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Recommendations for use and coverage of digital, binocular treatments for amblyopia

Brenda L. Bohnsack, MD, PhD; James Bowerman, MD; K. David Epley, MD

Plain language summary

Amblyopia is the most common cause of vision impairment in children. Traditionally, ophthalmologists apply treatments, such as patching the better-seeing eye, that do not completely treat amblyopia for most patients, resulting in permanent vision loss. Luminopia is the first treatment cleared by the US Food and Drug Administration for amblyopia in decades and has been demonstrated to be an effective option recommended by pediatric ophthalmologists and health plan leaders as a preferred treatment for amblyopia to be covered by insurance providers.

Implications for managed care pharmacy

A roundtable of payers and pediatric ophthalmologists recommends Luminopia for inclusion in medical or pharmacy payer formularies based on clinical efficacy, tolerability, and incorporation into amblyopia treatment guidelines by the American Academy of Ophthalmology as a recommended treatment option. Treatment of amblyopia with traditional modalities often results in extensive treatment periods, reduced patient and caregiver quality of life during and after treatment, permanent vision loss, poor long-term health outcomes, and excess health care resource utilization.

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ABSTRACT

Amblyopia is the most common cause of vision impairment in children and presents as reduced visual acuity caused by suppression of neurologic signals from an eye. Traditional treatments include penalizing the better-seeing eye by occlusion, most commonly with patching. This does not address the binocular vision deficits of amblyopia and leaves most patients with unresolved disease and permanent vision loss. Digital, dual-acting therapy (Luminopia, Luminopia, Inc) was cleared in October 2021 via US Food and Drug Administration de novo market authorization for the treatment of amblyopia associated with anisometropia and/or with mild strabismus in children aged 4-7 years. Binocular digital therapy is now included in the American Academy of Ophthalmology's amblyopia treatment guidelines, the Amblyopia Preferred Practice Pattern (PPP). The pivotal randomized, controlled phase 3 trial evaluating Luminopia was recognized in the PPP as Level I+ evidence. Pediatric ophthalmologists and national and regional health plan leaders formed a roundtable panel to evaluate disease impact, the current treatment landscape, and guideline-based treatment principles. At the conclusion of this discussion, the panel developed a unanimous recommendation for the appropriate clinical and value-driven use of Luminopia and payer coverage recommendations. Luminopia is recommended for use to treat amblyopia and should be covered by payer policies. Duration of therapy should be based on patient needs as determined by prescribing physician expertise. Luminopia may be covered under either medical or pharmacy benefit. Step-edits may be used, and documentation of inadequate response to other therapies may be necessary to obtain coverage. Clinical documentation and medical letters of exception may also be needed for off-label use of Luminopia. The recommendations achieved in this roundtable based on the clinical evidence available provide a justification for broad payer coverage and improved patient access to a full range of evidence-based amblyopia treatments.

Introduction

Amblyopia is the most common cause of vision impairment in children and young adults and may result in permanent vision loss without adequate, early treatment.[1–4] The US Preventive Services Task Force recommends children aged 3–5 years be screened at least once for amblyopia or its risk factors.[5] Amblyopia has been labeled as a public health crisis because of detrimental short- and long-term patient outcomes following traditional therapies.[6] Digital dual-acting

treatment (Luminopia, Luminopia, Inc.) was cleared by the US Food and Drug Administration (FDA) via de novo market authorization in October 2021 for the treatment of amblyopia associated with anisometropia and/or with mild strabismus in children aged 4-7 years.[7] Luminopia is incorporated into the American Academy of Ophthalmology's treatment guidelines as of February 2024.[2] At the time of this writing, more than 9,000 prescriptions have been written by more than 1,000 prescribers since becoming commercially available in November 2022. The current coverage landscape includes a medical policy covering Luminopia for a large national health plan, as well as inclusion on many regional plan formularies. As demand continues to increase, considerations for coverage are top of mind for payers. A practice management–centered recommendation for clinical use and payer policies is of timely discussion.

Amblyopia is defined as a reduction of best-corrected visual acuity (BCVA) that occurs in the setting of an otherwise healthy eye. Most commonly this reduction occurs in 1 eye, but it may also be bilateral. Abnormal processing of visual images is the most common cause. Rarely, a structural abnormality of the eye or visual pathway is involved.[2] The estimated North American and global pooled prevalences of amblyopia are 2%-4% and 1.44%, respectively.[1] Risk factors for amblyopia include premature birth, being small for gestational age, having developmental delay, or having a first-degree relative with amblyopia.[2,8–11] Amblyopia can be classified into subtypes such as refractive or strabismic, along with deprivation amblyopia.[2] Regardless of type, amblyopia presents during the critical window of visual development and neuroplasticity within early childhood.[12] Early and complete intervention is essential to minimize permanent neurological visual impairment or loss, prevent critical achievement gaps, and limit reductions in childhood and adult outcome measures.[13]

Clinical and socioeconomic outcomes remain poor for children and adults with amblyopia (Table 1). Children with amblyopia are at risk of decreased health-related quality of life and ability to engage in daily activities such as basic care, exercise, and education.[14] After years of traditional treatment, many children with amblyopia experience lifelong deficits in vision that refractive correction cannot resolve. In fact, less than 50% of treated children younger than age 7 years recover normal visual acuity.[13,28] The inability to see well with both eyes and impaired depth perception has profound lifelong implications. Lifetime risk of bilateral visual impairment is doubled in patients with unilateral amblyopia, often caused by trauma to the fellow eye.[2,3,23] Overall, diagnosis of amblyopia is associated with increased risk for other diseases such as Attention-Deficit/Hyperactivity Disorder (ADHD) and depression, in addition to impaired long-term health and educational achievement.[13,19–22,24,25]

Analyses of 18,841 children (aged 3–7 years) within the US-based Intelligent Research in Sight (IRIS) registry identified significant health disparities among children treated with traditional therapy.[26,27] These studies found reduced treatment success, as defined by the American Academy of Ophthalmology, for Black and Hispanic/Latino children compared with White children and for children with Medicaid compared with those who were commercially insured. Poor and inequitable outcomes across the lifetime of patients with amblyopia demonstrate the shortcomings of traditional treatments and highlight the need for innovation. In this expert review, we examine the impact of amblyopia without efficacious and tolerable treatments as well as the existing evidence supporting the use of an innovative prescription digital treatment for amblyopia, Luminopia, and we propose appropriate clinical use and policies for guideline-supported payer coverage to increase access to evidence-based amblyopia treatments.

Methods

A roundtable discussion panel was convened on June 21, 2024, in Chicago, Illinois, consisting of 2 board-certified pediatric ophthalmologists, 2 national payer pharmacy executives, 1 regional payer pharmacy executive, and 1 regional payer medical director. Pediatric ophthalmologists were selected based on their clinical expertise and combined experience treating more than 1,000 patients with amblyopia annually using all available treatments. Payers were selected based on their extensive experience with formulary development and review of novel therapies. The panel evaluated data and shared viewpoints, summarized below, on the following topics: (1) treatment outcomes of amblyopia and medical and societal impact of unresolved disease; (2) the current treatment landscape and medical necessity of Luminopia based on its differentiating mechanism of action, clinical trial results, and real-world efficacy and tolerability; (3) pediatric ophthalmologists' experience with all treatments; and (4) factors influencing payer policy management. Following presentations and group discussion, the panel engaged in small-group workshops and assessed the strengths and weaknesses of Luminopia treatment. Finally, the panel reviewed and discussed expert recommendations for appropriate clinical use and policies offering coverage of Luminopia. The following report summarizes the clinical data reviewed during the roundtable discussion and the subsequent recommendations produced.

TABLE 1 Health Outcomes, HRQoL, and Educational Impact for Patients With Amblyopia

Impact type	Impact
Impact of amblyopia on daily activities and HRQoL	Traditional therapies negatively affect HRQoL and the ability to engage in daily activities.[2,14–17] This includes negative impact on emotional well-being, social functioning, and financial implications, including affordability of glasses and patching[14]
	Patching is associated with low self-esteem, receiving unwanted attention, and pain/physical discomfort[14]
	Difficulties with daily activities include driving, reading, engaging in extracurricular activities, such as sports, and routine daily work and household tasks[18]

Long-term health risks and educational impact of amblyopia	Amblyopia diagnosis is a risk factor for other diseases
	- Increased risk of developing ADHD (adjusted OR = 1.687; 95% CI = 1.444-1.970)[19]
	- More likely to have anxiety and depression[20]
	- A cross-sectional and longitudinal analysis of patients in the UK Biobank registry found[21]
	  ○ Increased risk of myocardial infarction (adjusted HR = 1.38; 95% CI = 1.11-1.72) and death (adjusted HR = 1.36; 95% CI = 1.15-1.60)
	  ○ Higher risk of stroke (adjusted OR = 1.16; 95% CI = 0.83-1.61) and vascular disease (adjusted OR = 1.37; 95% CI = 1.02-1.82)
	  ○ More likely to have obesity (adjusted OR = 1.16; 95% CI = 1.05-1.28), hypertension (adjusted OR = 1.25; 95% CI = 1.13-1.38), and diabetes (adjusted OR = 1.29; 95% CI = 1.04-1.59)

	Long-term health implications of amblyopia - 27% higher risk of musculoskeletal injury in patients aged ≥65 y[22] - Doubled lifetime risk for bilateral visual impairment owing to accidental injury[2,3,23] - Adult patients with persisting amblyopia in the UK Biobank Registry were more likely to have worse general and mental health–related outcomes compared with those with normal vision[24] ○ The odds of persisting amblyopia are greater in older patients (OR [aged 60-70 y vs 40-49 y] = 5.91)[24]
	Long-term impact on educational achievement - Children with amblyopia have significantly lower reading rates (mean±SD = 148 ± 52 WPM) than those with strabismus without amblyopia (mean±SD = 198 ± 71 WPM) and normal vision (mean±SD = 204 ± 62 WPM)[25]
	Patients with amblyopia have a lower probability of completing a higher university degree compared with those with no amblyopia (2.5% vs 7.2%)[13]

	Socioeconomic inequities in outcome using traditional amblyopia treatment
	- The OR for success with traditional treatments, measured using the IRIS-50 visual acuity quality measure was significantly lower for
	  ○ Black and Hispanic/Latino children aged 3-7 y compared with White children (OR = 0.67; 95% CI = 0.58-0.78 and OR = 0.84; 95% CI = 0.75-0.94, respectively)[26,27]
	  ○ Multivariate analysis of these results identified Medicaid as an independent factor for lower success (OR = 0.65; 95% CI = 0.60-0.71)[26]

ADHD = Attention-Deficit/Hyperactivity Disorder; HR = hazard ratio; HRQoL = health-related quality of life; IRIS = Intelligent Research in Sight; OR = odds ratio; WPM = words per minute.

DATA AND VIEWPOINTS CONSIDERED BY ROUNDTABLE PARTICIPANTS

Traditional Amblyopia Treatments: Efficacy, Tolerability, Cost, and Treatment Window. The panel identified several barriers within the traditional treatment landscape. Traditional modalities have suboptimal efficacy and are not well tolerated. Up to 79% of patients who underwent patching therapy have persistent amblyopia.[29] Mean compliance for patching in a clinical trial setting was 44% in children aged 3-8 years,[30] leading the panel to agree that real-world adherence is likely much lower and may be overreported by caregivers. Ophthalmologist panel members attributed low adherence in young children to an inability to tolerate forced obstruction of their stronger eye during daily activities, psychological stress related to social and relational dynamics, and physical discomfort. Thus, children commonly remove patches repeatedly throughout each day. Atropine therapy is used less frequently, is associated with temporary

reduced visual acuity and light sensitivity that inhibit daily activities, and shows minimal efficacy in treatment of severe amblyopia.[2,31–37] Low tolerability to traditional therapies is also influenced by age at treatment, severity and type of amblyopia, and degree of binocularity, as these factors impact daily and long-term treatment duration.[38]

Premature patch removal increases treatment cost. Patching and atropine are often out-of-pocket expenses; neither are typically covered by a patient's health insurance. Traditional therapies are often repeated, despite limited efficacy and tolerability, as no other option existed before Luminopia for patients failing patching and atropine. Monitoring the response to traditional therapies is performed via specialty physician visits and, therefore, is typically extended over 24 to 36 months, leading to increased health care utilization.[27] This can be problematic, as timing is also critical for resolving amblyopia. Early treatment during the peak period of visual cortex neuroplasticity can lead to marked acuity gains and improvement in binocular fusion and depth perception.[12] Decreased improvement is observed as children age.[12] Repeating ineffective treatments risks losing an opportunity to improve vision with more effective and tolerable treatments.

Traditional Therapies Do Not Resolve Amblyopia for Most Children. Amblyopia treatment relies on refractive correction (glasses) paired primarily with monocular penalization of the better-seeing eye, typically using adhesive patching or atropine.[2] Monocular penalization reduces neurovisual suppression of the amblyopic eye and/or upregulates signal recognition and processing from the suppressed eye by minimizing competing visual signals. Other modalities include overplussed lenses, Bangerter filters, and refractive surgery. A summary of outcomes and adherence rates for traditional therapies can be found in Table 2. Panel members discussed efficacy, adherence, and outcome limitations of traditional therapies and the ophthalmologists' clinical experience. The panel concluded that most children with amblyopia do not achieve acceptable milestones after years of repeated cycles of traditional therapy.

Luminopia. Luminopia treatment consists of viewing real-time image modifications using software with a virtual reality headset in an at-home environment. Dual-acting binocular mechanisms of action are applied independently to each eye based on the patient's amblyopia diagnosis via 2 modifications: contrast reduction to the nonamblyopic eye and complementary dichoptic masking across both eyes' images. This encourages the brain to fuse images presented to each eye into a single complete image. Standard treatment is 1 hour per day, 6 days per week.[44] A patient portal allows health care practitioners to monitor adherence and assess patient treatment plans.[7]

Luminopia used a de novo pathway to FDA clearance using a series of clinical studies that included both treatment-naive and previously treated patients.[7,45] A phase 1/2 open-label pilot study (NCT02782117) of Luminopia among 90 participants aged 4-12 years with amblyopia showed BCVA improved 1.5 lines from baseline (95% CI = 1.2-1.8 lines; $P < 0.0001$) and 86% median adherence (treatment completed/prescribed) at 12 weeks.[46] The pivotal phase 3 randomized controlled trial (RCT; NCT03608150) enrolled 117 participants aged 4-7 years with anisometropic, strabismic, or mixed (anisometropic/strabismic) amblyopia.[47] Randomized participants received 12 weeks of Luminopia therapy with full-time refractive correction (treatment group) or continued full-time refractive correction alone (considered best practice for a control group). Eighty-four percent of the treatment group underwent prior treatment beyond glasses for up to 12 months before trial enrollment. Primary efficacy analysis was the mean change in visual acuity of the amblyopic eye from baseline to 12 weeks between groups. At planned interim analysis, amblyopic eye visual acuity significantly improved more in the treatment group than in the control group (1.8 lines [95% CI = 1.4-2.3] vs 1.0 lines [95% CI = 0.4-1.3], respectively; a 1.0 line difference between groups, $P = 0.0011$; 96.14% CI = 0.33-1.63 lines). Median adherence to treatment was 88%, with a robust beneficial effect observed in both previously treated and treatment-naive patients. No serious adverse events were reported.[47] Participants experienced nonserious adverse events in 19.6% and 13.0% of the treatment and control groups, respectively. Ocular adverse events were balanced between groups, and the most common nonserious adverse event reported was headache (14.3% in the treatment group vs 1.7% in the control group).[47]

The Patients Using Prescription Luminopia (PUPiL) Registry demonstrates similar results in real-world clinical practice (NCT06429280). An analysis of 123 patients shows significant mean±SD improvement in visual acuity at 12 ± 6 weeks of treatment (1.1 lines; 95% CI = 0.7-1.4) with a 72% median treatment to adherence (interquartile range = 45%-92%).[48] Unlike the clinical trial setting, real-world patients were older and more heavily pretreated. Of 123 patients, 44 (36%) were older than age 7 years and 58 (47%) received more than 12 months of prior treatment. These patients represent a population at greatest risk for permanent impairment that is least likely to respond to repeated traditional therapies. In a subgroup similar to participants evaluated in the pivotal trial, 27 (22%) of 123 registry patients showed similar efficacy to pivotal trial results.[48]

Luminopia's demonstrated efficacy compared with continued full-time refractive correction supports its use as an amblyopia treatment. Clinical trials show significant and

TABLE 2 Summary of Clinical Outcomes for Traditional Amblyopia Treatment Modalities

Amblyopia treatment modality	Clinical outcomes
Visual acuity outcomes in amblyopia patients using refractive correction	There is often an immediate improvement in visual acuity from improved image clarity, and glasses are generally well tolerated by children[2]
	Continued wear of refractive correction for 18 weeks has been shown to improve visual acuity in the amblyopic eye by ≥2 lines in children aged 3-7 y with untreated anisometropic amblyopia[2,39]
	A study in children aged 7-17 y found that approximately 25% of patients improved by ≥2 lines with optical correction alone[2,40]
	Despite positive findings with refractive correction, 1 study found that glasses alone resolved amblyopia in only 27% of patients[39]
Visual acuity outcomes and adherence in amblyopia patients using patching and atropine	
Patching and atropine	- A meta-analysis of 23 randomized clinical trials with 3,279 patients showed that monocular treatments provide 0.4-0.7 lines of vision gain beyond use of glasses alone with extended treatment duration[41] - May result in reduced visual acuity of the sound eye or reverse amblyopia that resolves following treatment cessation. These results are reported more often for atropine therapy compared with patching[2,32]
Patching	- Patching length has been optimized: o For severe amblyopia (20/100-20/400) in children aged >7 y, 6 h of daily patching improves visual acuity equivalent to patching for all but 1 waking hour[2,42] o For moderate amblyopia in children, 2 h of daily patching improves visual acuity equivalent to 6 h[2,39] o Improvement is stable through at least age 15 y[2,43] - Even with optimal patching treatment, 79% of patients experience residual amblyopia[29] - When compliance for patching was measured objectively using an occlusion dose monitor; mean adherence was as low as 44% in children aged 3-8 y in a clinical trial setting[30] - Low adherence may be caused by a variety of psychosocial and nonpsychosocial factors[38] o Psychosocial factors include relational dynamic perceptions, personal feelings of stigma, and responses of peers toward amblyopia treatment o Nonpsychosocial factors include discomfort, difficulty with tasks, and factors affecting daily and long-term duration of treatment (age at treatment, severity of amblyopia, type of amblyopia, and degree of binocularity)
Atropine	Atropine is used less frequently. This may be because of side effects such as transient reduction in visual acuity and photosensitivity, which may interfere with daily activities such as movement and educational activities. Systemic adverse effects include dryness of the mouth and skin, fever, delirium, and tachycardia[2,31]

clinically meaningful efficacy in patients previously treated for amblyopia, indicating Luminopia is also appropriate for patients who have not achieved resolution through traditional treatments. Luminopia presents an efficacious option as a first-line therapy and in patients who have failed patching. High adherence is demonstrated in both clinical trial and real-world settings.

2024 Updated American Academy of Ophthalmology's Amblyopia Treatment Guidelines. Referred to as the Amblyopia Preferred Practice Pattern (PPP) guidelines, the PPP guidelines outline suitable treatment options and management principles. According to the 2024 update,[2] suitable options include optical correction, patching, pharmacological treatment, optical treatment, Bangerter (translucent) filters, and digital therapeutics. Therapy choice is based on 3 principles: (1) correct any cause of visual deprivation; (2) correct refractive errors that likely cause blur; and (3) promote the use of the amblyopic eye by occluding, fogging, or reducing contrast input to the fellow eye. The guidelines do not specify preference for the method of occlusion, fogging, or reduced-image contrast and point out that amblyopia treatment is a long-term

challenge that necessitates commitment from the child, parent or caregiver, and ophthalmologist to achieve optimal treatment outcomes. Guideline recommendations include adherence and a child's social and psychological status among treatment selection considerations. PPP guidelines rated Luminopia's pivotal trial as "I+, good, discretionary."[2] This rating indicates well-conducted meta-analyses and systematic reviews of RCTs, or RCTs with a low risk of bias, and that further research is unlikely to change the American Academy of Ophthalmology's confidence in the estimate of effect. PPP guidelines also state that insurance plans should cover management of amblyopia, including treatment.

Clinical practice patterns of panel members align with PPP guideline principles and prioritize early, efficacious treatment with high adherence to reduce future visual disability and improve quality of life. Payer panel members viewed the inclusion of binocular digital therapy within treatment guidance as justification for inclusion of Luminopia within payer policies.

Results and Recommendations

After the roundtable reviewed and discussed amblyopia treatments, outcomes, and guidelines, the panel achieved unanimous expert recommendation on the following questions surrounding the appropriate use and coverage of Luminopia.

EXPERT PANEL RECOMMENDATIONS FOR LUMINOPIA CLINICAL USE AND PAYER COVERAGE

Expert Recommendation: Should Payer Policies Cover Luminopia? It is recommended that payer policies cover Luminopia based on the PPP guidelines' recognition of Luminopia as a suitable treatment option and the guidelines' emphasis on the clinical importance of treatment adherence within patient and prescriber choice. Inclusion of Luminopia on payer formularies would preserve this choice. Policy managers should be aware that the duration of treatment that is medically necessary will vary by patient and disease severity, and policies should support the heterogeneity of patient needs.

Expert Recommendation: When Should Pediatric Ophthalmologists Use Luminopia? Luminopia is recommended by the panel as a first- or second-line treatment in treatment-naive and pretreated patients.

Expert Recommendation: How Does One Demonstrate Treatment Progress Using Luminopia? Treatment progress is demonstrated through measuring the change in BCVA, primarily via an eye chart while the patient is wearing appropriate corrective refraction. The recommended time interval for follow-up is 8-12 weeks per the PPP.[2] Clinical improvement of amblyopia is assessed over several evaluations, and continuation of coverage submissions should reflect the individual patient's response to treatment and progress toward disease resolution. Consistent with the PPP, payers should consider discontinuing coverage after a plateau in treatment effect (defined as 2 consecutive visits without an improvement in visual acuity).

Expert Recommendation: Should the Panel Recommend Luminopia Coverage Within a Specific Benefit? Luminopia may be covered under medical or pharmacy benefits to provide flexibility for payers and maximize patient access.

Expert Recommendation: Should Payer Policies Require Step-Edits for Luminopia? Coverage for first-line treatment is recommended. Step-edits as utilization management were also discussed and deemed acceptable. Statements acknowledging lack of improvement using other treatments (eg, patching or atropine) may be considered as an authorization requirement.

Expert Recommendation: Should Coverage Include Periods of Re-verification or Re-authorization? Broad duration of coverage is recommended based on amblyopia treatment patterns and the low cost of Luminopia (approximately $479 per month). Re-verification more often than annually is not recommended as response to any amblyopia treatment is determined from serial measurements. Consideration of policy practices that require statements indicating projected clinical benefit of continued treatment is reasonable. Letters of medical necessity may be reasonable, but caution is warned regarding potential assessment of patient benefit based on individual clinical measurements.

Expert Recommendation: Should Luminopia be Covered for Ages Not Included in the Current Indication? Use of Luminopia in age groups outside of the indicated age range is off-label, and medical letters of exception for approval may be considered based on medical need and PUPiL registry results.

Conclusions

The panel recommends that payers cover Luminopia for amblyopia treatment in alignment with the American Academy of Ophthalmology's PPP guideline recommendations. Guidelines recognize Luminopia as a suitable treatment option, supported by robust data, and prioritize the importance of patient-prescriber choice to maximize treatment adherence and prioritize vision and mental health at early developmental stages of life. Guidelines also

emphasize the need for health care coverage of suitable treatment options. Traditional treatments, such as patching, commonly leave patients with unresolved amblyopia because of inadequate efficacy and tolerability. Luminopia offers measurable improvement in patient outcomes based on a novel mechanism of action, clinical efficacy, and tolerability. Lifelong impairment of functional, health, and economic outcomes can be minimized by ensuring that children with amblyopia have every opportunity to improve their vision.

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Drs Bohnsack, Bowerman, and Epley disclose honoraria from Luminopia, Inc. Dr Bohnsack discloses honoraria from Sparks Therapeutics, Johnson and Johnson, Glaukos Corporation, Carl Zeiss Meditec, and Alcon. Dr Epley discloses honorarium from Vyluma, is Board Director for the American Board of Ophthalmology, and holds committee chair positions with the American Academy of Ophthalmology and the Washington Academy of Eye Physicians and Surgeons. Luminopia funded the roundtable and provided input into the agenda. Luminopia did not influence the roundtable's execution or consensus formation. Luminopia conceptualized the roundtable and subsequent supplement report of the roundtable discussion, had contractual influence over the decision to publish, and provided funding to publish.

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