Briefing Paper for the Surrey Heartlands Integrated Care System Area Prescribing Committee

Commissioning of ranibizumab biosimilar for Surrey Heartlands ICS patients

Situation

NHS England published the national procurement for Anti-VEGF and intravitreal corticosteroids entitled: (August 2022)

Operational note: Commissioning recommendations following the national procurement for medical retinal vascular medicines
(Link) - Recommendations

Purpose

Eyecare is the highest volume outpatient specialty within the NHS and the medicines used for medical retinal vascular conditions account for some of the highest cost and volume treatments used within secondary care. Due to increasing life expectancy and an ageing population, the NHS expects that demand for medical retinal vascular treatments will continue to increase in the future as more patients with eye disease are diagnosed and treated. Continually rising demand has also impacted ophthalmology outpatient services, worsened by the pandemic.

The intent of the recent procurement exercise (concluded in May 2022) was to support delivery of the NHS Pathway Improvement Programme through the following key objectives.

- Reduction in unwarranted variation: Reduce the number of patients that should be, but are not currently treated, and reduce the number of patients who are treated for whom treatment is inappropriate or ineffective.
- Maintain clinical choice: Clinicians will continue to determine in discussion with their individual patients, which medical retinal vascular treatments are clinically appropriate for them and will be able to access all available treatments (in line with national guidance).
- Make best use of NHS resources: To support the transformation of eyecare services (subject to the criteria specified in the relevant NICE technology appraisal guidance) clinicians should, in consultation with the patient, use the lowest cost treatment option where this is clinically acceptable

There are 4 licensed intravitreal anti-VEGF treatments in England for use in medical retinal conditions these are:

- Aflibercept (Eylea®)
- Ranibizumab (Lucentis®)
- Brolucizumab (Beovu®)
- Faricimab (Vabysmo®)

In August 2022 the first ranibizumab biosimilar (Ongavia®) was launched in England by Teva, for use across all ranibizumab licensed indications and there will be a significant reduction in cost (commercially confidential).

Background

In 2019 the APC members agreed that biosimilar brands can be added to the PAD, without evidence review

- if the product is for the same indication(s) and in the same population as the original reference medicine (if the original reference product is already recommended for use), **and**
- the cost and patient accessibility and "usability" e.g. giving sets, needles etc, of the new biosimilar medicine is equivalent or lower than the reference medicine.

Assessment

Due to the nature of MHRA licensing of biosimilar products, it has already been demonstrated that biosimilars are as safe and as effective as the original reference medicine and have the same quality.

The principle already agreed (2019) will reduce the APC workload, allow quicker access to more cost-effective treatments for patients, therefore generating possible savings to the NHS in general.

A full submission will still be required for indication(s) / populations:

- where the reference product has been appraised by APC / NICE, and is not recommended for use,
- where costs or patient accessibility is a factor or
- where the reference product has not been appraised by APC / NICE.

Recommendations

The APC are asked to agree to:

1. Support the use of biosimilar ranibizumab to the Surrey Heartlands Health economy in the following licensed indications, in line with the commissioning recommendations following the national procurement for medical retinal vascular medicines
    - Wet Age-Related Macular degeneration (Wet AMD)
    - Central Retinal Vein Occlusion (CRVO)
    - Branch Retinal Vein Occlusion (BRVO)
    - Diabetic Macular Oedema (DMO)
    - Myopic Choroidal Revascularisation (CNV)

2. Support ranibizumab biosimilar (in line with original NICE guidance) instead of the originator ranibizumab (Lucentis®) where this is clinically appropriate and there is capacity to do so.
   If ranibizumab biosimilar is contraindicated or not clinically appropriate for the specific patient or there are specific clinical considerations then, subject to the criteria specified in the relevant NICE technology appraisal guidance, clinicians should consider aflibercept, brolucizumab or faricimab.

N.B. For those areas who do not have the capacity to use biosimilar ranibizumab, as recommended, this has been escalated for Surrey Heartlands ICB consideration

3. Originator ranibizumab should not be used for new initiations, and clinicians should consider switching patients on originator ranibizumab to biosimilar ranibizumab with patient consent.

This was discussed at the Surrey Heartlands Ophthalmology Medicines Network, where it

was agreed that this switching should not take place in the patients are in the middle of the loading phase of treatment, but it would be reasonable to do so afterwards in patients who responded well.

Implementation information:

- Blueteq forms will not be amended to reflect this decision. Teams will indicate that the patient has either been initiated on biosimilar ranibizumab or has been switched to biosimilar ranibizumab by adding a comment in Blueteq.
- A switch back to the originator product form will be developed for use by the teams (as used for previous biosimilar implementations)
- Patient consent letter from Kent (for biosimilar Ongavia®) has been sent to all trusts for local adaptation
- Trusts are in discussion with NHS commercial solutions (Regional Procurement Specialists) who are asking for information on patient numbers, timelines for use of the biosimilar & expected local distribution centres.

Coming to a future APC for the Ophthalmology Medicines Network:

- Switching TO ranibizumab biosimilar (within NICE thresholds) will NOT be counted (as a switch) for all indications (e.g., 'free' switch).
    - Ranibizumab (Lucentis) to ranibizumab (Ongavia®) – Free Switch
    - Ranibizumab (Ongavia®) to aflibercept, brolucizumab or faricimab (counts as switch)
    - Switching between aflibercept, brolucizumab or faricimab (counts as a switch)
- NICE briefing for brolucizumab for treatment DMO (NICE publication 31st August 2022 – 30 day implementation timeline expected
- Switching in other indications (to include anti- VEGF & intravitreal corticosteroids)
- Treatment pathways to include treat and extend protocols

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