# DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

**Derbyshire commissioning pathway for the treatment of Age-Related Macular Degeneration (ARMD)**
**March 2021**

This algorithm is a tool to aid the implementation of NICE guidance for the treatment of ARMD. This treatment algorithm includes CCG commissioned drugs approved by NICE for treatment and local variations to the commissioning algorithm
Relevant NICE documents: NICE TA68 – PDT; NICE TA 155 – Ranibizumab; NICE TA294 – Aflibercept

**Wet/exudative/ neovascular ARMD**

**Minority pathway**
e.g. caution, CI to anti-VEGF, unable to attend 4-8weekly etc

For use in
All lesions types: classic, predominantly classic, minimally classic, occult and RAP lesions.

- BCVA 6/12 to 6/96
- There is no permanent damage to central fovea
- Lesion ≤ 12disc areas in greatest linear dimension
- There is evidence of recent presumed disease progression (blood vessel growth, as indicated by fluorescein angiography or recent visual acuity changes) (See appendix 2)

Recommended only if:

- Classic (no occult) subfoveal CNV only
- BC VA 6/60 or better

**Anti-VEGF treatments**

**Ranibizumab (Lucentis)** – 1st line option as per NICE TA155
(For dosing details see appendix 1)
***for switching**

**or**

**Aflibercept (Eylea)** – 1st line option as per NICE TA294
(For dosing details see appendix 1)

**or**

**Monoclonal antibody**

**Brolucizumab** – 1st line option as per NICE TA672
(For dosing details see appendix 1)

**Photodynamic therapy (PDT)**

**Verteporfin (Visudyne) as** per NICE TA68
Monitor every 3 months.
In the event of recurrent CNV leakage, verteporfin therapy may be given up to 4 times per year (SPC)

Local variation to NICE

***Local variation to NICE***

*Suboptimal responders have the option of switching to aflibercept if:

- >6 consecutive injections from initiation or
- >4 consecutive after loading or
- >8 per year

Existing patients will be switched to brolucizumab only where it is not possible to extend their respective treatment regimen to a 12 weekly schedule.

**Last updated:** March 2021

**Appendix 1**
**Recommended dosage as per SPC**

| **Ranibizumab 0.5mg injection** | **Aflibercept 2mg injection** | **Brolucizumab 6mg injection** |
|---|---|---|
| **Initiation** - 0.5mg monthly for the first 3 months<br>• Until maximum visual acuity is achieved and/or there are no signs of disease.<br>**Review after 4 weeks and asses stability**<br>If patient is **stable** (maximum visual acuity is achieved and/or there are no signs of disease activity), the patient may be progressed to treat-and-extend<br><br>**Treat-and extend** - extend the treatment interval by 2 weeks at a time, up to a maximum of 12 weeks.<br><br>• If OCT dry and VA stable/improved – treat and extend regimen – increase injection interval at each visit until max interval of 12 weeks reached.<br>• If OCT "wet" or VA decreases, reduce treatment interval by 2 weeks until stable. | **Year 1 - Initiation -** 2mg monthly for the first 3 months<br>Followed by one injection every two months. There is no requirement for monitoring between injections.<br><br>If patient is **stable** (maximum visual acuity is achieved and/or there are no signs of disease activity), the patient may be progressed to treat-and-extend<br><br>**Treat-and extend** - extend the treatment interval by 2 weeks at a time, up to a maximum of 12 weeks.<br><br>• If OCT dry and VA stable/improved – treat and extend regimen – increase injection interval at each visit until max interval of 12 weeks reached.<br>• If OCT "wet" or VA decreases, reduce treatment interval by 2 weeks until stable. | **Year 1 – initiation** - 6mg every 4 weeks for the 1st three doses.<br><br>Thereafter :<br>In patients **without disease activity**, treatment every **12 weeks** (3 months) should be considered.<br><br>In patients **with disease activity**, treatment every **8 weeks** (2 months) should be considered.<br><br>A disease activity assessment is suggested 16 weeks (4 months) after treatment start.<br><br>New patients will be initiated on brolucizumab following 3 initial doses, then continue on 12 week dosing. |

**Temporary discontinuation** (dose withholding) is observed when disease becomes inactive (RCO, Sep 2013)

**No disease activity**
The disease should be considered to have become inactive when there is:
a) Absence of FFA leakage or other evidence of disease activity in the form of increasing lesion size, or new haemorrhage or exudates (i.e. no increase in lesion size, new haemorrhage or exudates) even if there is persistent fluid (intraretinal cysts or tubulation denoting chronic changes) on OCT.
b) No re-appearance or further worsening of OCT indicators of CNV disease activity on subsequent follow up following recent discontinuation of treatment.
b) No additional lesion growth or other new signs of disease activity on subsequent follow up following recent discontinuation of treatment.
c) No deterioration in vision that can be attributed to CNV activity.

**Consider discontinuing treatment permanently if there is**:
1. Hypersensitivity reaction to a licensed anti-VEGF agent is established or suspected.
2. Reduction of BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributable to AMD in the absence of other pathology.
3. Reduction in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate lack of responsiveness to treatment, or adverse event or both

There is evidence of deterioration of the lesion morphology despite optimum treatment.

**Appendix 2**

**Disease progression** (RCO, Sep 2013)

- is defined by the presence of at least one of the following criteria:

- The appearance of sight threatening CNV which was not previously suspected or thought to be present.
- Evidence of new haemorrhage and/or subretinal fluid.
- A documented recent visual decline in the presence of CNV.
- An increase in CNV size between visits.

- BCVA should be equal to or better than Snellen visual acuity > 6/96 (LogMar 1.2 or 24 ETDRS letters).
- There should be no significant permanent structural damage to the fovea before treatment is commenced. Significant structural damage is defined as longstanding fibrosis or atrophy in the fovea, or a significant chronic disciform scar which, in the opinion of the treating clinician, would prevent the patient from deriving any functional benefit (i.e. prevent further loss of vision) from treatment.

**Definitions:**

- **'Classic with no occult'** – lesions that are composed of classic CNV with no evidence of an occult component.
- **'Predominantly classic with occult'** – lesions in which 50% or more of the entire area is classic CNV but some occult CNV is present.
- **'Minimally classic'** – lesions in which less than 50% but more than 0% of the area is classic CNV.
- **'Occult only'** – lesions in which there is occult CNV with no evidence of classic CNV.