Macular Disease Foundation Australia
POST-MARKET REVIEW OF AUTHORITY REQUIRED PBS LISTINGS

Recommendation 1: To increase the authority script for intravitreal anti-VEGF injections (ranibizumab and aflibercept) from the existing 1 plus 2 repeats to 1 plus 5 repeats.

Background
The use of intravitreal anti-VEGF drugs ranibizumab (Lucentis® - Novartis) and aflibercept (Eylea® - Bayer) has revolutionised the management of neovascular ("wet") age-related macular degeneration, the main cause of blindness and serious vision loss in Australia. Most people who were previously rendered blind from this disease are now able to maintain good and often excellent functional vision, preserving independence and quality of life.

It should be noted:

- The majority of people receiving intravitreal anti-VEGF treatment for 'wet' age-related macular degeneration are elderly (aged 65+).
- People receiving intravitreal anti-VEGF drugs are treated on an individualised basis. Initiation of treatment will typically involve one injection per month for three months with subsequent timing of injections determined by the time to reappearance of sub- or intra-retinal blood or fluid. This usually involves a 'treat and extend' protocol whereby the time between injections is progressively increased until leakage is observed, with subsequent injections being given at a slightly shorter spacing to avoid further leakage. Excessive leakage is to be avoided as this may accelerate scarring of the retina with permanent vision loss. The majority of people with 'wet' age-related macular degeneration will be able to have injections spread to somewhere between 8 to 12 weeks but rarely beyond this.
- The initiation of treatment as soon as possible after diagnosis of neovascularisation is critical to ensuring the best outcomes. Given the typical age of patients and the difficulty they experience in attending treatment, most ophthalmologists will prefer to initiate treatment on the day of diagnosis rather than bringing the patient back some time later.
- 20 to 30% of people will require injections every 4 weeks on an ongoing basis in order to maintain control of neovascularisation and preserve vision.
- About 20% of people require bilateral injections (necessitating separate scripts per eye).
- The overwhelming majority of people receiving intravitreal anti-VEGF injections for age-related macular degeneration will require treatment indefinitely.

Currently, the authority script for ranibizumab and aflibercept allows one injection plus 2 repeats. This represents between 3 and 9 months treatment, per eye.

The initial authority for anti-VEGF treatment requires evidence from a fluorescein angiogram of sub-foveal neovascularisation. Subsequent authorities do not require further angiograms. Indeed, this would be unnecessary, counter-productive and potentially dangerous, given the following:

a) the well characterised chronic nature of the disease
b) significant risks associated with fluorescein angiography

c) the intent of the treat and extend protocol is to avoid further leakage, hence a requirement to show leakage could, in fact, jeopardise vision
d) the increasing evidence that treatment needs to be maintained in most people to preserve vision by preventing further leakage
e) response to treatment is universally (periodically) monitored with the use of OCT.

The PBS recently announced that in order to reduce their workload, faxed authority requests for anti-VEGF scripts would no longer be allowed, however we understand that following complaints from clinicians, faxed requests for initial treatments (with photographic evidence) are again being accepted. This helps to ensure that patients can receive treatment on the day of initial diagnosis. As such, the Foundation commends the PBS for allowing faxed approvals to continue.

Giving due regard to the following:
a)treatment is invariably ongoing
b)treatment is managed in a way that avoids or minimises further leakage
c)any delay in treatment can potentially jeopardise vision
d)approval is extremely unlikely to be withheld,
the existing authority restriction for only 3 doses appears to add unnecessary administrative burden to the PBS, clinicians and patients. Increasing the number of repeats to 5 would appear to be a common sense move to reduce administrative burden for all parties.

It is also recommended that the PBS needs to implement a mechanism whereby any dispensed scripts that are not subsequently used can be reclaimed by Medicare.

Recommendation 2: That consideration be given to extend the hours of operation of the PBS Authority Review department from 9-5 Eastern time to enable clinicians in WA to apply for initial authority scripts during afternoon clinics. If this is not possible, provide some other mechanism to enable WA to obtain same day (within an hour) approvals.

Background
Currently, if an ophthalmologist in Western Australia diagnoses a new case of wet age-related macular degeneration during an afternoon clinic, it will typically not be possible to obtain same day (faxed) approval for treatment due to the time differences between WA and Tasmania. This is especially apparent in summer, when WA is three hours behind the east coast. This means that the patient will have to return the next working day (or possibly later depending on availability of appointments). Such a delay is highly inconvenient to all parties, but especially patients, and any carers who will typically accompany patients. It will also result in patients and carers from rural and remote communities having to find and pay for additional accommodation, any may place the patient at a greater risk of vision loss is the treatment has to be delayed for any reason.