# PBS Authority Quick Eligibility Checklist

ikervis®
ciclosporin 1mg/ml
ONE DROP. ONCE DAILY.

**Ikervis Indication:** Severe keratitis in an adult patient with dry eye disease which has not improved despite treatment with tear substitutes.[1]

## INITIAL TREATMENT PHASE[2]

**Initiation**
Initial treatment for up to the first 180 days of treatment with Ikervis

→

**Corneal Fluorescein Staining (CFS)**
Patient must have a CFS grade of 4 at treatment initiation using the Oxford scale or equivalent

+

**Ocular Surface Disease Index (OSDI)**
Patient must have an OSDI score of ≥23 at treatment initiation

+

**Artificial Tear (AT) substitutes**
- The condition must be inadequately controlled by monotherapy with a preservative free AT substitute; AND
- Patient must be undergoing simultaneous treatment with a preservative free AT substitute.

## CONTINUING TREATMENT PHASE[2]

**Continuation**
Patient must have received PBS-subsidised treatment with Ikervis for this condition

→

**Corneal Fluorescein Staining (CFS)**
Improvement (reduction) in CFS by ≥3 grades from baseline (as measured by the same scale as initiation)

+

**Ocular Surface Disease Index (OSDI)**
OSDI score has improved by ≥30% compared to value stated at treatment initiation

→

**If YES to all, contact PBS for Authorisation**
(see next)

If **NO** to any PBS criteria for initiation and continuing phase; and **YES** to Ikervis® indication

→

**Private (non-PBS):** Patient is not eligible for PBS. The RRP of Ikervis® is $81.90 as a non-PBS prescription^

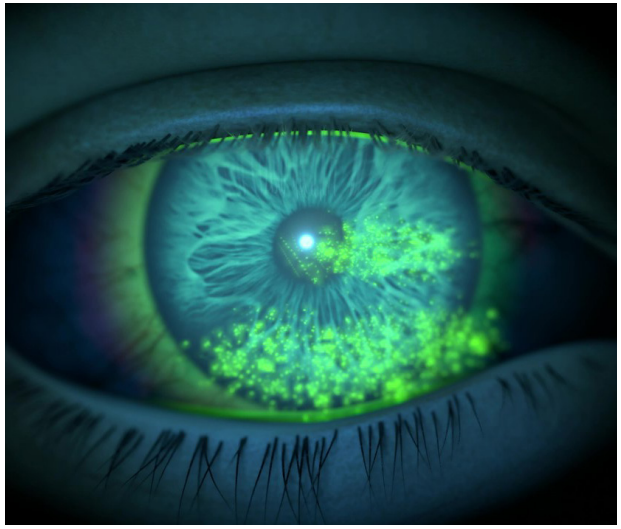
^RRP is a guide only and there is no obligation to comply with recommended retail prices, retailers are free to set their own prices.

# PBS Eligibility Criteria Explained

## CORNEAL FLUORESCEIN STAINING (CFS)

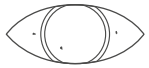
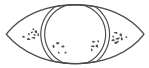
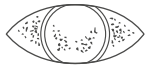
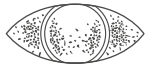
To assess the integrity of the corneal and conjunctival surface[3,4]

### Severe epithelial damage at the centre of the cornea using CFS



### Modified Oxford Scale

Grade 0 = absence of dot

| | | |
|---|---|---|
| A |  | Grade 0.5 |
| B |  | Grade I |
| C |  | Grade II |
| D |  | Grade III |
| E |  | Grade IV |
| | >E | Grade V |

**Signs of severe keratitis**

# PBS Eligibility Criteria Explained

## OSDI QUESTIONNAIRE

To assess symptoms of dry eye disease[5,6]

### Patient's OSDI score

- Patients answer each question on a scale of 0–4, with 4 being 'all of the time' and 0 'none of the time'
- OSDI is assessed on a scale of 1–100, higher scores representing greater disability
- Patients are classed as normal, mild, moderate or severe DED, depending on their score

**Scan the QR code** to download the OSDI questionnaire
Click here to access the OSDI questionaire
https://www.tfosdewsreport.org/public/images/OSDI.png)

# How to contact PBS for Authority Required approval
(immediate/real-time assessment)

ikervis®
*ciclosporin 1mg/ml*
ONE DROP. ONCE DAILY.

**1800 888 333** (24 hours)

**www.servicesaustralia.gov.au/HPOS**

## Checklist for application

### PATIENT INFORMATION

- ☐ Medicare number
- ☐ First and last name
- ☐ Full residential address
- ☐ CFS grade
- ☐ OSDI score

### PRESCRIBER INFORMATION

- ☐ Your prescriber number
- ☐ PBS Authority Prescription Number

### IKERVIS INFORMATION

- ☑ PBS item number (12663L)
- ☑ Quantity (30 x 0.3mL units)
- ☑ Number of repeats (max. 5)
- ☑ Ikervis indication


Please see the PBS website for more information

**PBS Information:** Authority Required. Refer to PBS Schedule for full information.

Before prescribing, please review the Approved Product Information available on request to Seqirus Medical Information (1800 642 865) or www.seqirus.com.au/products

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

**MINIMUM PRODUCT INFORMATION: IKERVIS®** (ciclosporin 0.1% ophthalmic emulsion) **Indication:** Treatment of severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes. **Contraindications**: Hypersensitivity to the active substance or any of the excipients; Ocular or peri-ocular malignancies or premalignant conditions; Active or suspected ocular or peri-ocular infection. **Precautions:** Any reversible underlying conditions, not associated with dry eye disease, should be treated prior to initiating IKERVIS®; History of ocular herpes; Contact lenses should be removed before instillation of eye drops and re-inserted at wake-up time and careful monitoring of severe keratitis is recommended; Glaucoma – limited experience with IKERVIS®. Exercise caution especially with concomitant beta-blockers; Co-administration with eye drops containing corticosteroids may potentiate effects of IKERVIS® on the immune system; May affect host defences against local infection and malignancies. **Use in Pregnancy (Category C):** No data available; Not recommended in pregnancy unless the potential benefit to mother outweighs the potential risk to fetus. **Use in Lactation:** Insufficient information on breastfed infants; it is unlikely that sufficient amounts are present in breast milk. A decision must be made to discontinue either IKERVIS® or breastfeeding during treatment. **Use in Children:** No data available. **Interactions with other medicines:** No data available. **Adverse Effects:** Common: erythema of eyelid; lacrimation increased; ocular hyperaemia; vision blurred; eyelid oedema; conjunctival hyperaemia; eye pruritus. Very common: eye pain, eye irritation. **Dosage and administration:** The recommended dose is one drop of IKERVIS® once daily to be applied to the affected eye(s) at bedtime.

**References: 1.** Ikervis Product Information. **2.** Pharmaceutical Benefits Scheme (https://www.pbs.gov.au). **3.** Bron AJ, *et al. Cornea* 2003;22:640–650. **4.** Kaido M, *et al. Invest Ophthalmol Vis Sci* 2011;52:9516–9522. **5.** Chan C. Practical Office Based Screening and Diagnostics. In: Chan C, ed. Dry Eye: A Practical Approach. Springer, 2015:31–44. **6.** Schiffman RM, *et al. Arch Ophthalmol* 2000;118:615–621.

Seqirus (Australia) Pty Ltd. ABN 66 120 398 067. 63 Poplar Road, Parkville Australia 3052. Seqirus Medical Information: 1800 642 865. Seqirus is a trademark of Seqirus UK Limited or its affiliates. IKERVIS is a registered trademark of Santen S.A.S. and distributed by Seqirus (Australia) Pty Ltd under license from Santen Pharmaceutical Asia Pte Ltd. Date of Preparation: September 2021. ANZ-Iker-21-0052.

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