NHS
Calderdale
Clinical Commissioning Group

Commissioning Policy

Treatment (brand name, manufacturer if applicable)	Dexamethasone 700 microgram intravitreal implant (Ozurdex, Allergan)
For use in	Non-infective uveitis
Background	OZURDEX is indicated for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis. Dexamethasone, a potent corticosteroid, has been shown to suppress inflammation by inhibiting oedema, fibrin deposition, capillary leakage, and phagocytic migration of the inflammatory response. Vascular Endothelial Growth Factor (VEGF) is a cytokine which is expressed at increased concentrations in the setting of macular oedema. It is a potent promoter of vascular permeability. Corticosteroids have been shown to inhibit the expression of VEGF. Additionally, corticosteroids prevent the release of prostaglandins, some of which have been identified as mediators of cystoid macular oedema.
Commissioning position	NHS Calderdale CCG will fund the administration of dexamethasone implants for the treatment of non- infectious uveitis under the following conditions : 1. The diagnosis is non-infectious posterior uveitis The patient has been treated with all of the following: • High dose rescue corticosteroid treatment ie. prednisolone 1mg/kg/day. • Visual maintenance with Azathioprine 2.5mg/kg/day **or** Mycophenolate Mofetil 1g bd and concomitant oral steroids 2. If uveitis remains uncontrolled or vision deteriorates despite the above treatment plan or steroid maintenance dose exceeds 10mg/day prednisolone despite maximal concomitant Aza/mycophenolate or aza/mycophenolate cannot be tolerated * A maximum of one implant per eye every six months will be funded in line with licensing information. Funding will only be maintained for ongoing treatment where it can be demonstrated that: 1. There is a > 15 letter improvement in best corrected visual acuity (BCVA) after 12 weeks following the first administration or the patient achieves driving visual acuity 2. The patient's visual acuity is maintained to at least 50% of the best recorded following diagnosis of uveitis.

	*Intolerance of prednisolone/DMARD drugs is defined as severe debilitating side effects as a result of treatment e.g. hepatic dysfunction, neutropaenia, severe nausea and vomiting etc.
Effective from	December 2011
Summary of evidence/rationale	The clinical efficacy of OZURDEX has been assessed in a single, multicentre, masked, randomised study for the treatment of non-infectious ocular inflammation of the posterior segment in patients with uveitis. A total of 229 patients were randomised to receive dexamethasone 350 µg or 700 µg implants or sham. Of these, a total of 77 were randomised to receive OZURDEX, 76 to dexamethasone 350 µg and 76 to sham. A total of 95% of patients completed the 26-week study. The proportion of patients with vitreous haze score of 0 in the study eye at week 8 (primary endpoint) was 4-fold higher with OZURDEX (46.8%) compared to Sham (11.8%), $p < 0.001$. Statistical superiority was maintained up to and including week 26 ($p \leq 0.014$) as shown in Table 4. The cumulative response rate curves (time to vitreous haze score of 0) were significantly different for the OZURDEX group compared to the Sham group ($p < 0.001$), with patients receiving dexamethasone showing an earlier onset and greater treatment response. The reduction in vitreous haze was accompanied by an improvement in visual acuity. The proportion of patients with at least 15 letters improvement from baseline BCVA in the study eye at week 8 was more than 6-fold higher with OZURDEX (42.9%) compared to Sham (6.6%), $p < 0.001$. Statistical superiority was achieved at week 3 and maintained up to and including week 26 ($p < 0.001$) as shown in Table 4.
Date	December 2011
Policy to be reviewed by	December 2013
Contact for this policy	Helen Foster – Medicines Management Lead Helen.Foster@calderdaleccg.nhs.uk