Clinical Policy Recommendation Committee Minutes

Wednesday 26th April 2023
via Microsoft Teams

Present:

Name	Job Title	Organisation
Dr Glen Allaway	Chair	NHS Devon
Dr Andrew Craig	Voting Member	NHS Devon
Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon
Dr Lucy Harris	Voting Member	NHS Devon
Dr Claire Hooper	Voting Member	NHS Devon
Barbara Jones	Head of Contracting	NHS Devon
Susan Masters	Deputy Chief Nursing Officer	NHS Devon
Dr Paul Melling	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
Dr Dominique Parslow	Consultant Clinical Oncologist (Uro-oncology and hepato-pancreato-biliary)	UHP
Amy Rice	Clinical Effectiveness Pharmacist – Commissioning Projects Lead	NHS Devon

Observers:

Harriet Enoch	Registrar in Public Health	Torbay Council

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
Dr Kay Brennan	Voting Member	NHS Devon
Paul Foster	Clinical Director of Pharmacy and Prescribing	T&SD

Confirmation of voting members and Declarations of interest

The five voting members present were identified.
Kay Brennan had delegated voting to Susan Masters.
Declarations of Interest were collected. No declarations of interest were made.

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
High Intensity Focussed Ultrasound (HIFU) and Cryotherapy for recurrent prostate cancer	Providers of surgical treatment options for patients with recurrent prostate cancer
Alternative treatments:	
Radical prostatectomy	} Providers of surgical treatment options for
Radiotherapy	} patients with recurrent prostate cancer
Androgen deprivation therapy	
Orchidectomy	Providers of surgical treatment options for patients with recurrent prostate cancer
Abiraterone (Zytiga®)	Janssen-Cilag Ltd
Darolutamide (Nubeqa®)	Bayer plc
Goserelin (Zoladex®)	AstraZeneca UK Limited
Triptorelin (Decapeptyl®, Gonapeptyl Depot®)	Ipsen Ltd, Ferring Pharmaceuticals Ltd
Focal hyperhidrosis	
Hyperhidrosis management and the use of systemic oral anticholinergic drugs (propantheline bromide and oxybutynin):	
Propantheline bromide	Kyowa Kirin Ltd
Oxybutynin	Various manufacturers
Glycopyrronium bromide	Various manufacturers
Aluminium chloride hexahydrate	Dermal laboratories Ltd/GlaxoSmithKline Consumer Healthcare
Botulinum toxin A (Botox®, Dysport®, Xeomin®)	AbbeVie Ltd, Ipsen Ltd, Merz Pharma UK Ltd

Notification of Any Other Business

No other items of business were noted.

2. Minutes of the meeting held on Wednesday 16 November and matters/actions arising

The minutes of the meeting held on Wednesday 16th November were approved.

Summary of actions			
	Action	**Lead**	**Status**
22/08	Continuous Glucose monitoring: Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		The policy was published on 7th December 2022. Action Complete
22/11	Guanfacine for the management of ADHD in children and adolescents: Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		The policy was published on 26th January 2023. Action Complete
22/12	Nefopam for the management of chronic pain: Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		The policy was published on 3rd January 2023. Action Complete
22/13	Ear wax removal in secondary care: Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		The policy was published on 6th February 2023. Action Complete
22/14	Surgical interventions for chronic rhinosinusitis: Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		The policy was published on 6th February 2023. Action Complete
22/15	Otigo for acute otitis media: Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.		The policy was published on 3rd January 2023. Action Complete

3. High Intensity Focussed Ultrasound (HIFU) and Cryotherapy for recurrent prostate cancer

HIFU

HIFU is not routinely commissioned in NHS Devon. Despite this, UHP is currently referring patients with localised recurrent prostate cancer to an out of area provider for salvage HIFU which prompted a need to review the commissioning policy.

The strategic position is unclear. NICE clinical guideline NG131 states that for localised and locally advanced prostate cancer, HIFU should only be used as part of controlled clinical trials comparing its use with established interventions. NICE have also published IPGs however their recommendations directly conflict with those of NG131.

Amy Rice, Clinical Effectiveness Pharmacist presented a paper. Dr Dominique Parslow was present for discussion of this item.

Evidence for effectiveness is extremely limited. No studies have been published which compare outcomes with hormone therapies. Only one study drew direct comparisons between salvage HIFU and salvage radical prostatectomy, reporting no difference in overall survival, cancer specific survival, metastasis free survival, or androgen deprivation therapy (ADT) initiation. The incidence of prostate cancer recurrence was not reported. A meta-analysis of observational studies showed that at 2 years, salvage HIFU had a significantly lower recurrence free survival rate than salvage radical prostatectomy, however at 5 years the difference was not significant. An additional study comparing salvage cryotherapy and HIFU found that cryotherapy had a significantly lower estimated recurrence rate, but differences in mortality, metastatic disease and ADT initiation were not significant. The reliability of each of these studies is limited by the presence of significant heterogeneity, largely driven by non-randomised study designs (with resultant variations in patient characteristics and potential selection bias), and inconsistent definitions for prostate cancer recurrence. Additional findings have also been published in a number of single-arm observational studies however in the absence of control or active comparators, the relevance of their findings are difficult to interpret. Follow up periods are limited.

Reported adverse events are primarily genitourinary or gastrointestinal in nature. Erectile dysfunction has also been reported but the incidence, compared to other treatments, has not been reported. Only one study directly compared the incidence of adverse events for salvage HIFU versus salvage radical prostatectomy, reporting a significantly lower rate of urinary incontinence and rectal injury for salvage HIFU but the rate of urinary retention was significantly higher. Differences in other adverse events including rectal fistula were not significant. A meta-analysis found no significant differences in the incidence of severe gastrointestinal or severe genitourinary adverse events between these two treatments. As previously highlighted, these studies are subject to heterogeneity.

No cost-effectiveness studies have been published. At a cost of approximately £4,700 per procedure, treatment is between £230 and £2,000 cheaper than prostatectomy, dependent on the prostatectomy technique used. Compared to the use of hormone therapy alone, i.e., with no salvage treatment, in order for salvage HIFU to represent a lower cost treatment it would need to delay progression onto androgen deprivation therapy by 5.7 years. It is not clear from available efficacy data whether, on average, this could be achieved.

Specialists at UHP propose the use of salvage HIFU with specific clinical criteria, for which they estimate there would be approximately 5 patients per year. RDUH have indicated that they would not use this treatment. This would equate to a total cost of approximately £23,500 per year. The alternative would be salvage radical prostatectomy. Using HIFU instead would result in a saving of approximately £1,200 to £10,500 per year.

The committee considered issues pertinent to the review of the commissioning policy for HIFU for recurrent prostate cancer. The key points of the discussion included:

- Treatment options HIFU is offered to otherwise fit patients who have had a recurrence of prostate cancer following radical radiotherapy and have a natural life expectancy of more than five years. Patients who have had low-dose rate (LDR) brachytherapy and subsequently relapse are not offered HIFU due to concerns the brachytherapy seeds affect the HIFU treatment. HIFU offers a potentially curative treatment that is less invasive than radical

prostatectomy which for some patients also involves complete removal of the bladder (cystoprostatectomy). HIFU is not available locally, UHP refers patients to Southampton. RDUH does not offer HIFU to patients as specialists feel there is not sufficient evidence to support it. Patients are instead offered HDR radiotherapy or salvage radical prostatectomy.

- Evidence Published evidence investigating HIFU is limited. The specialist highlighted that as patient numbers are small it can be difficult to conduct randomised controlled trials in this area. The reliability of the published observational studies is limited by inconsistencies in patient characteristics and criteria used to define prostate cancer recurrence. This makes comparison of outcomes from studies of other therapies inappropriate. Follow up periods for studies of HIFU are limited despite this therapy being available for many years. Provision of treatment with HIFU nationally is lacking; it was suggested that this may be due to lack of clinical trial evidence.

The group agreed to consider Cryotherapy before voting on HIFU and Cryotherapy.

The committee later voted unanimously against the routine commissioning of HIFU for the treatment of recurrent prostate cancer.

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

CRYOTHERAPY

Cryotherapy is currently commissioned for patients with recurrent prostate cancer. This policy was published in 2011. Current specialist opinion and provision differs within Devon. Alongside an unclear position from NICE, it was felt that the policy required review. UHP is the only provider offering salvage cryotherapy with patients referred to an out of area provider.

The strategic position is unclear. NICE clinical guideline NG131 states that for localised and locally advanced prostate cancer, cryotherapy should only be used as part of controlled clinical trials comparing its use with established interventions. NICE have also published IPGs however their recommendations directly conflict with those of NG131.

Amy Rice, Clinical Effectiveness Pharmacist presented a paper. Dr Dominique Parslow was present for discussion of this item.

Evidence for effectiveness is extremely limited. No studies have been published which compare outcomes with hormone therapies. Only one study drew direct comparisons between salvage cryotherapy and salvage radical prostatectomy, reporting that cryotherapy had a significantly lower recurrence free survival and overall survival rate. The difference in cancer specific survival was not significant. The relevance of these findings to current clinical practice is unclear as procedures in both groups were completed 25 to 30 years ago. A meta-analysis of observational studies showed no difference in recurrence free survival between salvage cryotherapy and salvage radical prostatectomy. An additional meta-analysis estimated mortality rates for studies of salvage cryotherapy versus salvage radical prostatectomy, reporting no significant difference in overall or cancer specific survival. The reliability of each of these studies is limited by the presence of significant heterogeneity, largely driven by non-randomised study designs (with resultant variations in patient characteristics and potential selection bias), and inconsistent definitions for prostate cancer recurrence. The only study comparing salvage cryotherapy and salvage HIFU found that cryotherapy had a significantly lower estimated recurrence rate, but differences in mortality, metastatic disease and ADT initiation were not significant. Additional findings have also been published in a number of single-arm observational studies however in the absence of control or active comparators, the relevance of their findings are difficult to interpret. Follow up periods are longer than those reported for studies of salvage HIFU.

Adverse events were primarily genitourinary or gastrointestinal in nature. Erectile dysfunction has also occurred, but the incidence compared to other treatments has not been reported. No studies report a direct comparison of adverse events for cryotherapy versus salvage radical prostatectomy. However, a meta-analysis of observational studies demonstrated no significant difference in severe genitourinary or severe gastrointestinal events between these two treatments. In the only study directly comparing salvage cryotherapy to salvage HIFU, cryotherapy had a significantly higher incidence of urinary retention, and mild to moderate urinary incontinence but differences in other adverse events were not significant.

Cost-effectiveness has been considered in a cost-utility analysis, comparing salvage cryotherapy to two different regimens of ADT. Cryotherapy dominated both ADT regimens with lower costs, and higher QALY gains. Since the study was published, there has been a reduction in costs for cryotherapy and one of the hormone therapies. In an adjustment to reflect this change, cryotherapy has a higher cost than deferred ADT but, assuming no change to QALY gains, cryotherapy remains a cost-effective option with an ICER of £3,262 per QALY gained. This model is however subject to uncertainty owing to assumptions made in the absence of published data, particularly regarding the response to hormone therapy after salvage cryotherapy, and the initiation of ADT at the point of biochemical recurrence rather than the development of advanced disease.

Specialists at UHP propose the use of salvage cryotherapy with specific clinical criteria, for which they estimate there would be approximately 5 patients per year. RDUH have indicated that they would not use this treatment. This would equate to a total cost of approximately £14,200 per year. The alternative would be salvage radical prostatectomy. Using cryotherapy instead would result in a saving of approximately £10,400 to £19,700 per year. The difference in cost compared to ADT is difficult to estimate. Using salvage cryotherapy would need to delay progression onto hormone therapy by 3.5 years in order for it to represent a lower cost treatment. This is shorter than the requirement for salvage HIFU or salvage radical prostatectomy.

The committee considered issues pertinent to the review of the commissioning policy for HIFU for recurrent prostate cancer. The key points of the discussion included:

- Equal access to treatment options for patients in Devon It was noted that few centres offer cryotherapy in the UK. Patients from UHP are referred to Southampton where the options are discussed by a multidisciplinary team. The specialist stated that some patients from Plymouth who have declined other options have experienced good outcomes. Cryotherapy is not offered to patients from RDUH due to doubts of its effectiveness. There is a need to ensure that all patients in Devon are offered the same treatment options.
- Clinical Trial Evidence The evidence of the effectiveness and tolerability of cryotherapy in a salvage setting is extremely limited. Studies can be difficult to undertake with the majority adopting a single arm observational design which limits the ability to draw comparisons to other treatments. Recruitment to randomised controlled trials can be difficult as participants often have strong opinions regarding their preferred treatment option and may pull out of trials if they are not happy with their allocation. Nevertheless, alternative comparative study designs are available. No records of planned or in progress clinical trials making direct comparisons between salvage cryotherapy and salvage radical prostatectomy have been identified.
- Use of NHS resources Cryotherapy is less expensive than prostatectomy. Devon wide routine offer of cryotherapy may result in more patients taking this option rather than salvage radical prostatectomy. Whilst cryotherapy is cheaper to perform than prostatectomy the possible reduction in NHS costs needs to be considered in the context of the limited evidence of effectiveness.

The committee voted three to two in favour of stopping the routine commissioning of cryotherapy for the treatment of recurrent prostate cancer.

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

The Chair thanked Dr Parslow for attending the meeting for the discussions on HIFU and cryotherapy for recurrent prostate cancer.

4. Focal hyperhidrosis

The current commissioning policy for focal hyperhidrosis, which was published in 2013, is not reflective of clinical practice at providers within NHS Devon. An update to the Devon Formulary, agreed through the Devon Formulary Interface Group, means that there is no longer a need for a specific commissioning policy for the use of topical aluminium, oral anticholinergic drugs, and iontophoresis with content now covered in the formulary. Furthermore, endoscopic thoracic sympathectomy which is the only surgical intervention included in the current commissioning policy, is no longer recommended by specialists due to poor outcomes and risks of complications.

No clinical guidelines on the management of hyperhidrosis have been published by NICE. Interventional procedures guidance has been issued for endoscopic thoracic sympathectomy, and whilst the procedure is recommended under standard arrangements, the risks of complications and uncertain outcomes alongside a need for specialist expertise is highlighted.

Amy Rice, Clinical Effectiveness Pharmacist presented a paper.

Following consultation with specialists, an update to the commissioning policy has been developed which now relates to the only intervention provided by secondary care services for focal hyperhidrosis, intradermal injections of botulinum toxin A. Revised criteria for treatment of axillary hyperhidrosis with botulinum toxin have been proposed by specialists which are more restrictive than the current commissioning policy. This ensures that treatment is only provided to those with severe hyperhidrosis, which is in line with the product license. These criteria have been discussed and agreed with dermatologists across the peninsula. In addition, specialists propose that the unlicensed use of botulinum toxin for palmar or plantar hyperhidrosis is no longer commissioned. Administration to these sites is extremely painful, requiring the use of anaesthetic, usually a nerve block, which specialists feel is inappropriate. Consequently, it is not offered by specialists in Devon.

Whilst the proposed criteria for treatment with botulinum toxin for axillary hyperhidrosis are more restrictive, the extent of any reduction in activity is difficult to ascertain, including what financial benefits such as drug acquisition costs and nominal savings in outpatient services would be achieved. Specialists have stated that they do not offer botulinum toxin for other sites, including palms and feet, and so removal of this unlicensed treatment option from the policy is not expected to have a significant impact. The removal of endoscopic thoracic sympathectomy is not expected to impact services. Specialists report that there are no clinicians within Devon with the relevant expertise to perform the procedure and they have not felt the need to offer this option in over 10 years.

The committee considered issues pertinent to the proposed update to the commissioning policy for focal hyperhidrosis. It was noted that the updated policy would be helpful to dermatologists.

The committee voted unanimously in favour of recommending the proposed update to the commissioning policy for focal hyperhidrosis.

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

5. 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 16th November 2022. The NPAG meetings took place on Tuesday 29th November 2022 and Tuesday 21st February 2023.

Across the two meetings the group considered:

- Nine ICB commissioned Technology Appraisals
- 19 NHS England commissioned Technology Appraisals
- 12 NICE Guidelines
- Two Diagnostic Guidelines
- One Clinical Guideline
- Six Interventional Procedures Guidelines
- Four Medical Technology Guidelines

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

The committee received an update from the Clinical Policy Engagement and Consultation Panel meeting which took place via Microsoft Teams on Thursday 8th December 2022.

The Clinical Policy and Engagement Panel had considered 5 items. The panel made a recommendation for one item. This was:

- Ear wax removal in secondary care.

  For this item the panel recommended that no further engagement or formal consultation was required at this point. However, the panel noted that, resulting from enquiries received, the communications team would discuss with the primary care commissioning team difficulties in patient access to ear irrigation.

For the other four items the panel saw no reason for further engagement or consultation actions. These items were:

- Guanfacine for the management of attention deficit hyperactivity disorder (ADHD) in children and adolescents
- Nefopam for the management of chronic pain
- Surgical interventions for chronic rhinosinusitis
- Otigo for acute otitis media

7. Clinical Policy Recommendation Committee Annual Report 2022-23

The Committee received the Clinical Policy Recommendation Committee Annual Report 2022-23.

Through the 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 Committee builds on the previous CCG arrangements for clinical policy making, providing 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. Existing CCG clinical commissioning policies were grandfathered across to the ICB on 1st July 2022.

The period of the report starts at the point of the establishment of the ICB on 1st July 2022.

Three meetings of the Committee have been held since 1st July 2022, considering evidence assessments which resulted in 10 new or updated commissioning policy recommendations, plus the withdrawal of one existing policy which had been superseded by mandatory NICE Technology Appraisal guidance.

The items considered by the committee have resulted from a range of inputs, including changing NICE and national guidance, the MedTech Funding Mandate, Evidence Based Interventions guidance and requests from local clinicians and NHS colleagues for treatments to be considered to provide clarity on their availability for patients in Devon.

Meetings have continued to be held virtually via Microsoft Teams, with a survey of members and attendees conducted last year supporting this as the principal method of holding Committee meetings. The notable advantages were felt to be supporting more effective use of members' time, i.e. reducing travel time and costs, and better supporting the balance with clinical and personal commitments; and also facilitating easier specialist engagement with the process.

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. In addition the Clinical Policy Engagement and Consultation Panel 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 a Quality and Equality Impact Assessment (QEIA) undertaken as an integral step in the process following the recommendation of the Committee.

Susan Masters, Deputy Chief Nursing Officer joined the Committee in July 2022 to replace Lorraine Webber who had previously fulfilled this role.

Two voting member vacancies remain following the departures of Dr Andrew Harrison and Dr Simon Jones in March 2021 and May 2022 respectively. There are also outstanding secondary care advisory member vacancies.

The Terms of Reference of the Committee reflect the changing context in the legislation which refers to clinical leadership and sets out an aspiration to include a wider range of professionals. They permit a wider group membership, potentially including both medical and non-medical clinical colleagues. There is also provision for additional secondary care advisory members, who may be drawn from across all secondary care providers who are part of the ICS and could include any clinical speciality (both medical and non-medical). However there remain significant challenges in filling the outstanding vacancies on the Committee and attracting additional members despite approaches via Trust Medical Directors and the Associate Medical Director for Primary Care to facilitate expressions of interest. This poses a risk to the resilience and quoracy of the Committee and therefore its ability to fulfil its functions on behalf of the ICB.

The committee accepted the report which will now be submitted to the Strategy and Transformation SLT on behalf of NHS Devon ICB for information and assurance.

The committee noted the need for sufficient membership to provide resilience and quoracy to the group, together with the importance of the membership coming from a variety of organisations in both Primary and Secondary Care.

ACTION: Clinical Policy Recommendation Committee Annual Report 2022-23 to be submitted to the Strategy & Transformation SLT on behalf of NHS Devon ICB for information and assurance, and the risk posed by ongoing membership challenges to be escalated.

8. Any other business

There was no other business to report.

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.	Rebecca Owen	Pending
23/02	Cryotherapy for recurrent prostate cancer – Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval and communication.	Rebecca Owen	Pending
23/03	Focal hyperhidrosis – Policy recommendation and QEIA to be prepared and subsequently progressed to final ICB approval 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.	Rebecca Owen Chris Roome	Pending