**Dear [Appeals Analyst]:**

I am writing, on behalf of [Name of plan member], to appeal the [Name of health plan and policy number] decision to deny Luminopia for [Name of patient].

It is our understanding that [Name of health plan] is denying coverage on the basis that "[Cite health plan’s language in the denial letter]." Amblyopia is the leading cause of vision loss among children in the U.S. and today’s treatments leave a significant unmet need as nearly 75% of patients who have been patched are left with a permanent vision deficit1. I believe that Luminopia is needed to fully treat [Name of child]’s amblyopia and that Luminopia needs to be covered to ensure access to all children who might benefit from this treatment.

I and my treatment team at [Practice name] recommended that Luminopia is medically necessary for [Name of child]. [Child’s name] has already gone through [Describe any prior treatment] and still has a vision deficit between his/her eyes and now needs a different option. If left untreated, amblyopia can result in permanent vision loss.

Luminopia was shown to improve vision in new and previously treated patients and we believe it provides [Child’s name] with the best opportunity to improve their vision even further.

Contrary to your letter, Luminopia should be covered for the following reasons:

1. Luminopia was proven safe and effective in three confirmatory clinical trials, including a randomized Phase 3 trial2, 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 De Novo pathway in October 2021 and is available by prescription only3.

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 pharmaceutical, the software is an effective and safe treatment and if Luminopia were a medicine that improved vision in children by nearly 2 lines on an eye chart, we don’t believe it would be denied like this.

As [Name of child]’s vision is at stake here, we respectfully request an expedited hearing and look forward to a response within 72 hours of receipt of this letter.

Thank you for your immediate attention to this matter.

Sincerely,

[Your name]

[Practice 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. 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.
2. Xiao, S., et.al, *Ophthalmology*, Volume 129, Issue 1, P77-85, JANUARY 01, 2022
3. FDA letter: <https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210005.pdf>