NHS
London Procurement Partnership

Pan London High Cost Drugs Pathway for wetAMD

Background

Following the conclusion of the London Lean pathway for wet AMD in February 2024, it was decided that a Pan-London High-Cost Drugs Pathway for wet AMD would be required. Under the coordination of the NHS London Procurement Partnership, a working group including consultant ophthalmologists in medical retina and pharmacy representatives from all five ICBs with input from an ICB Deputy/Chief Pharmacist as nominated SRO was developed in April 2024. The objective of the group was to develop recommendations for a Pan-London High-Cost Drugs pathway for wet AMD to help optimise treatment and resources while reducing inconsistencies in access. The pathway was developed using published data and data collected locally within London to feed the health economic modelling of multiple treatment pathways which informed the optimum pathway.

It is recommended that the pathway will guide local implementation and individual ICBs will still retain autonomy on the local pathways and are advised to undertake the appropriate local processes for pathway implementation.

This pathway was approved by the London Ophthalmology and Eyecare Board on the 20th of January 2025 and presented to the London Pharmacy Leaders.

Working Group

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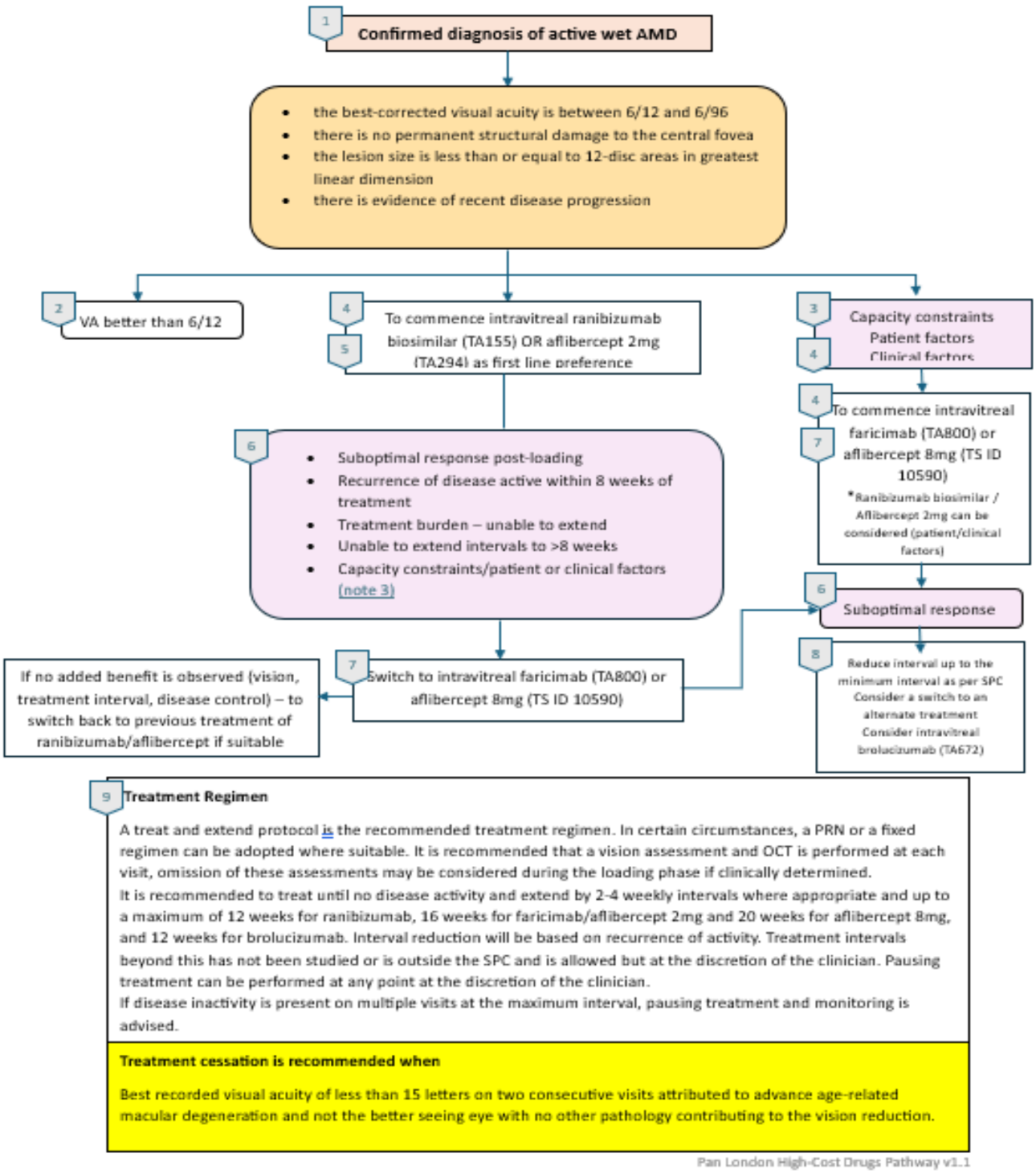
Pan London High-Cost Drugs Pathway for wet AMD



List of Abbreviations

AMD Age-related macular degeneration
FAF Fundus Autofluorescence
FFA Fundus Fluorescein Angiography
ICGA Indocyanine Green Angiography
nAMD neovascular age-related macular degeneration
NICE National Institute for Health and Care Excellence
NOD National Ophthalmology Database
OCT Optical Coherence Tomography
OCT-A Optical Coherence Tomography Angiography
PCV Polypoidal Choroidal Vasculopathy
SPC Summary of Product Characteristics
TA Technology Appraisal

Note 1:

Diagnosis of wet AMD requires a clinical assessment and OCT. OCT angiography and/or fluorescein angiography may aid the diagnosis if clinical assessment and OCT is not conclusive of wet AMD. The Royal College of Ophthalmologists recommends clinical examination, OC, OCT-A, FFA, ICGA and FAF and most diagnosis can be made by clinical examination, OCT and OCT-A with OCT being the sole investigation to detect wet AMD when there no ready access to tests such as OCT-A or FFA to avoid delay in receiving treatment or patient factors such as difficulty prohibiting the use of intravenous contrast for angiography. FFA and ICGA is indicated in specific cases.
Royal College of Ophthalmologists Commissioning Guidance for AMD Services May 2024

Note 2:

6/12 is the threshold for driving and represents good functional vision. Treatment with antiVEGF for patients with vision of better than 6/12 is not recommend in NICE technology appraisals, however, NG82 suggested that it may be cost effective depending on the regimen used. In the 2024 National Ophthalmology Database (NOD) audit, 26.9% of eyes receiving treatment had baseline visual acuity of 70 letters or better (6/12 or better) and 77.1% of this cohort maintained this level of good vision at 12 months. When compared to the whole cohort, only 41.7% achieved good vision at 12 months. It is recommended that a ranibizumab biosimilar is used to treat patients with good baseline vision (better than 6/12). A licensed drug should be preferred instead of an unlicensed drug. At this stage, Ongavia, Byooviz and Ximluci are all approved ranibizumab biosimilars in the UK and should be considered. At the time of this pathway development, bevacizumab gamma (Lytenava) was not NICE recommended for treating wet AMD (TA1022).
NOD Audit: Second Report of AMD Audit
NICE Guideline (NG82): Age-related macular degeneration

Note 3:

NHS England: Operational note: updated commissioning recommendations for medical retinal vascular medicines following the national procurement for ranibizumab biosimilars (July 2023);

1. Subject to the criteria specified in the relevant NICE technology appraisal guidance, clinicians should consider ranibizumab biosimilar where this is clinically appropriate and there is capacity to do so.
2. If ranibizumab biosimilar is contra-indicated or not clinically appropriate for the specific patient, or if there are specific clinical considerations (such as non-responder to ranibizumab in fellow eye previously, subretinal bleed >50% of lesion, idiopathic polypoidal choroidal vasculopathy [PCV]) then, subject to the criteria specified in the relevant NICE technology appraisal guidance, clinicians should consider aflibercept, brolucizumab or faricimab.

Operational note: updated commissioning recommendations for medical retinal vascular medicines following the national procurement for ranibizumab biosimilars

The NICE recommendation for faricimab (TA800) recommends if patients and their clinicians consider faricimab to be 1 of a range of suitable treatments (including aflibercept and ranibizumab), choose the least expensive treatment. Take account of administration costs, dosage, price per dose and commercial arrangements.

NICE TA800: Faricimab for wet AMD

Capacity constraints

Capacity constraints is represented by inability within a service to deliver treatment to patients with wetAMD timely due to capacity limitations. This is represented by frequent and regular out of hours clinics or significant long-term appropriately trained staff shortages to meet intravitreal treatment demand. Efforts should be made to convert this activity as business as usual however, appreciation that vacancies due to shortage of appropriately trained staff or limitation in available estate will prohibit this.

Patient factors

Patients with the criteria below are best managed with the least number of injections and this outweighs the cost;

- learning difficulties
- dementia
- hospital transport
- requiring treatment in the operating theatre under sedation/deep sedation/general anaesthesia
- frequent inpatient hospital admissions

Patient education on the efficacy and benefits of the treatment options in this pathway should be made to the patient.

Clinical factors

For exceptional circumstances, an alternative treatment option may be chosen based on clinical considerations. Examples of clinical decisions.

- Previous adverse event to a drug in the fellow eye
- Clinical concern that a patient will come to harm with the recommended drug
- To harmonise treatment options with the fellow eye

In these scenarios, the selection of a treatment with the least number of injections is advised. However, where clinically indicated, ranibizumab biosimilar or aflibercept 2mg can be considered.

The criteria for these (capacity, patient factors and clinical factors) should be decided by local ICBs with their provider organisations

Note 4:

The Health Economic modelling revealed that the total cost over 5 years for an incidence of 100 patients a year at the time of the pathway development, are ranked as below;
The total **drug cost only** (excluding non-drug costs and impact on capacity)

1. Ranibizumab biosimilar monotherapy
2. Aflibercept monotherapy (switch to biosimilar when available)
3. Ranibizumab biosimilar to Faricimab
4. Aflibercept (switch to biosimilar when available) to Faricimab / Aflibercept 8mg
5. Faricimab / Aflibercept 8mg monotherapy
6. Aflibercept monotherapy (Eylea 2mg)

The capacity impact and ranking based on **capacity saving/least number of treatments** is ranked below;

1. Faricimab / Aflibercept 8mg monotherapy
2. Aflibercept (switch to biosimilar when available) to Faricimab / Aflibercept 8mg
3. Aflibercept monotherapy
4. Ranibizumab biosimilar to faricimab
5. Ranibizumab biosimilar

**Eylea 8mg is presumed to reflect outcomes in Faricimab due to lack of real-world data or head to head trials in wet AMD*

The **combined costs of the drug and visit cost** is ranked below;

1. Aflibercept (switch to biosimilar when available)
2. Ranibizumab biosimilar monotherapy
3. Aflibercept (switch to biosimilar when available) to Faricimab / Aflibercept 8mg
4. Ranibizumab biosimilar to faricimab
5. Faricimab / Aflibercept 8mg monotherapy
6. Aflibercept monotherapy (Eylea 2mg)

Note 5:

Ongavia/Byooviz/Ximluci are licensed ranibizumab biosimilar options in the UK
When an aflibercept 2mg biosimilar is available, this should be preferred ahead of Eylea and efforts to switch pre-existing patients to an aflibercept biosimilar must be made

Note 6:

Sub-optimal response is defined as persistence of disease activity on OCT within 4 weeks post-completion of loading dose. This is usually due to aggressive disease and early recurrence, but alternate diagnosis should be explored in resistant cases with persistence of activity 2 weeks post-treatment.

Note 7:

The process for switch in therapy should be simple and protocol driven to maximise the efficiencies as it is anticipated that 40-50% of patients may require an escalation of treatment if commencing on aflibercept or ranibizumab. Upon switching to a different drug, it is at the clinician's discretion to re-load the patient as per license. However, on escalating to a more durable drug, it is reasonable to consider a reduced loading regimen but as this is not per license, it will be at the clinician's discretion. If a patient commences on ranibizumab and a switch is decided, it is also reasonable to consider a switch to aflibercept 2mg. Treatment intervals should be tailored to patient needs and follow the minimum intervals post-loading as per SPC recommendations as below.
Ranibizumab biosimilar 1 month
Aflibercept: 4 weeks
Aflibercept 8mg: 2 months
Faricimab: 21 days
Brolucizumab: 2 months

Note 8:

A switch to brolucizumab should be a consultant ophthalmologist decision and consideration made on the risks and benefits to the patient taking into account the increased risk of intraocular inflammation and low risk of vision loss from retinal vasculitis.

Note 9:

Treatment switch should be considered in patients experiencing an adverse event to a drug, e.g. Intraocular inflammation. Treatment can be switched to an alternate drug within the same section of the pathway.
There is no limit to the number of switches to a new drug which should be based on capacity or clinical need but one switch back to a particular drug is allowed.