

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Dexamethasone intravitreal implant for treating diabetic macular oedema in people without a pseudophakic lens (part review of TA349)

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of dexamethasone intravitreal implant within its marketing authorisation for treating diabetic macular oedema in people without a pseudophakic lens.

Background

Diabetic macular oedema (DMO) is a common complication associated with diabetic retinopathy, and is the most common cause of visual impairment in diabetes mellitus. It occurs as a result of changes in retinal blood vessels in people with diabetes. Disruption of the blood–retinal barrier allows fluid to leak from blood vessels in the central part of the retina (the macula), leading to fluid accumulation and thickening of the macula. This can lead to severe visual impairment in the affected eye.

DMO can be classed as focal, diffuse or ischaemic (although no universal definition has been agreed). The majority of vision loss occurs when DMO involves the centre of the macula. This is known as clinically significant macular oedema (CSMO), and is regarded as the threshold for treatment.

More than 3.5 million people have been diagnosed with diabetes in England and Wales (2019)¹, and the condition is more common in people of African–Caribbean and South Asian family origin than in those of European family origin. Approximately 7% of people with diabetes may have DMO in England, of whom 39% have CSMO². The prevalence of DMO is related to the duration and severity of diabetes, and to numerous risk factors including age, pregnancy, smoking, hypertension, nephropathy, obesity and high cholesterol.

Good management of diabetes and other risk factors may delay the onset and progression of DMO. This includes diet and lifestyle modification, blood pressure control and pharmacological treatments. For DMO specifically, NICE technology appraisals TA274 and TA346 recommend anti vascular endothelial growth factor (anti-VEGF) treatments ranibizumab and aflibercept as options for treating visual impairment caused by DMO if the eye has a central retinal thickness (CRT) of 400 micrometres or more at the start of treatment. For eyes with a CRT of less than 400 micrometres, laser photocoagulation may be a treatment option. In addition, bevacizumab, another anti-VEGF treatment, is used outside its marketing authorisation in some NHS centres. In NICE technology appraisal TA613 (a partial review of TA301), fluocinolone was not recommended for treating chronic diabetic macular oedema that is insufficiently responsive to available therapies in an eye with a natural lens (phakic eye). In cases where there is no suitable treatment available, a watch-and-wait strategy may be adopted until the point where treatment with anti-VEGFs becomes suitable, or surgical intervention is required.

NICE technology appraisal TA349 recommends dexamethasone intravitreal implants as an option for treating DMO that is insufficiently responsive to available therapies if the implant is to be used in an eye with an intraocular (pseudophakic, or artificial) lens. There is new evidence supporting the clinical and cost effectiveness of dexamethasone intravitreal implants for people with phakic (natural) lenses. Therefore, the decision was taken to part-review TA349 in an appraisal for people with phakic lenses.

The technology

Dexamethasone intravitreal implant (Ozurdex, AbbVie) contains a corticosteroid which suppresses inflammation and thereby inhibits oedema. It is administered by injection into the vitreous cavity of the eye, where it delivers dexamethasone to the posterior segment of the eye for up to 6 months.

Dexamethasone intravitreal implant is indicated for “the treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.”

Intervention(s)	Dexamethasone intravitreal implant
Population(s)	People with phakic lenses and diabetic macular oedema that is insufficiently responsive to, or is unsuitable for, non-corticosteroid treatment
Comparators	<ul style="list-style-type: none"> • Laser photocoagulation alone • Watch-and-wait (for people who are unsuitable for treatment with both anti-VEGFs and laser photocoagulation) <p>The following technologies alone or in combination with laser photocoagulation:</p> <ul style="list-style-type: none"> • Aflibercept (only if the eye has a central retinal thickness of 400 micrometres or more) • Bevacizumab (does not currently have a marketing authorisation in the UK for this indication) • Ranibizumab (only if the eye has a central retinal thickness of 400 micrometres or more)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • best corrected visual acuity (the affected eye) • best corrected visual acuity (both eyes) • central foveal subfield thickness • central retinal thickness • contrast sensitivity

	<ul style="list-style-type: none"> • mortality • need for cataract surgery • adverse effects of treatment (including cataract formation and glaucoma) • health-related quality of life, including the effects of changes in visual acuity.
<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>Cost effectiveness analysis should include consideration of the benefit in the best and worst seeing eye.</p>
<p>Other considerations</p>	<p>If the evidence allows the following subgroups will be considered. These include:</p> <ul style="list-style-type: none"> • type of DMO (focal or diffuse, central involvement, ischaemic or non-ischaemic maculopathy) • duration of DMO • baseline visual acuity • baseline central retinal thickness • previous treatment history (including people who have received no prior treatment, and those who have received and/or whose disease is refractory to laser photocoagulation, aflibercept, ranibizumab or bevacizumab) • prior cataract surgery <p>The availability and cost of biosimilar and generic products should be taken into account.</p> <p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations,</p>

	<p>guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy (2019) NICE Technology Appraisal 613. Review date 2022.</p> <p>Dexamethasone intravitreal implant for treating diabetic macular oedema (2015) NICE Technology Appraisal 349. Reviewed May 2021.</p> <p>Aflibercept for treating diabetic macular oedema (2015) NICE Technology Appraisal 346. Next review date to be confirmed.</p> <p>Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy (2013) NICE Technology Appraisal 301. Next review date to be confirmed.</p> <p>Ranibizumab for treating diabetic macular oedema (2013) NICE Technology Appraisal 274. Next review date to be confirmed.</p> <p>Appraisals in development (including suspended appraisals):</p> <p>Faricimab for treating diabetic macular oedema NICE technology appraisal guidance [ID3899]. Publication expected June 2022.</p> <p>Brolucizumab for treating diabetic macular oedema NICE technology appraisal guidance [ID3902]. Publication date to be confirmed.</p> <p>Related Guidelines:</p> <p>Type 1 diabetes in adults: diagnosis and management (2015; updated 2021) NICE guideline NG17.</p> <p>Type 2 diabetes in adults: diagnosis and management (2015; updated 2020) NICE guideline NG28.</p> <p>Related Quality Standards:</p> <p>Diabetes in adults (2016) NICE quality standard QS6.</p> <p>Related NICE Pathways:</p> <p>Identifying and managing complications in adults with type 1 diabetes: eye disease (2021) NICE pathway</p>

	<p>Identifying and managing complications in adults with type 2 diabetes: eye disease (2021) NICE pathway</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 12 Adult specialist ophthalmology services.</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2 https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p>

References

- 1 Diabetes UK (2020) [Diabetes prevalence 2019](#). Accessed September 2021.
- 2 Minassian DC, Owens DR, Reidy A. Prevalence of diabetic macular oedema and related health and social care resource use in England. *British Journal of Ophthalmology* 2012;96:345-349.