

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Ciclosporin for treating dry eye disease

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of ciclosporin within its marketing authorisation for treating dry eye disease.

Background

Dry eye disease (keratoconjunctivitis sicca) is chronic inflammation of the eyes caused by reduced tear production or excessive tear evaporation. It can be attributed to a variety of factors, including dry or air-conditioned environments, auto-immune diseases (such as Sjogren Syndrome, rheumatoid arthritis, and lupus), and the adverse effects of some medications. Symptoms include irritation and redness in the eyes, blurred vision, and a sensation of grittiness or a foreign body in the eye. In severe cases, it can cause damage to the surface of the eye, irreversible loss of visual acuity and corneal perforation. Dry eye disease can be painful and can have serious effects on quality of life and vision-based activities such as driving and reading.

Dry eye disease may be classified as aqueous-deficient (in which the lacrimal glands fail to produce enough of the watery component of tears to maintain a healthy eye surface) or evaporative (in which the meibomian glands in the eyelids do not produce enough of the lipid or oily part of tears that slows evaporation). The severity of dry eye disease can be measured using the Dry Eye Workshop (DEWS) classification system, which describes 4 levels of disease severity, ranging from 1 (least severe) to 4 (most severe). Patients with a score of 3-4 are generally considered to have severe dry eye disease.

The prevalence of dry eye disease is difficult to estimate as there is no defined diagnostic test. Although it can affect people of any age, it is more prevalent in women and in older people. It is reported that 15 to 33% of people aged 65 years or over have dry eye disease. This is likely to be an underestimate of the true prevalence as people with mild symptoms may not report the condition to their doctor. Approximately 20% of people with dry eye disease have severe disease.

There is no cure for dry eye disease. Management aims to relieve discomfort and prevent damage to the cornea at the front of the eye. Current treatment options for dry eye disease depend on the severity of the condition. Lubrication treatments such as artificial tears and eye ointments may be used for the treatment of mild to moderate dry eye disease along with advice on lessening the impact of environmental factors that exacerbate dry eyes, for example, by using room humidifiers and re-assessing the use of some

medications. In moderate cases, additional treatment options include anti-inflammatory agents (including acute use of topical corticosteroids such as betamethasone, dexamethasone, fluorometholone or prednisolone) and specialised eyewear. In severe cases, ocular preparations of ciclosporin (which are not currently licensed for dry eye disease) are used, or in people with aqueous-deficient dry eye disease, punctual plugging (in which tear ducts are blocked with dissolvable collagen) can be undertaken. In very severe cases, autologous serum tears or surgery may be considered.

The technology

Ciclosporin (Ikervis, Santen) is a cationic emulsion that reduces inflammation in the eye by increasing secretions from the tear (lachrymal) gland. It is administered as an eye drop.

Ciclosporin does not currently have a marketing authorisation in the UK for treating dry eye disease. It has been studied in clinical trials compared to a vehicle (similar to an ocular lubricant) in adults with moderate to severe dry eye disease, whose disease has not adequately responded to conventional management (including artificial tear drops, gels or ointments).

Intervention	Ciclosporin
Population	People with severe dry eye disease (DEWS 3 or 4) whose disease has not adequately responded to tear substitutes
Comparators	Standard treatment for dry eye disease without ciclosporin (such as artificial tears, eye ointments, and acute use of topical corticosteroids)
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • eye pain and discomfort • symptoms of dry eye disease (including photosensitivity, ability to open eyes, visual acuity and ability to concentrate) • adverse effects of treatment • health-related quality of life.

<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>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>Other considerations</p>	<p>If the evidence allows, a subgroup analysis of people with Sjogren syndrome should be considered.</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, 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>None</p>
<p>Related National Policy</p>	<p>None</p>