures within NHS Devon. 06/09/23 The Annual Report has been shared with Nigel Acheson for information and advice on any onward reporting within the ICB.	Rebecca Owen Chris Roome	Pending
23/05	Lurasidone for schizophrenia in adults – policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 06/09/23 The policy has been approved by the ICB and is due for publication and communication following FIG discussion.	Rebecca Owen	Pending
23/06	Lurasidone for schizophrenia in children and adolescents - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 06/09/23 The policy has been approved by the ICB and is due for publication and communication following FIG discussion.	Rebecca Owen	Pending

3. Breast Implant Removal and Replacement

A review of the ICB's policy for Breast Implant Removal was identified in response to recommendations published in the latest edition of the Evidence Based Interventions guidelines

(EBI). These recommendations were prompted by reports of concerns from patients about the potential side effects of breast implants, and subsequent requests for their removal in the absence of a recognised medical condition.

Amy Rice, Clinical Effectiveness Pharmacist provided an overview of the EBI programme and presented a paper in relation to the EBI recommendations for breast implant removal.

The side effects identified are linked to breast implant illness, or autoimmune syndrome induced by adjuvants, which are two terms used by some people to describe a constellation of symptoms which they feel are associated with their breast implants. However, neither presentation is a disease recognised by the World Health Organisation, and the MHRA states that there is no evidence to indicate a link between breast implants and these reported health problems. In addition, there are reports of patients requesting implant removal due to concerns about developing breast implant associated anaplastic large cell lymphoma, which is a form of non-Hodgkin's lymphoma. Whilst this is a serious condition, requiring removal of the implant and surrounding tissue, it is an uncommon presentation. International regulators, including the MHRA, state that current evidence indicates no reason to remove implants in the absence of any symptoms of this condition.

As such, EBI does not recommend the removal of implants for these scenarios. In addition, EBI outlines the medical conditions for which removal of breast implants are recommended, as well as the guidance for patients whose original augmentation procedure was privately funded.

Activity data for NHS Devon shows that for the period of April 2022 to March 2023, 52 breast implant removals were performed. The reason for removal cannot be determined in most cases due to limitations in the specificity of ICD-10 diagnostic criteria, therefore it is unclear whether current local activity is aligned with EBI recommendations. At present, no activity targets have been set in relation to this edition of the EBI guidelines, however this may change in the future.

Conditions where implant removal are routinely commissioned in Devon are outlined in the breast implant removal and replacement commissioning policy. This was last reviewed in 2012, the criteria in this policy differ from the EBI recommendations.

Consultation with specialists at all three providers and with the Devon Referral Support Service identified that within the current policy, the criteria of implant rupture and capsular contracture could remain as these are supported by the EBI recommendations. Poly Implant Prothèse implants are however not mentioned in the EBI recommendations, and further investigation identified that the MHRA now advises that there is no data to justify the removal of intact PIP implants. As such, it was agreed that this criterion could be removed from the policy. Significant breast pain is also not included as a criterion in the EBI guidelines. Consultation with specialists identified that the majority of presentations with breast pain where implant removal would be indicated are covered by other criteria, with the exception of pain due to capsular contracture. The existing criterion of capsular contracture grade 4 captures most cases of pain associated with this presentation, however they highlight that, as a subjectively measured classification system, some patients may also present with grade 2 contractures in which there is less noticeable firmness or deformity in the implant, but still experience significant pain which can only be resolved by implant removal. Consequently, it was agreed that the criterion of significant breast pain could be removed from the policy but that capsular contracture grade 2 with associated significant pain would be added in its place. As this represents existing practice it is not felt that this change would result in an increase in activity.

The EBI guidelines also recommend implant removal for recurrent implant infection or seroma, cases of breast implant associated anaplastic large cell lymphoma, and capsular contracture grade III. None of these criteria are included in the current NHS Devon policy. Specialists confirmed that they would already remove implants complicated by infection, seroma, or lymphoma and supported the addition of these criteria to the policy. However, regarding capsular contracture grade III, NHS Devon have historically made a conscious decision not to commission removal for this presentation

as it represents a cosmetic rather than a medical issue. Specialists agreed that we should continue to follow this position.

DRSS also requested clarification of the wording in relation to implant replacement. The intention of the current policy is that when removing implants, they would only be replaced for patients whose original augmentation was performed by the NHS. This position is reflected in the EBI guidelines. As such, alternative wording has been developed to make this position clearer.

The committee received the proposed policy together with feedback from specialists. Since the circulation of these papers, specialists from RDUH have confirmed their support for the proposed policy update.

The committee considered issues pertinent to the proposed update to Devon ICB's policy for Breast Implant Removal and Replacement. There was discussion about:

- Patients previously treated privately: Policy wording for patients whose original augmentation was privately funded was discussed. Stronger wording to support redirection of this cohort to their original private provider was suggested however it was highlighted that, provided patients had a medical need for removal (in line with the policy criteria), this patient cohort has an equal right to request implant removal by the NHS.
- Patients previously treated by the NHS: The position for replacement of implants for patients previously treated by the NHS who would not be eligible for treatment now was raised. Whilst the cosmetic treatments policy has been in place for a long time, requests are still received for implant replacement for patients whose original augmentation was performed before this policy was in place. It was acknowledged that these cases would meet criteria for consideration at the exceptional funding panel. Confirmation was provided that the proposed policy wording had been agreed with DRSS.
- Eligibility for the removal of implants: Questions were raised about the criteria for removal. The NHS has a duty of care to offer removal where there is a medical need but not where changes are purely cosmetic. Patients should have been informed of the finite lifespan of implants by their breast surgeon as part of the consenting process prior to the original augmentation procedure.
- Removal due to painful capsular contracture: Subjectivity of pain associated with capsular contracture was raised. Feedback from specialists stated that removal of implants with capsular contracture was only indicated where there was associated pain, which is reflected in the proposed criteria. The only classification systems in use are subjective (mainly in relation to appearance and the presence of pain) but specialists provided assurance that they do not want to remove implants unnecessarily. It was noted that the much broader criterion of 'significant breast pain' had been included in the policy for 11 years; the proposed update provides greater clarity.

The committee voted unanimously in favour of recommending the recommendations of the policy review.

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

4. Penile circumcision

The third edition of the EBI guidelines, published in May 2023, include recommendations for penile circumcision in children under 16 years of age. These recommendations were prompted by variations in circumcision activity at providers across England identified in the Getting It Right First Time (GIRFT), paediatric general surgery and urology national report, published in 2021. This report highlights higher than expected circumcision rates in children under the age of 5, a group where medical reasons for circumcision are limited, with substantial variation between different providers. Data presented by GIRFT indicates that the majority of circumcisions in young children were

performed due to physiological phimosis. As this condition naturally resolves with age in most boys, performing a circumcision would have been unnecessary in a large proportion of cases. EBI recommends that circumcision for physiological phimosis is restricted to persistent cases which have not responded to non-operative management. The guidelines also outline additional medical reasons for circumcision in children. At present, EBI have not set any targets for a reduction in activity, but a consultation for the development of coding sets to monitor activity is in progress, so this position may change in the future.

Amy Rice, Clinical Effectiveness Pharmacist presented a paper.

Activity data for NHS Devon shows that for the period of April 2022 to March 2023, circumcision rates in children under 5 years of age were lower than the overall average for England cited in the GIRFT report. Analysis of ICD-10 diagnostic codes indicates a small number of cases which could indicate circumcision for physiological phimosis, but limitations in the specificity of the diagnostic codes prevents an accurate assessment. As such, it is possible that there is some inappropriate activity in NHS Devon, albeit in very small numbers. The current commissioning position for circumcision in NHS Devon is outlined in the circumcision policy which covers both children and adults. Last reviewed in 2011, the criteria in this policy differ from the EBI guidelines.

Consultation with specialists at all three providers and with the Devon Referral Support Service identified that within the current policy, the criterion of balanitis xerotica obliterans could remain as this is supported by the EBI guideline. Circumcision due to balanoposthitis is not included in the EBI guidelines, however circumcision for recurrent cases is supported by guidelines from the Royal College of Surgeons, the British Association of Paediatric Urologists, and the European Association of Urologists. Specialists indicated a need to retain this criterion but as it is a commonly presenting condition in primary care, a definition of recurrence was required. There is no nationally recognised definition but best practice guidelines currently in development by the South West surgery in children operational delivery network, propose an incidence of 3 episodes per year. Specialists and DRSS agreed with the adoption of this definition. Finally, the current criterion of phimosis or paraphimosis is also supported by EBI but more specificity is required to promote non-operative management and restrict circumcision for physiological phimosis to persistent symptomatic cases. During consultation with specialists and DRSS, alternative wording to the EBI guidelines were developed, so that this criterion gives a clear indication of symptoms for which circumcision for physiological phimosis should be commissioned.

The EBI guidelines also recommend circumcision for acquired trauma, and the prevention of urinary tract infections, or UTIs. Neither of these criteria are included in the NHS Devon policy. Specialists confirmed that they would already perform circumcision for acquired trauma, as such adoption of this criterion would not represent an increase in activity. Concerns were however raised about ambiguity in the wording of EBI's criterion for circumcision to prevent UTI. Further investigation, including review of the national guidelines on which the EBI recommendations are based, confirmed that this relates to cases of physiological phimosis in patients with urinary tract abnormalities, and cases of infections caused by balanitis or balanoposthitis. An adaptation of the physiological phimosis criterion was therefore developed with specialists to provide a more prescriptive description. Again, specialists indicated these are existing reasons for which they would perform circumcision and so their adoption would not represent an increase in activity.

The committee received the proposed policy together with feedback from specialists.

The committee considered issues pertinent to the review of Devon ICB's policy for Penile Circumcision. There was discussion about:

<u>The process for consulting with specialists</u>: This process began with EBI. The Clinical Effectiveness Team then undertook an initial consultation with specialists on a first proposal. Specialists provided comments which were reviewed and included in the policy as appropriate. The proposed policy was

then recirculated to specialists for further comment. If there are any difficulties, specialists are informed that they will be discussed by the Clinical Policy Recommendation Committee and are encouraged to attend.
Risk of UTI: Circumcision is only indicated for patients with a condition which puts them at an increased risk of recurrent UTIs which would be reduced by this procedure.
Rates of procedure in NHS Devon compared to other areas: Activity data for children under 5 years in NHS Devon are lower than the national average cited in the GIRFT report. Activity in this cohort is largely unnecessary so this suggests good local practice, but the committee queried whether, being so much lower, was appropriate. Limitations in the specificity of diagnostic coding makes it difficult to definitively establish reasons for circumcision; it is possible that some areas undertake more activity because the data includes cohorts of children treated at specialist children's centres. It was agreed that Amy Rice would attempt to obtain activity data for other areas for reassurance.

ACTION: Amy Rice to attempt to obtain activity data for other areas for reassurance.

The committee voted unanimously in favour of recommending the recommendations of the policy review.

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

5. Botulinum Toxin for urinary incontinence due to detrusor overactivity

As part of the routine management of clinical commissioning policies some minor amendments are proposed to the rationale of the existing NHS Devon policy for Botulinum Toxin for urinary incontinence due to detrusor overactivity, for governance purposes.

Rebecca Owen, Clinical Effectiveness Governance Manager, presented the proposals.

These acknowledge that NICE clinical guideline CG171 on Urinary incontinence in women which is referred to in the policy rationale has subsequently been updated by NG123, and also the changes to some of the specialised commissioning arrangements following the establishment of ICBs.

The changes bring the policy up to date, but they retain and do not alter the reasons for the original policy decision, which remains current.

The committee considered issues pertinent to the proposed minor amendment to the rationale of the existing policy for Botulinum Toxin for urinary incontinence due to detrusor over activity. No areas of concern were noted.

Rebecca Owen to publish the updated policy.

ACTION: Rebecca Owen to publish the updated policy

6. Update from NICE Planning Advisory Group (NPAG)

The committee received an update from the NICE Planning Advisory Group. Two meetings of the group had taken place since the last CPRC meeting on 28th June 2023. The NPAG meetings took place on Tuesday 13th June and Tuesday 8th August.

Across the two meetings the group considered:

- Eight ICB commissioned Technology Appraisals

- 21 NHS England commissioned Technology Appraisals
- Five NHS England Commissioned Highly Specialised Technologies
- 11 Clinical Guidelines
- 15 Interventional Procedures Guidelines
- Seven Medical Technology Guidelines

7. 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 in County Hall on Thursday 20th July 2023.

The Clinical Policy and Engagement and Consultation Panel (CPEC) considered 2 items:
- Lurasidone for schizophrenia in adults
- Lurasidone for schizophrenia in children and adolescents

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

8. Formulary Interface Group (FIG) Annual Report

The committee received the annual report of the Devon Formulary Interface Group (FIG) 2022 - 2023.

The report provides an overview of the work undertaken by the Devon FIG from 1St April 2022 to 31 March 2023. During this time the FIG delivered the Devon formulary to promote prescribing, which is safe, clinically appropriate, and cost-effective in both primary and secondary care by providing guidance on locally recommended treatment choices.

The Annual Report details the governance processes that support the FIG, including the terms of reference, quoracy, declarations of interest, FIG process and meeting arrangements.

Dr Tawfique Daneshmend, Consultant Representative (RDUH) and Chair, stepped down from the FIG in January 2023. Dr Daneshmend had supported the development of the local formularies in Devon for over 25 years. Dr Daneshmend had been instrumental in the development of the first Exeter, East and Mid Devon Formulary, and had Chaired both the North and East Devon Formulary Interface Group, and subsequently the Devon Formulary Interface Group which brought together the two predecessor groups. Since March 2023 Dr Susie Harris, Consultant Representative (RDUH) has Chaired the group.

Dr Jamie Smith, Consultant Representative (T&SD) and Samantha Smith, Pharmacist Representative (RDUH) stepped down from the group in August 2022, Dr William Nolan, GP Representative stepped down in October 2022. Dr Smith, Ms Smith and Dr Nolan had been committed FIG members over a number of years and made significant contributions to support the work of the group.

Becki Lowe, Joint Formulary Pharmacy Technician, NHS Devon, joined the Group in October 2022.

To demonstrate compliance with the ICB's statutory obligation to fund and resource medicines and treatments recommended by NICE guidance; 78 Technology Appraisals and 5 Highly Specialised Technologies were added to the Devon Formulary during the period of this annual report. During the period of this report, the FIG agreed formulary entries for three treatments which the CPRC had recommended for commissioning. These were included in the formulary once the final policy had

been ratified. As were two ICB ratified CPRC recommendations not to routinely commission a treatment.

The focus of the Devon FIG has been to maintain a reliable and up-to-date resource while considering every opportunity to harmonise recommendations across both presentations. Devon Formulary recommendations have been steadily converging, and recommendations between localities are now more similar than different. Although a Devon-wide perspective is already adopted when developing or updating formulary guidance and recommendations, some variation remains for variety of reasons. This supports a consistent approach to prescribing across the county, whilst promoting safe, effective, and economic prescribing in primary and secondary care.

The FIG considered several individual product applications which provided financial savings (totalling almost £1million) and/or clinical benefits (such as products to support patients with swallowing difficulties or those requiring enteral feeding).

In Devon, “Shared Care” arrangements are resourced via the Specialised Medicines Service (SMS). Specific financial arrangements are not within the remit of the FIG, however the FIG is responsible for deciding whether a medicine is appropriate for “Shared Care” and for agreeing the clinical content of SMS guidelines. To reduce differences between historical individual trust guidelines and multiple guidelines for the same indication, the Devon FIG has endorsed a Devon-wide approach wherever possible when reviewing and updating local “shared care” / SMS guidelines. During the period of this report, the FIG considered and agreed seven new or updated SMS guidelines for use locally.

Supporting safe use of medicines is an important part of the formulary. Each month the MHRA publishes a Drug Safety Update (DSU) for healthcare professionals. Between April 2022 and March 2023, the FIG considered MHRA DSU advice for 20 treatments and noted 66 letters and drug alerts sent to healthcare professionals. Following a National Patient Safety Alert on the inadvertent oral administration of potassium permanganate in April 2022, this product was reclassified as specialist input and the supporting notes on the formulary entry were updated accordingly.

The Devon Formulary has a bespoke website which is geographically tailored to reflect the decisions of the Devon FIG. Although the S&W and N&E Devon FIGs merged in February 2021, the two presentations of the Formulary website have been retained whilst content is reviewed, and recommendations harmonised. Website traffic has increased substantially year on year since its launch and the clinical content has expanded to meet more of the needs of users. As a result, the underpinning infrastructure requires upgrading; a new Devon Formulary & Referral website is in development. The new website will provide improved features such as advanced searching functionality, a browsable A-Z drug list, and a revitalised design. Between April 2022 and March 2023, the combined number of page views was 2,660,898 (1,448,338 for S&W Devon and 1,212,560 for N&E Devon).

The Devon Formulary & Referral App was no longer able to support the volume of information and the frequency of updates required, it was therefore withdrawn in the summer of 2022 as the new website will be optimised for use on mobile devices.

The Devon FIG annual report for 2022 - 2023 has been accepted by the FIG.

The committee accepted the FIG annual report. The committee noted that the Devon Formulary is an amazing resource which makes a difference to healthcare in Devon. The committee thanked the Formulary Team for their hard work and commitment to the Devon Formulary.

The FIG membership was thanked for their continued support and the quality of their input and engagement.

9. Any other business

ICB Reorganisation

The group discussed clinical representation on the group, and whether this was being considered during the ICB reorganisation.

It was noted that the need for clinical membership was recognised in principle by the ICB. However, finding the right people to fill the gaps in membership is not straightforward, clarity is required to ensure that those joining the group have the right expertise and motivations to fulfil the expectations of the role.

Summary of actions			
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23/03	Focal hyperidrosis – Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 06/09/2023 The policy has been approved by the ICB and is pending confirmation from DRSS colleagues of any referral implications before publication and communication.	Rebecca Owen	Pending
23/04	Clinical Policy Recommendation Committee Annual Report 2022-23 to be submitted to the Strategy and Transformation SLT on behalf of NHS Devon ICB for information and assurance, and the risk posed by ongoing membership challenges to be escalated. 28/06/23 This action is progressing within the context of changes to organisational structures within NHS Devon. 06/09/23 The Annual Report has been shared with Nigel Acheson for information and advice on any onward reporting within the ICB.	Rebecca Owen Chris Roome	Pending
23/05	Lurasidone for schizophrenia in adults – policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. 06/09/23 The policy has been approved by the ICB and is due for publication and communication following FIG discussion.	Rebecca Owen	Pending

23/06	Lurasidone for schizophrenia in children and adolescents - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication. <u>06/09/23</u> The policy has been approved by the ICB and is due for publication and communication following FIG discussion.	Rebecca Owen	Pending
23/07	Breast Implant Removal and Replacement - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
23/08	Penile circumcision – attempt to obtain activity data for other areas for reassurance.	Amy Rice	Pending
23/09	Penile circumcision - policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
23/10	Botulinum Toxin for urinary incontinence due to detrusor overactivity – publish updated policy.	Rebecca Owen	Pending