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Position statement on the use of dexamethasone (Ozurdex®) implant for Diabetic Macula Oedema

The pathophysiology of Diabetic Macula Oedema (DMO) is complex. We know that the two key underlying pathways causing the disease are chronic inflammation and angiogenesis with overexpression of vascular endothelial growth factor. Both processes cause vascular instability with breakdown of the blood retina barriers, resulting in intraretinal and subretinal accumulation of fluid at the macula[1]. If not treated timeously and effectively this can cause irreversible loss of vision in these patients[2].

Anti – vascular endothelial factor (anti-VEGF) therapy acts against vascular endothelial growth factor and dexamethasone targets the inflammatory pathway[3].

Anti-VEGF therapy is generally considered first line in the treatment of DMO, however many patients with early DMO respond well to dexamethasone and anti - Vascular Endothelial growth factor therapy (anti-VEGF)[4]. Some patients with DMO are non-responsive to anti-VEGF drugs [1,5].

Dexamethasone is a second line therapeutic option for these patients and needs to be continued to have an optimal effect. The number of dexamethasone implants required per year may vary from patient to patient, some may require more than two per year. In the MEAD study (which was a randomized controlled trial and not “real -world evidence”) an average of four implants was required over three years of treatment for the 0.7 mg implant group and five treatments for the 0.35mg implant group[7].

In a real-world setting, eyes with DMO considered refractory to anti-VEGF therapy after three monthly injections, which were switched to dexamethasone implant had better visual and anatomical outcomes at 12 months than those that continued treatment with anti-VEGF therapy.[8]

In a recent prospective study evaluating visual and anatomic outcomes after dexamethasone implant treatment in retinal diseases including DMO, the optimal interval for dexamethasone implant retreatment, based on efficacy and safety outcomes, was determined to be 20 weeks (4 to 5 months). Thus, it is likely that more frequent dosing of dexamethasone implant than the ≥6 month intervals used in the MEAD study would have provided more consistent improvement in BCVA over time and at study end, and the MEAD study outcomes may underestimate the true value of dexamethasone implant in DMO.

These results are consistent with the previous report of dexamethasone implant effectiveness in the treatment of DMO that had not responded to 3 monthly injections of intravitreal bevacizumab anti-VEGF therapy[9]. The multifactorial nature of DMO may explain why some patients are refractive to anti-VEGF treatment but respond to steroids.

Patient characteristics should be taken into consideration when selecting therapy and treatment should be individualized as best possible[6]. Dexamethasone may cause raised intra-ocular pressure in some patients[7]. This pressure increase can usually be controlled with topical therapy[7]. Steroid therapy is known to cause earlier onset of cataracts which is a treatable and reversable cause of vision impairment[7]. As seen in the MEAD study where vision was restored after cataract removal[7].

SAVRS recommends the availability of an alternative agent to treat this common sight threatening Prescribed Minimum Benefit (PMB) condition (Diabetic Macula Oedema). The evidence is clear that not every patient will respond to an anti-VEGF agent and dexamethasone (Ozurdex®) provides an alternative agent whose efficacy is well established in the literature. The longer intervals of dosing make it a cost effective additional measure to treat this condition.

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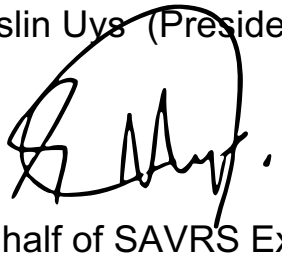

On behalf of SAVRS Exco
November 2023