**Dear [STATE or INSURANCE COMMISSION or HEALTH PLAN]**

We are writing on behalf of [Practice Name] to request that [STATE or INSURANCE COMMISSION or HEALTH PLAN] cover Luminopia, an FDA-approved1 treatment for pediatric amblyopia.

Luminopia is the first FDA approved treatment for pediatric amblyopia in nearly 15 years. Amblyopia is the leading cause of vision loss among children in the U.S., affecting 3% of the population. It is a neuro-visual disease where the visual pathway to the brain never fully develops and can be caused by unequal refractive errors between the eyes (anisometropia) or a physical eye turn (strabismus). The visual cortex ultimately suppresses the input from the weak eye as it only receives blurry or rivalrous images, leading to visual acuity loss and deficits in binocular function. If left untreated, amblyopia can result in permanent vision impairment and increase the risk of lifetime blindness2.

It is critical to treat amblyopia patients as early as possible as neuroplasticity begins to decline by age 7 and these patients lose the ability to regain their full vision as they grow older3. Current treatments, such as eye patches, leave up to 75% of patients with a permanent visual deficitdue to lack of efficacy4 and poor compliance5,6, demonstrating a significant unmet need. Additionally, patients who don’t respond to eye patches or atropine drops currently have no other treatment options. We believe that Luminopia is **medically necessary** to treat pediatric amblyopia and that Luminopia needs to be a covered plan benefit to ensure rapid and broad access to all children who would benefit from this treatment.

Our [treatment team or organization] believes that Luminopia is medically necessary for the following reasons:

1. Luminopia was proven safe and effective in three confirmatory clinical trials, including a randomized Phase 3 trial at 21 sites across the US7, in which:
   1. Luminopia improved vision in pediatric amblyopia patients by 1.81 lines on an eye chart, compared to just .85 lines of improvement in the control arm (p<0.01).
   2. 84% of children in the trial had already tried other treatments and when switched to Luminopia, they also experienced 1.8 lines improvement in vision.
   3. There were no SAEs in the trials and the most common AE was mild, transient headaches (14.3% vs. 1.7%).

2) Luminopia received FDA approval through a 10-month De Novo pathway review in October 2021.

3) Luminopia is available by prescription only and is distributed through a retail pharmacy, much like eyedrops or other medicines. The NDC code for Luminopia is 60007088710 and it is listed in the drug file of all four major compendia databases. Further, Luminopia is available in a 30-day supply and the prescription is refilled or canceled based on the Pediatric Ophthalmologists’ decision as to whether the patient is still benefiting from the treatment.

While Luminopia is not a drug in the narrow sense, the software has been proven effective and safe as a medical therapy in clinical trials. In fact, if Luminopia were a traditional medicine that improved vision in children by nearly 2 lines on an eye chart, we believe insurers would cover it immediately.

Children’s vision is at stake, we therefore respectfully request a response within 72 hours of receipt of this letter.

Thank you for your immediate attention to this matter.

Sincerely,

[Your name, title and practice or organization name]

cc: [Possible people to whom you should consider sending copies of your letter, such as:]

[Health Plan Medical Director]

[Medical Group Medical Director]

[Your state representative if you expect more denials]

1. FDA letter: <https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210005.pdf>
2. van Leeuwen R, Eijkemans MJ, Vingerling JR, Hofman A, de Jong PT, Simonsz HJ. Risk of bilateral visual impairment in individuals with amblyopia: the Rotterdam study. Br J Ophthalmology 2007;91(11):1450-1451
3. Holmes JM, Lazar EL, Melia BM, et al. Effect of age on response to amblyopia treatment in children. Arch Ophthalmol. 2011;129(11):1451-1457
4. Wallace DK; et al. A randomized trial to evaluate 2 hours of daily patching for strabismic and anisometropic amblyopia in children. *Ophthalmology*. 2006;113(6):904-912.
5. Wallace MP, Stewart CE, Moseley MJ, et al. Compliance with occlusion therapy for childhood amblyopia. Invest Ophthalmol Vis Sci. 2013;54(9):6158-6166. Published 2013 Sep 17
6. Steward CE, Moseley MJ, et al. Treatment Dose-Response in Amblyopia Therapy: The Monitored Occlusion Treatment of Amblyopia Study (MOTAS),Investigative Ophthalmol Vis Sci. 2004, Vol.45, 3048-3054
7. Xiao, S., et.al, Ophthalmology, Volume 129, Issue 1, P77-85, JANUARY 01, 2022