

Meeting Title	Collaborative Commissioning Committee (Joint Committee) - Meeting in <u>Public</u>	Date	Thursday 16 July 2020
Meeting no.	7	Time	1:00pm – 1:30pm
Chair	Professor Mayur Lakhani Clinical Chair West Leicestershire CCG	Venue / Location	Webex or MS Teams

REF	AGENDA ITEM	ACTION	PRESENTER	PAPER	TIMING
CCCP/20/55	Welcome and Introductions		Professor Lakhani		1:00pm
CCCP/20/56	Apologies for Absence	To receive	Professor Lakhani	verbal	1:00pm
CCCP/20/57	Notification of Any Other Business	To receive	Professor Lakhani	verbal	1:00pm
CCCP/20/58	Declarations of Interest on Agenda Topics	To receive	Professor Lakhani	verbal	1:00pm
CCCP/20/59	To receive questions from the Public in relation to items on the agenda only	To receive	Professor Lakhani	verbal	1:00pm
CCCP/20/60	Minutes of the Collaborative Commissioning Committee (CCC) meeting held on 21 May 2020	To approve	Professor Lakhani	A	1:05pm
CCCP/20/61	Matters Arising from Collaborative Commissioning Committee (CCC) meeting held on 21 May 2020	To receive	Professor Lakhani	B	1:10pm
ITEMS FOR DECISION, ACTION AND ESCALATION					
CCCP/20/62	Ciclosporin eye drops (Verkazia®) for the treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents	To approve	Gillian Stead	C	1:15pm
ANY OTHER BUSINESS					
CCCP/20/63	Items of any other business.	To receive	Professor Lakhani		1:30pm
The next meeting of the Collaborative Commissioning Committee will take place on Thursday 20 August 2020					

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Minutes of the LLR CCGs' Public Collaborative Commissioning Committee meeting held on Thursday 21 May 2020 at 1:00pm via Webex

Present:

Dr Ursula Montgomery	Clinical Chair, East Leicestershire and Rutland CCG (Chair)
Professor Azhar Farooqi	Clinical Chair, Leicester City CCG
Mr Andy Williams	Accountable Officer, LLR CCGs
Ms Caroline Trevithick	Executive Director of Nursing, Quality and Performance LLR CCGs
Ms Sarah Prema	Executive Director of Strategy and Planning, LLR CCG
Ms Gillian Adams	Independent Lay Member, West Leicestershire CCG
Mr Zuffar Haq	Independent Lay Member, Leicester City CCG
Ms Fiona Barber	Independent Lay Member, East Leicestershire and Rutland CCG
Mrs Yasmin Sidyot	Interim Director of Urgent and Emergency Care, West Leicestershire CCG
Mr Tim Sacks	Chief Operating Officer, East Leicestershire and Rutland CCG
Dr Avi Prasad	Co-Chair, Leicester City CCG
Mr Spencer Gay	Chief Finance Officer, West Leicestershire CCG

In attendance:

Mrs Jayshree Raval	Commissioning Collaborative Support Officer (minutes)
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PUBLIC GALLERY

No members of Public

ITEM		LEAD RESPONSIBLE
CCCP/20/48	<p>Welcome and Introductions</p> <p>The public meeting was chaired by Dr Montgomery as Professor Lakhani was unable to join the meeting due to some technical problems.</p> <p>Dr Montgomery welcomed the Committee members to the Collaborative Commissioning Committee meeting held via Webex.</p>	
CCCP/20/49	<p>Apologies for absence:</p> <ul style="list-style-type: none"> Professor Mayur Lakhani, Clinical Chair, West Leicestershire CCG Mrs Donna Briggs, Interim Executive Director of Finance and Corporate Governance, LLR CCG Mrs Michelle Iliffe, Director of Finance, Leicester City CCG Dr Nick Pulman, Deputy Chair, West Leicestershire CCG 	
CCCP/20/50	<p>Notification of Any Other Business</p> <p>Dr Montgomery had not received notification of any other business for discussion.</p>	
CCCP/20/51	<p>Declarations of Interest</p> <p>Dr Montgomery reminded members of their obligation to declare any interest they may have on any business arising at the meeting which might conflict with the business of NHS Leicester City CCG, East</p>	

ITEM	LEAD RESPONSIBLE	
	<p>Leicestershire and Rutland CCG or West Leicestershire CCG.</p> <p>Each CCG maintains a conflicts of interest register and any declarations raised at this meeting will be documented in the minutes of the meeting and action(s) will be taken to manage the conflict(s) at the meeting in in line with the conflicts of interest policy.</p> <p>It was noted that there were no items on the public agenda apart from the draft minutes for the 16 April 2020 Collaborative Commissioning Committee and action log.</p> <p>No other conflicts of interest were declared.</p> <p>It was RESOLVED to:</p> <ul style="list-style-type: none"> • NOTE the conflicts of interest declared and actions taken 	
CCCP/20/52	<p>To receive questions from the Public in relation to items on the agenda.</p> <p>There were no questions received in advance of the meeting from embers of the public in relation to the items of the agenda.</p>	
CCCP/20/53	<p>To Approve minutes of the previous meeting of the Collaborative Commissioning Committee held on 16 April 2020 (Paper A)</p> <p>The minutes of the meeting held in April 2020 were accepted as an accurate record of the meeting.</p> <p>It was RESOLVED to:</p> <ul style="list-style-type: none"> • APPROVE the minutes of the meeting 	
CCCP/20/54	<p>To Receive Matters Arising following the meeting held on 16 April 2020 (Paper B)</p> <p>There were no matters arising from the meeting held on 16 April 2020.</p> <p>It was RESOLVED to:</p> <ul style="list-style-type: none"> • RECEIVE the matters arising. 	
CCCP/20/55	<p>Any other business:</p> <p>Dr Montgomery did not receive any notification of any other business.</p> <p>Meeting concluded at 1:10pm</p>	
<p>Date of next meeting:</p> <p>The date of the next LLR CCGs' Collaborative Commissioning Committee will be held on Thursday 18 June 2020 1:00pm</p>		

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Leicester, Leicestershire and Rutland (LLR) CCGs Collaborative Commissioning Committee (CCC)

Key

Public Action Log

Completed	On-Track	No progress made
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Minute No.	Meeting Date	Item	Responsible Officer	Action Required	To be completed by	Progress as at 18 June 2020	Status

There were no matters arising from the May 2020 meeting.

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**Leicester City Clinical Commissioning Group
West Leicestershire Clinical Commissioning Group
East Leicestershire and Rutland Clinical Commissioning Group**

Name of meeting:	LLR CCGs' Collaborative Commissioning Committee	Date:	16th July 2020	Paper:	C
	Public <input checked="" type="checkbox"/> Confidential				
Report title:	Ciclosporin eye drops (Verkazia®) for the treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents				
Presented by:	Gill Stead Head of Medicines Optimisation WLCCG				
Report author:	<ul style="list-style-type: none"> • Vishal Mashru, Head of Medicines Optimisation ELRCCG • Ms Nagini Sarvananthan, Consultant Ophthalmologist • Rebecca Dickenson, LLR interface pharmacist • Mohammed Karolia, TAS secretary 				
Executive lead:					
Action required:	Receive for information only:		Progress update:		
	For assurance:		For approval / decision:		<input checked="" type="checkbox"/>
Executive summary:	<p>Vernal keratoconjunctivitis (VKC) is a rare allergic disorder of the eye affecting children.</p> <p>Verkazia ® is a new specifically licensed formulation of ciclosporin for VKC and would replace unlicensed ciclosporin drops in this indication. The product has been shown to be effective in this indication and would be used instead of long term topical corticosteroids which can cause significant ocular adverse effects particularly in children</p> <p>Leicestershire Medicines Strategy Group (LMSG) and Therapeutic Advisory Service (TAS) are supportive of the Verkazia® being prescribed in primary care after specialist request.</p>				
Appendices:	<ul style="list-style-type: none"> • None. 				
Recommendations:	<p>LLR CCGs' Collaborative Commissioning Committee is asked to:</p> <ul style="list-style-type: none"> • APPROVE the LMSG and TAS recommendation for use of Verkazia in VKC. 				
Report history and prior review:	<ul style="list-style-type: none"> • Not applicable 				

Aligned to Strategic Objectives		
Leicester City CCG	West Leicestershire CCG	East Leicestershire and Rutland CCG
✓	✓	✓

Implications	
a) Conflicts of interest:	

b) Alignment to Board Assurance Framework	
c) Resource and financial implications	<p>Cost implication estimated to be £140,000-£23,000 depending on dose and whether patients can stop the drops out of season.</p> <p>Offset cost estimate £12,500 to £10,000</p>
d) Quality and patient safety implications	<p>Less hospital visits</p> <p>Less use of steroids eye drops and their harmful effects</p> <p>Significant improvement in health related quality of life at 12 months in terms of symptoms and daily activities</p>
e) Patient and public involvement	<p>Patient representative on LMSG</p>
f) Equality analysis and due regard	<p>Higher incident of VKC in children from an Asian background.</p>

Ciclosporin eye drops (Verkazia) for the treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.

Introduction

Vernal keratoconjunctivitis (VKC) is a rare allergic disorder of the eye affecting children. Attacks associated with VKC are common in the spring (hence the name "vernal") and summer but often reoccur in the winter. Signs and symptoms usually begin before 10 years of age and may include hard, cobblestone-like bumps (papillae) on the upper eyelid; sensitivity to light; redness; sticky mucus discharge; severe itching; foreign body sensation; blurring of vision and involuntary blinking or spasms of the eyelid.

This application is for the licensed Verkazia product, a ciclosporin single use eye drop indicated specifically for severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents. Patients are given topical ciclosporin four times a day until symptoms are under control, and then twice a day until symptoms have resolved. Topical ciclosporin would be used as a steroid sparing option to reduce the use of long term steroids in patients who don't respond to topical antihistamines.

Verkazia offers a licensed treatment option for children and adolescents when they would otherwise use off-label treatment or unlicensed medication. The European medicines agency (EMA) have accepted the utility of ciclosporin eye drops due to concerns with long term topical corticosteroid use in children.

LMSG and TAS are supportive of the Verkazia® being prescribed in primary care after specialist request.

The current management of children with vernal keratoconjunctivitis involves the use of topical mast cell stabilisers in combination with topical steroid therapy over long periods of time. Unlike most cases of atopic conjunctivitis, this condition has long periods of symptoms interspersed with relapses. This has meant that most children are exposed to long periods of topical steroid therapy with added risks of secondary glaucoma and secondary cataract formation. In addition, there is the added risk of amblyopia in younger patients who develop secondary side effects of topical steroid therapy.

Evidence review

The evidence for the use has already been reviewed by the Scottish Medicines Consortium and the All Wales Medicines Strategy Group. Both bodies have recommended ciclosporin eye drops for use in respective countries^{1,2}. At the time of writing, similar arrangements occur in England in several Trusts including Moorfields

Eye Hospital, Birmingham Childrens Hospital, Lancashire medicines management group, Manchester and greater Manchester hospital trusts.

Superior efficacy over placebo was demonstrated in a four month double-blind RCT in patients aged 4 to 183. 169 patients were randomised (1:1:1) to receive topical ciclosporin four times a day, twice a day or receive the eye drop vehicle control four times a day, and 168 patients completed the four month trial. Any other treatments for VKC were stopped prior to study treatment. There was no requirement for patients to have already tried established treatments prior to enrolment. The primary end point was an improvement in keratitis as measured by the corneal fluorescein staining score (CFS) and adjusted for use of rescue medication and for the appearance of ulcers. A lower score represents improvements in keratitis. Key secondary endpoints included a comparison of responder rates (a 50% reduction in adjusted CFS at four months).

In the primary endpoint, in comparison to the control arm, both the BD and QDS doses of ciclosporin achieved statistically significant least squares mean difference (LSMD) in the adjusted CFS. At month 4 the LSMD was 0.76 between the QDS and vehicle arm (95% CI 0.26 to 1.27, $p=0.007$) and 0.67 between BD ciclosporin and the Vehicle arm (95% CI 0.16 to 1.18, $p=0.010$). The improvements in CFS were seen rapidly, with the greatest improvement in month 1

In the secondary endpoint of responder rates, 34.5% responded in the vehicle arm, 57% in the QDS arm (OR 2.583, 95% CI 1.207 to 5.531, $p=0.013$) and 61% in the BD arm (OR 3.486, 95% CI 1.576 to 7.713, $p=0.003$). The difference in the use of rescue medication reached statistical significance in the QDS arm (LSMD 0.220, $p=0.010$) but not the BD arm. The small patient numbers were deemed acceptable due to the rarity of the condition.

There was also a significant improvement in health related quality of life at 12 months in terms of symptoms and daily activities and 50% less use of topical corticosteroids.

Epidemiology and Needs Assessment

Overall VKC has an incidence of 1.3 to 3.2 per 10 000 population with a higher incidence in children from Asian ethnicity. This is approx. 150 patients in total with all grades of VKC across LLR. The incidence of severe cases for which Verkazia is suitable, is approximately 40 patients, or approx. 30% of the total cases. Please note, this is a rare ocular disease and the medication is considered 'orphan' status medication. Therefore we expect a small number of patients.

Place in Therapy

Verkazia ® would be used as a step up therapy in patients who do not respond to oral or topical antihistamine, and who would otherwise require long term topical corticosteroids. Treatment duration would depend on response to treatment, but may be over 6 months. Patients would initially be started on topical steroids which would be tapered off once ciclosporin eye drops are started.

Financial considerations

The dose of Verkazia ranges from 1 drop in the affected eye(s) four times daily tapering to 1 drop twice a day once stabilised. Treatment duration could be between six months to twelve months. Patient's treatment may be stopped out of season.

Using the numbers above a maximum of 40 children across LLR would require Verkazia at any time. This could be 4 drops a day or down to 2 drops as suitable or out of season. Therefore at £288 per 30 day 4 drop pack the maximum per patient per year would be approx. £3500 for a full year's treatment. This would be halved for the lower dose of course, and would be less for patients that come off treatment out of season if suitable.

Based on reduction in use of topical steroids, we estimate 1/3 less clinic visits overall with an estimated saving of at least three visits per patient per year and with a tariff of £80 per follow up visit, this would reduce the costs by approximately £9600 per year.

Additional offset costs include less clinic visits for complications associated with severe uncontrolled disease or topical steroid and its secondary complications and this could include the cost of additional outpatient visits, amblyopia treatment which will include purchase of glasses and eye patches and additional visits to the optometrist and orthoptist. Amblyopia and permanent visual loss pose additional long term costs to both the health and social care services.

Steroid eye drops use would be reduced by an estimated 50%. Typically only the first month of steroid eye drops are supplied by secondary care. These eye drops include:

1. Dexamethasone 0.1% estimated cost £2.80 a month per patient based on May 2020 drug tariff
2. Fluomethalone estimated cost £2.95 a month per patient based on May 2020 drug tariff
3. Softacort estimated cost £10.99 a month per patient based on May 2020 drug tariff
4. Predforte estimated cost £3.66 a month per patient based on May 2020 drug tariff

This then gives an additional offset cost of between £131.88 and £33.60 per patient per year. Using an estimated 20 patients (as offset only by 50%) the offset cost is between £2637.60 and £672

No additional costs for complications with Verkazia outside normal management.

References

1. Scottish Medicines Consortium. ciclosporin 1mg/mL (0.1%) eye drops emulsion (Verkazia®). 2018. SMC 2111
2. All Wales Medicines Strategy Group Secretariat Assessment Report. Ciclosporin (Verkazia®) 1 mg/ml eye drops, emulsion. 2019 Ref 2908.

Recommendation:

LLR CCGs' Collaborative Commissioning Committee is asked to:

- **APPROVE** the LMSG and TAS recommendation for use of Verkazia in VKC.