Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

Integrated Care Partnerships (ICPs) (Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey (as part of the CRESH system) & associated partner organisations.

NICE Technology Appraisals: Local implementation

NICE TA Guidance	Baricitinib for treating moderate to severe atopic dermatitis - TA681		
Available at	https://www.nice.org.uk/guidance/ta681/chapter/1-Recommendations		
Date of issue	3rd March 2021	**Implementation deadline**	3 months from publication – 3rd June 2021

Medicine details	
Name, brand name	Baricitinib (Olumiant)
Manufacturer	Eli Lilly
Licensed indication	Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.
Formulation	Film-coated oral tablet
Usual dosage	The recommended dose of Olumiant is 4 mg once daily. A dose of 2 mg once daily is appropriate for patients such as those aged ≥ 75 years and may be appropriate for patients with a history of chronic or recurrent infections. A dose of 2 mg once daily should be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 8 weeks of treatment.
NICE recommended dosage/schedule	As above

Disease and potential patient group	
Brief description of disease	Atopic eczema (atopic dermatitis) is the most common form of eczema, a condition that causes the skin to become itchy, red, dry and cracked. Atopic eczema is more common in children, often developing before their first birthday. However, it may also develop for the first time in adults. It's usually a long-term (chronic) condition, although it can improve significantly, or even clear completely, in some children as they get older. https://www.nhs.uk/conditions/atopic-eczema/
Potential patient numbers per 100,000	Information below taken directly from NICE resource template. Making local assumptions for Surrey Heartlands CCG population

People eligible for treatment	Local assumption current practice % of people	Local assumption current practice number of people	Local assumption future practice % of people	Local assumption future practice number of people
Total population for area selected (all ages)	-	1,049,170	-	1,049,170
Population of England 18 years or older	-	815,884	-	815,884
Prevalence of atopic dermatitis	2.50%	20,397	2.50%	20,397
People diagnosed with atopic dermatitis and receiving treatment	69.00%	14,074	69.00%	14,074
People with moderate to severe atopic dermatitis	7.00%	985	7.00%	985
People with moderate-to-severe AD eligible for systemic therapy	27.00%	266	27.00%	266
People with moderate-to-severe AD with a history of systemic therapy treatment failure	53.00%	141	53.00%	141
Treatments				
Number of people receiving standard care	85%	120	40%	56
Cumulative number of people starting treatment with dupilumab	15%	21	35%	49
Cumulative number of people starting treatment with baricitinib	0%	0	25%	35

SUMMARY

NICE recommendation

1.1 Baricitinib is recommended as an option for treating moderate to severe atopic dermatitis in adults, only if:

•the disease has not responded to at least 1 systemic immunosuppressant, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are not suitable, and
•the company provides it according to the commercial arrangement.

1.2 Assess response from 8 weeks and stop baricitinib if there has not been an adequate response at 16 weeks, defined as a reduction of at least:

•50% in the Eczema Area and Severity Index score (EASI 50) from when treatment started and
•4 points in the Dermatology Life Quality Index (DLQI) from when treatment started.

1.3 When using the EASI, take into account skin colour and how this could affect the EASI score, and make appropriate clinical adjustments.

1.4 When using the DLQI, take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI, and

make any appropriate adjustments.

1.5 These recommendations are not intended to affect treatment with baricitinib that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Why the committee made these recommendations

People with moderate to severe atopic dermatitis that has not responded to at least 1 systemic immunosuppressant are usually offered either dupilumab or best supportive care. Dupilumab does not always work, and some people stop taking it because of side effects. Baricitinib is an alternative to dupilumab and best supportive care. It is likely to be offered alongside topical corticosteroids.

Clinical trial results show that baricitinib reduces the severity and symptoms of atopic dermatitis compared with placebo. Baricitinib has not been directly compared with dupilumab. The results of an indirect comparison suggest that baricitinib is less effective than dupilumab.

The most likely cost-effectiveness estimates for baricitinib are within what NICE considers an acceptable use of NHS resources. Therefore, baricitinib is recommended as an option for moderate to severe atopic dermatitis when at least 1 systemic immunosuppressant has not worked or is not suitable.

Cost implications*

Cost of product:
£805.56 per 28 tablet pack (2mg & 4mg) as per British National Formulary online accessed 13/04/2021 N.B. a PAS price is available which is commercial in confidence

Annual cost per patient: *£9,666.72 at tariff price however PAS price has been used in costing table below*

Has dose escalation been considered as part of the NICE costing template? *No (dose escalation not licensed at time of writing paper)*

Costing information/100,000 population and per CCG: *From NICE costing template:*
Cost per ICP for adults based on NICE TA recommendation

	Baricitinib costs (£'000)				
	Year 1	Year 2	Year 3	Year 4	Year 5
East Surrey	£4	£7	£11	£15	£18
G & W	£4	£8	£12	£16	£21
North West Surrey	£7	£13	£20	£27	£33
Surrey Downs	£6	£11	£17	£23	£28

	Full impact if guidance including reduced dupilumab costs (£'000)				
	Year 1	Year 2	Year 3	Year 4	Year 5
East Surrey	£4	£5	£7	£5	£2
G & W	£5	£6	£8	£5	£3
North West Surrey	£7	£10	£13	£9	£4
Surrey Downs	£6	£8	£11	£7	£3

Availability of PAS and details (if appropriate): *Yes – included in calculations above*

Availability of homecare service (if appropriate): *Yes – to be arranged by Trusts*

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

Alternative treatments and cost per patient (per year / per month as appropriate)

Other NICE recommended products:

Dupilumab (NICE TA534 – August 2018) is recommended as an option if the atopic dermatitis has not responded to at least 1 other systemic therapy (4th or 5th line – see treatment pathway in line with CKS (Clinical Knowledge Summaries below).

Annual cost per patient: Induction – 600mg (2 x 300mg injections) - £1,264.89 Maintenance – 300mg every other week - £632.44/dose (25 further doses) =£15,811 1st year cost (with induction) - £17,075.89 2nd year cost - £16,443.44

PAS price available commercial in confidence

Options not reviewed by NICE but used in standard practice:

Although clinicians individualise therapy for patients, a typical treatment pathway involves:

- emollients and topical corticosteroids (first-line)
- topical calcineurin inhibitors (second-line)
- phototherapy (third-line) – may be considered but is not a pre-requisite for treatment with dupilumab or baricitinib
- systemic immunosuppressant therapies (third or fourth-line)

Fourth-line treatments include ciclosporin (the only systemic immunosuppressant with a marketing authorisation for atopic dermatitis), methotrexate, azathioprine and mycophenolate mofetil.

For people whose disease has not responded to all available systemic therapies, the only remaining treatment option is best supportive care. This may include education, psychological support, emollients, topical corticosteroids, bandages and hospitalisation.

Exacerbations (flares) in atopic dermatitis are managed using short-term high-potency topical corticosteroids, oral corticosteroids and systemic therapy.

https://www.nice.org.uk/guidance/ta681/resources/baricitinib-for-treating-moderate-to-severe-atopic-dermatitis-pdf-82609375014853

Positioning in the treatment pathway, comparators and sequencing

Baricitinib would be used after at least 1 systemic immunosuppressant

'The marketing authorisation for baricitinib is 'for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy'. The company positioned baricitinib as a fifth-line treatment, after at least 1 systemic immunosuppressant, as an alternative to dupilumab and best supportive care. Clinical experts agreed that they would prefer to offer baricitinib as an alternative to systemic immunosuppressants, because it needs less monitoring. However, they acknowledged that in clinical practice people are likely to have had at least 1 systemic immunosuppressant before having baricitinib. The committee concluded that it would appraise baricitinib for moderate to severe atopic dermatitis after at least 1 systemic immunosuppressant, in the same position as dupilumab.

Impact to patients

- This additional treatment option will be valued by patients with atopic dermatitis.
- The option of an oral preparation.
- Another treatment option before/ after or as an alternative to dupilumab (to decide place in treatment).
- Available via homecare.

Impact to primary care prescribers

- This is a PbRe drug and is commissioned by CCGs for use in secondary care. There should be no prescribing in primary care.

- Primary care prescribers should be aware that their patient is receiving baricitinib and ensure that this is recorded in the patient's notes in order to be alert to potential side effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication. and

Impact to secondary care

- The initiation, administration and on-going treatment will be managed by secondary care.
- Homecare arrangements will be managed by the trust.
- As this is an oral treatment, it will not require nurse visits to administer alternative (dupilumab).
- An additional treatment option for atopic dermatitis would be valued by clinicians.
- Blueteq forms for initiation and continuation will need to be completed by dermatology specialists.

Impact to CCGs

- This is a new treatment option available for this cohort of patients and this will be a cost pressure to CCGs.
- Baricitinib is PbRe and if a patient meets NICE criteria, treatment can be initiated and invoiced to the commissioner (if Blueteq forms have been completed).

Implementation

- CCGs are required to comply with the recommendations within 3 months.
- There will be discussion with the Dermatology Clinical Network to consider the place in therapy for baricitinib. NICE considers (indirect comparison) that baricitinib is less effective than dupilumab.
- Blueteq forms will be developed.
- Treatment pathway will be updated in collaboration with the dermatology network and discuss place in therapy.

Recommendation to APC

PbRe: Yes
Recommended traffic light status (see attached guidelines): RED

- Baracitinib is a Payment by Results excluded drug
- Treatment should be initiated and continued by dermatology specialists in secondary or tertiary care.
- Blueteq forms for initiation and continuation will be developed for specialists to complete.

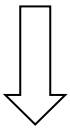
Recommendations for tick box proformas & proposed pathway below

- Baricitinib use in conjunction with TOPICAL corticosteroids
- The disease has not responded to the following (or these are not tolerated or CLINICALLY contraindicated)
    - Topical corticosteroids monotherapy
    - Topical tacrolimus (NICE TA82)
    - At least 1 systemic immunosuppressant (ciclosporin, methotrexate, azathioprine or mycophenolate)
    - If patient has trialled phototherapy this can be indicated on the form, although this is not a pre-requisite to treatment.
    - EASI score ≥ 16 (indicates moderate disease) & DLQI ≥10 (indicates moderate impact on patients life) as per dupilumab criteria

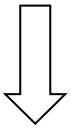
Additional questions for specialists:

- Baricitinib is another treatment option for the treatment of Atopic Dermatitis but is not considered to be as clinically effective as dupilumab. Would specialists consider using baricitinib for all new patients, switching to dupilumab for primary/secondary failure or primary/secondary intolerance?
- Note that baricitinib will be a treatment option after dupilumab has failed in line with NICE guidance

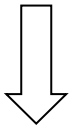
DRAFT TREATMENT PATHWAY IN LINE WITH NICE Clinical Knowledge Summaries (CKS) for Eczema – atopic www.nice.org.uk



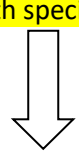
Emollients



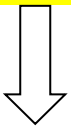
1ST LINE: Topical corticosteroids (maintenance regimen to control skin prone to flares) Consider 'step down' approach or intermittent treatment



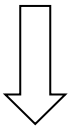
CONSIDER REFERRAL or GP with specialist interest (GPSI) to consider



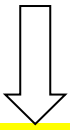
2ND LINE: Calcineurin inhibitors (Tacrolimus) NICE TA82



3RD LINE (if used): Phototherapy may be considered here although this is not a pre-requisite to treatment with dupilumab or baricitinib



3RD OR 4TH LINE: Oral systemic immunosuppression (secondary care specialists)



4TH OR 5TH LINE: BARICITINIB INITIATION (in line with TA681) OR DUPILUMAB INITIATION (in line with NICE TA534)

References:

1. NICE TA681 Baricitinib for treating moderate to severe atopic dermatitis https://www.nice.org.uk/guidance/ta681 (March 2021)

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Declaration of Interest:

None

Date: 30/04/2021

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Declaration of Interest:

None

Date: 05/05/2021

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	*30/04/2021*	*Hannah MacDonald/Clare Johns*		*Out for consultation*
v.2				