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	Brolucizumab for treating wet age-related macular degeneration – TA672		
Available at	www.nice.org.uk/guidance/ta672		
Date of issue	Publication date 3 February 2021	**Implementation deadline**	5 March 2021

Medicine details	
Name, brand name	Brolucizumab (Beovu®)
Manufacturer	Novartis Pharmaceuticals UK
Licensed indication	Indicated for adults for the treatment of neovascular (wet) age-related macular degeneration (AMD)[(1)],
Formulation	Solution for injection, pre-filled syringe and vial[(1)]
Usual dosage	6 mg of brolucizumab in 0.05 ml[(1)],
NICE recommended dosage/schedule	NICE TA refers directly to eSPC for dosage/ schedule [(2)]

Disease and potential patient group	
Brief description of disease	Brolucizumab is used to treat wAMD. In AMD the central area of the retina (called the macula) at the back of the eye is damaged. It is known as wet AMD when lots of blood vessels that are not needed grow under the macula. These vessels can leak fluid and blood and cause swelling. This can lead to a gradual loss of central vision which is needed for everyday tasks[(3).]
Potential patient numbers per 100,000	NICE resource impact template indicates that in Surrey Heatlands, the expected incidence of Wet AMD eligible for NICE funded treatment is 60 per 100,000 population, total 658 people. This cohort is the same as the population receiving either ranibizumab or aflibercept and does not extend patient cohort[(2)].

SUMMARY

NICE recommendation
1.1 Brolucizumab is recommended as an option for treating wet age-related macular degeneration in adults, only if, in the eye to be treated: • the best-corrected visual acuity is between 6/12 and 6/96 • there is no permanent structural damage to the central fovea • the lesion size is less than or equal to 12 disc areas in greatest linear dimension and • there is recent presumed disease progression (for example, blood vessel growth, as

shown by fluorescein angiography, or recent visual acuity changes).
- It is recommended only if the company provides brolucizumab according to the commercial arrangement.

1.2 If patients and their clinicians consider brolucizumab to be one of a range of suitable treatments, including aflibercept and ranibizumab, choose the least expensive (taking into account administration costs and commercial arrangements).

1.3 Only continue brolucizumab in people who maintain an adequate response to therapy. Criteria for stopping should include persistent deterioration in visual acuity and identification of anatomical changes in the retina that indicate inadequate response to therapy.

1.4 These recommendations are not intended to affect treatment with brolucizumab 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.

Cost implications*

Cost of product: **Commercial in confidence**

Annual cost per patient:
The NHS price is in the same bracket as the current treatments, ranibizumab and aflibercept, however the proposal is that 1/3 fewer injections would be required per year, thus reducing pressure in outpatient departments and reducing drug costs.

Has dose escalation been considered as part of the NICE costing template? *Consider whether dose escalation might be a development need.*

Costing information/100,000 population and per CCG:
The NICE costing template is complicated.
An indicative completion of the template proposes the following cost savings for Surrey Heartlands CCG (£000's):
COMMERCIAL IN CONFIDENCE

Availability of PAS and details (if appropriate): *Yes – commercial in confidence*

Availability of homecare service (if appropriate): *No*

**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:
Ranibizumab and aflibercept

Options not reviewed by NICE but used in standard practice:
Bevacizumab

Impact to patients

The proposal and evidence presented to NICE indicates that patients are expected to require fewer injections than the alternatives in class[2]

	Brolucizumab	Aflibercept	Ranibizumab
Acquisition cost*	[redacted]	[redacted]	[redacted]
Dose	6 mg	2 mg	0.5 mg
Dosing regimen	Loading phase [LP] → quarterly [q12w] or bi-monthly[q8w] dosing	Weighted average of continuous and flexible dosing regimens**	Weighted average of continuous and flexible dosing regimens***
No. of injections	Year 1: 6.66 Year 2: 4.76 Year 3+: 4.76	Year 1: 8.82 Year 2: 6.85 Year 3+: 6.85	Year 1: 9.16 Year 2: 7.91 Year 3+: 7.91
Total no. of visits (incl. monitoring)	Year 1: 6.66 Year 2: 4.76 Year 3+: 4.76	Year 1: 8.82 Year 2: 8.17 Year 3+: 8.17	Year 1: 10.97 Year 2: 10.12 Year 3+: 10.12

*Includes PAS discounts; ** includes PRN and TREX; ***includes PRN, PRNX and TREX

NICE indicates that adverse events are similar to other treatments in class, the EMEA did suggest an increase in intraocular inflammations and ocular occlusive events:
The EMA considered that overall the safety profile of brolucizumab appears to be similar to aflibercept, except for intraocular inflammations and ocular occlusive events which were reported more frequently with brolucizumab. Close monitoring is requested by the EMA in the postmarketing setting to further investigate these events.(3)
The committee was aware that brolucizumab's summary of product characteristics notes a risk of retinal vasculitis and retinal vascular occlusion. The ERG explained that because these adverse events were rare, it was not likely to affect the view that the overall impact on health of those associated with brolucizumab are similar to those of aflibercept and ranibizumab. The committee concluded that adverse events with brolucizumab are likely to be similar to aflibercept and ranibizumab(2)

Impact to primary care prescribers

No impact expected

Impact to secondary care

It is expected to reduce the number of appointments required per patient, if real life experience matches evidence presented to NICE.
It is unlikely this will release resources. Patients with Wet AMD tend to be seen as urgent priorities in secondary care, but it may release pressures and allow for patients with other conditions to be seen earlier

Impact to CCGs

Non-drug activity is expected to be reduced
NICE did not take into consideration the expected lunch of ranibizumab biosimilars in the next year.

Implementation

This Technology appraisal has been launched as rapid access with only 30 days for implementation.
This has not allowed for local costings to be calculated in time for launch of this consultation – it is expected to be available at APC.
There is additional work required to discuss local pathways, with a view to consider the Black Triangle status, differences in adverse events indicated by the EMEA and how to manage them, and to consider the place in therapy with the imminent availability of biosimilar ranibizumab, as the NICE TA indicates that the least expensive treatment should be used (taking into account administration costs and commercial arrangements).
There will be discussions required about switching (NICE takes this into account in its evidence, suggesting a 5% switch)
It is expected that pathway work will be carried out with the Ophthalmology network

Recommendation to APC

PbRe: Y

Colour classification guidelines

Recommended traffic light status (see attached guidelines):

RED
For Wet AMD in line with NICE guidance, taking into account that this is a black triangle drug to be used when the benefits outweigh the risks.

Switching to broluzicumab subject to further comment during agenda consultation.

Additional comments:
Blueteq form required

References:

1. eSPC Beovu®, https://www.medicines.org.uk/emc/product/11145 , accessed 11/02/2021

2. Brolucizumab for treating wet age-related macular degeneration Technology appraisal guidance Published: 3 February 2021 www.nice.org.uk/guidance/ta672

3. Scottish Medicines Consortium (SMC) brolucizumab (Beovu®) **,** August 2020, https://www.scottishmedicines.org.uk/medicines-advice/brolucizumab-beovu-full-smc2272/

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Declaration of Interest:

None

Date: 12 February 2021

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

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Date: XXXX

1st March 2021 – additional costing information –unavailable at the circulation.

The NHS price is in the same bracket as the current treatments, ranibizumab and aflibercept, however the proposal is that 1/3 fewer injections would be required per year, thus reducing pressure in outpatient departments and reducing drug costs.

The NICE costing template is complicated.
An indicative completion of the template proposes the following cost savings (£000's):
Commercial in confidence

Until there is real life data on efficacy and adverse effects, the cost benefits will be less clear. There is the imminent availability of biosimilar ranibizumab, which will, again affect costs and will play a role in determining local pathways to meet the NICE determination that the health economy should choose the least expensive (taking into account administration costs and commercial arrangements).

The Company costing model has been included with this paper with permission, please do not share outside the NHS.