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## [SAVRS consensus guideline: Management of Exudative Age-Related Macular Degeneration \(AMD\)](#)

The Academic Advisory Committee of the SA Vitreoretinal Society (SAVRS) would like to record their concern about the fragmented implementation of the treatment of AMD. The committee would like to record the following points:

1. Age-related Macular Degeneration is the leading cause of irreversible visual loss in patients over 65 years of age. It is a chronic condition that requires life-long management. AMD is a PMB condition (ICD-10 H35.3)
2. Anti-VEGF monotherapy with Ranibizumab (Lucentis®) or Bevacizumab (Avastin®) intra-vitreous injections is the standard of care for the management of choroidal neovascularisation secondary to AMD, as demonstrated by multiple international, multi-centre peer-reviewed, randomised controlled trials. Guidelines for treatment are detailed in Appendix 1
3. Ranibizumab (Lucentis®) is the only medication that is registered internationally for the treatment of AMD and remains the only agent registered for the treatment of AMD by the South African Medicines Control Council (M.C.C).
4. Bevacizumab (Avastin®) carries international registration and MCC registration for the treatment of carcinoma of the colon but is NOT registered for use in the eye. The use of Bevacizumab (Avastin®) for the management of AMD is therefore in an "off-label" capacity. The SAVRS would like to emphasize that although the use of Bevacizumab (Avastin®) for the treatment of AMD is widespread practice due to price, the decision to use Bevacizumab (Avastin®) is in most cases dictated by funding/funders and may not be the first choice of the treating surgeon.
5. Bevacizumab (Avastin®) is packaged in a single, sterile vial for use as an intravenous agent. The fluid content of each vial is commonly compounded into smaller quantities in order to make the unit cost more affordable. In other countries where Bevacizumab (Avastin®) is used, compounding pharmacies undertake the process of preparing the units under strict aseptic conditions. No such pharmacies exist in South Africa, forcing pharmacists or surgeons to perform the compounding process themselves.
6. In the absence of a compounding pharmacy, the SAVRS recommends the compounding is performed under sterile conditions in the operating theatre or laminar flow hood suitable for preparation of sterile intravenous medication.
7. Compounding costs are expected to vary between centres with the usage patterns, facility costs and other economic determinants
8. The SAVRS would like to record its concern that the clinical (and indeed medico-legal) responsibility for treating AMD is currently borne by the treating ophthalmologist despite the fact that the decision to use an off-label drug may be forced upon them by funding/funders.
9. Certain sub-types of AMD with choroidal neovascularisation require special consideration. The use of Visudyne Photodynamic Therapy (PDT), with or without Anti-VEGF therapy may be indicated for choroidal neovascularisation secondary to Idiopathic Polypoidal Choroidal Vasculopathy, Retinal angiomatous

proliferation or neovascularisation resistant to monotherapy with an anti-VEGF agent. Numerous studies have documented significantly improved success rate over anti-VEGF monotherapy.

10. The appropriate management of this devastating blinding condition is critical and the Academic Advisory Committee of the SAVRS would like to invite stakeholders to utilise the committee to guide best practice in the interests of appropriate and evidence-based treatment options.

## **APPENDIX 1: Recommended treatment algorithm for subfoveal choroidal neovascularisation (CNV) in AMD**

1. Patients should be referred to a suitably trained ophthalmologist for treatment.
2. Diagnosis of exudative AMD should be confirmed by the ophthalmologist and baseline visual acuity should be recorded. There are no visual acuity exclusions for treatment and treatment should be discussed and offered, unless contra-indicated, for all levels of vision.
3. Current standard of care recommendations include the performing of a fluorescein angiogram of the eye at baseline to confirm the diagnosis. The fluorescein angiogram is performed either in a hospital or at the doctor's rooms depending on the doctor's discretion and the emergency facilities available. Indications for repeating the fluorescein angiogram include failure to respond to treatment and worsening of visual acuity. Indocyanin green angiography is indicated for non-responders or suspected atypical neovascularisation.
4. The Optical Coherence Tomography (OCT) scan is a pivotal investigation for the diagnosis and follow-up of the therapy. OCT scan should be performed at least at baseline, month 3 after initiation of therapy and repeated if clinical history or examination suggests activity.
5. The standard of care dictates treatment with a single intravitreal injection of either 0.5mg Ranibizumab (Lucentis®) or 1.25mg Bevacizumab (Avastin®) monthly for the first 3 months, followed by re-assessment and further therapy if required.
6. The place where the injection is performed is in a suitable sterile environment which may either be in a hospital setting or in the doctor's rooms depending on the treating doctor's discretion.
7. Current evidence suggests the best visual outcome is achieved with monthly intravitreal injections for the first 2 years, with further injections when there is clinical deterioration as evidenced by activity on OCT or decrease in visual acuity.
8. Alternative treatment regimens would include the "treat-and-extend" regimen and the PRN dosing schedule. Whilst both of these protocols aim to reduce the burden of monthly injections, frequent re-assessments are required and repeat injections are recommended with any drop in vision or evidence of exudation.
9. As not all lesions respond to anti VEGF agents, this group of non-responders will require alternative strategies.

**Reference:** Preferred therapies for neovascular age-related macular degeneration. Review in Curr Opin Ophthalmol 2012, 23: 182-188. Lally DR et al