THE ROYAL COLLEGE OF OPHTHALMOLOGISTS'

COLLEGE STATEMENT

Ocriplasmin intravitreal injection for the treatment of vitreomacular traction

Ocriplasmin is a recombinant protease enzyme that is effective in lysing fibronectin and laminin bonds at the vitreoretinal interface thus relieving vitreoretinal traction following intravitreal injection. Pivotal phase III trials have shown its effectiveness in treating vitreomacular traction leading to European Union approval in March 2013.

The Royal College of Ophthalmologists welcomes the decision by the National Institute for Health and Care Excellence (NICE) to recommend 125 micrograms Ocriplasmin intravitreal injection as an option for the treatment of vitreomacular traction (VMT) in adults who have either:

a)stage II full thickness macular holes (FTMH) with a diameter of ≤ 400um
and/or

b)severe symptoms

Ocriplasmin is not recommended in either scenario if an epiretinal membrane (ERM) is present.

For stage II FTMH with a diameter of ≤ 400um this is a significant innovation in management and the pivotal trials have shown success in up to 40% of cases. However, it will be critically important for local management pathways to ensure that the implementation of Ocriplasmin use in such patients does not delay appropriate and timely referral to suitable vitreoretinal units for subsequent management of the 60% of patients that fail to have closure of the FTMH.

In the absence of a FTMH and ERM then the use of Ocriplasmin is considered both clinically and cost effective in patients with VMT when severe symptoms are present. In such cases, relief of VMT is achieved in up to 30% of cases by day 28 following injection. Although NICE has found it difficult to define a precise threshold of severity of symptoms it is acknowledged in the guidance that the symptoms of metamorphopsia can be severe and distressing and have a significant impact on such patients. In addition, NICE accepted that the patients enrolled in the pivotal trials were representative of those with severe distressing symptoms. In such trials, patients were eligible if acuity was 6/7.5 or worse and the mean baseline acuity in this particular sub-group of pts was 6/12. In addition, 80% of cases at enrollment were considered to be sufficiently affected to be considered for vitrectomy surgery.

Intravitreal Ocriplasmin injection appears to be well tolerated in the majority of patients with the most common reported adverse events being mild transient floaters and eye pain.

However, up to 8% of patients can experience a 2 line drop in acuity in the first week which generally recovers within a further 2 weeks without intervention. In addition, up to 7% of cases following treatment for VMT can develop new FTMH. These factors will need to be considered in the immediate postoperative follow up planning and monitoring of patients.

As Ocriplasmin is an enzyme, special precautions are required for its storage and immediate preparation prior to intravitreal injection to prevent degradation. Clear guidance is provided in the summary of product characteristics for the agent but essential are correct storage at -20°C and immediate preparation, dilution and injection following thawing.

The college believes that there should be no barrier to introduction of this technology and thus the duty of clinical commissioning groups to support implementation of the guidance should not be delayed beyond the 3 month period.

September 2013 (slight amendment October 2013)