

Safety Guidance

# Clinical Prioritisation Guidance for Limited Stock of Verteporfin (Visudyne) for Photodynamic Therapy (PDT) for Central Serous Chorioretinopathy (CSR)

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## 1 Summary

Since October 2021, the UK has been experiencing a shortage of Verteporfin 15mg powder for use in PDT for patients for a variety of conditions. Due to this shortage, the Department for Health and Social Care (DHSC), the Royal College of Ophthalmologists (RCOphth) and the National Clinical Director for Ophthalmology (NCD) have worked together to develop a system for prioritising the conditions which PDT can be offered as a treatment option. Due to the severity of the shortage, this has meant that supplies have been reserved for ocular oncology indications within the UK's ocular oncology centres.

Unfortunately, the supply situation for Verteporfin is unlikely to improve in the near future and the DHSC, RCOphth and NCD have evaluated the current supply situation for the potential to treat patients with PDT for non-ocular oncology conditions. This is primarily for patients with chronic CSR and the DHSC, RCOphth and NCD have made the decision to release any UK supplies not required by the ocular oncology centres for the treatment of chronic CSR patients. However, an evaluation of waiting lists in the UK has highlighted that there is insufficient supply of Verteporfin within the UK to treat chronic CSR patients currently on waiting lists. The RCOphth has therefore developed a list of prioritisation factors which should be used to evaluate waiting lists of chronic CSR patients for those who are most at need of treatment:

### 2 Clinical Prioritisation Factors for ½ dose PDT laser.

- CSR in patients with monocular vision
- · Patients with bilateral CSR
- Patients with caring responsibilities
- Duration of CSR patients should have been diagnosed with CSR for more than 4 months and showing no improvement
- Location of sub-retinal fluid –sub-retinal fluid should extend beneath the fovea
- Corrected visual acuity should be worse than or equal to 6/12

#### **Exclusion criteria**

Permanent macular damage for which treatment will not improve vision

#### 3 Half-Dose Protocol

Whilst PDT has been well established as a therapy for treatment of chronic CSR, more recent trials have shown that a half dose of Verteporfin is the most effective treatment option for chronic CSR patients. The SPECTRA and PLACE trials have established the increased efficacy of half-dose Verteporfin against both Eplerenone and High-Density Subthreshold Micropulse Laser (HSML)<sup>3,4</sup>. It is therefore important that centres offering PDT for chronic CSR patients utilise a half dose protocol both for efficacy of treatment but also to ensure as many patients are treated with the limited supply of Verteporfin as possible. Centres should ensure lists are appropriately coordinated so that each vial of Verteporfin can be used to treat 2 patients.

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If you have any queries regarding this guidance or the situation regarding the on-going shortage of Verteporfin please contact Jonathan Baker, Quality improvement Manager at jonathan.baker@rcophth.ac.uk

#### 4 References

- 1. van Dijk, E.H.C., van Rijssen, T.J., Subhi, Y. *et al.* Photodynamic Therapy for Chorioretinal Diseases: A Practical Approach. *Ophthalmol Ther* **9**, 329–342 (2020).
- 2. Chan, W. M., Lai, T. Y., Lai, R. Y., Liu, D. T., & Lam, D. S. (2008). Half-dose verteporfin photodynamic therapy for acute central serous chorioretinopathy: one-year results of a randomized controlled trial. Ophthalmology, 115(10), 1756-1765.
- 3. van Dijk, E. H., Fauser, S., Breukink, M. B., Blanco-Garavito, R., Groenewoud, J. M., Keunen, J. E., ... & Boon, C. J. (2018). Half-dose photodynamic therapy versus high-density subthreshold micropulse laser treatment in patients with chronic central serous chorioretinopathy: the PLACE trial. Ophthalmology, 125(10), 1547-1555.
- 4. van Rijssen, T. J., van Dijk, E. H., Tsonaka, R., Feenstra, H. M., Dijkman, G., Peters, P. J., ... & Boon, C. J. (2022). Half-dose photodynamic therapy versus eplerenone in chronic central serous chorioretinopathy (SPECTRA): a randomized controlled trial. American Journal of Ophthalmology, 233, 101-110.

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