# SCE 0810 Public Evidence Appendix

Ophthalmology

**Literature review date:** September 13, 2026

**Controlling principle.** Ophthalmic evidence is anatomy-, disease-, product-, route-, and endpoint-specific. Structural or mechanistic signals must not be converted into claims of restored vision, and the documented risk of severe irreversible injury from unapproved ocular injections must remain explicit.

## Point-by-point evidence framework

| Controlling Point | Evidence focus | Interpretive boundary |
|---|---|---|
| Retinal degeneration | Photoreceptors, retinal pigment epithelium, oxidative stress, trophic support, neuroprotection, and cell-replacement concepts. | Structural or electrophysiologic changes do not automatically establish durable visual benefit; MSC/EV support is biologically distinct from true retinal-cell replacement. |
| Macular degeneration | Geographic atrophy, neovascular AMD, RPE support or replacement, central vision, and disease-stage-specific outcomes. | Evidence from one product or AMD phenotype cannot be generalized to another; visual acuity, reading function, anatomy, progression, treatment burden, and safety remain distinct outcomes. |
| Optic-nerve injury | Retinal ganglion-cell loss, axonal damage, glial responses, neuroprotection, trophic signaling, and axonal-support mechanisms. | Neuroprotection is not optic-nerve regeneration; retinal nerve-fiber-layer or electrophysiologic change does not prove restored axonal connectivity or functional vision. |
| Corneal disease | Epithelium, stroma, endothelium, limbal stem-cell deficiency, scarring, inflammation, and layer-specific repair. | Evidence from one corneal layer or disease cannot be generalized across the cornea; epithelial closure, transparency, endothelial function, pain, graft need, recurrence, and vision must be distinguished. |
| Diabetic retinopathy | Retinal microvascular injury, leakage, ischemia, inflammation, edema, and pathologic neovascularization. | Angiogenic effects are context-dependent and may be hazardous; investigational biologics do not replace glycemic/BP control, anti-VEGF therapy, laser, or vitreoretinal surgery when indicated. |
| Documented risks of unapproved ocular injections | Procedure- and product-related ocular injury including infection, inflammation, retinal detachment, proliferative vitreoretinopathy, elevated intraocular pressure, and irreversible vision loss. | Unapproved or poorly characterized ocular injections can cause catastrophic harm; absence of established product identity, dose, route, sterility, and evidence is itself a major safety concern. |

## Evidence-handling rules

Positive, negative, null, mixed, and inconclusive findings are weighted by design quality and directness rather than by whether they favor the intervention.

Mechanistic evidence, development stage, clinical efficacy, safety, regulatory status, guideline position, and manufacturing quality remain separate analytical dimensions.

Disease-specific ophthalmic standard care remains the appropriate comparator, and high-risk invasive ocular procedures require particularly strict product and safety scrutiny.

## Principal references


1. Galipeau J, Sensebé L. Mesenchymal stromal cells: clinical challenges and therapeutic opportunities. Cell Stem Cell. 2018;22:824-833.

2. Pittenger MF, Discher DE, Péault BM, Phinney DG, Hare JM, Caplan AI. Mesenchymal stem cell perspective: cell biology to clinical progress. NPJ Regen Med. 2019;4:22.

3. Relevant contemporary clinical and translational literature concerning MSC/EV, retinal-cell, RPE, optic-nerve, limbal, and corneal-cell interventions.

4. Disease-specific ophthalmology guidance and regulatory safety communications should control statements concerning established treatment and unapproved ocular cell interventions.

5. Exact product identity, ocular anatomy, disease stage, laterality, route, dose, surgical technique, comparator, functional endpoint, structural endpoint, and follow-up must be matched before evidence is generalized.