



MANAGING MYOPIA

A Clinical Response to the Growing Epidemic

This document is intended to provide guidance for eye care practitioners in the management of myopia in clinical practice. Those who developed this guidance recognize that research is continually evolving, and thus the content provided herein has been informed by currently available scientific research and may be reviewed and updated periodically. Care has been taken to ensure the information provided is balanced and objective to enable practitioners to manage their patients holistically.

Managing Myopia: A Clinical Response to the Growing Epidemic has been created in collaboration with those listed below and is endorsed by the following organizations: American Optometric Association, Singapore Optometric Association, American Academy of Optometry, Johnson & Johnson Vision.

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WHAT IS MYOPIA?

Myopia¹ is a chronic, progressive disease characterized by excessive eye elongation, risk of associated sight-threatening complications, and a negative-powered refractive error.

GROWING GLOBAL EPIDEMIC

- Reports of increased myopia prevalence in children first emerged in the 1980s^{2,3}
- The prevalence has nearly doubled within the past 20 years in both eastern and western societies
- Prevalence among young adults is above 80% in many Asian regions,⁴ and 50% in the U.S. and parts of Europe^{5,6}
- Children in the first wave of high myopia prevalence (those born after 1970) are now on the cusp of experiencing sight-threatening complications as adults

NO SAFE LEVEL OF MYOPIA

- The elongated eye is susceptible to pathological complications with significant risks to eye health and vision
- Any degree of myopia increases the risk of sight-threatening complications, with some complications leading to blindness in adulthood^{7,8}
- Each diopter increase in myopia results in 67% increased risk of myopic macular degeneration (MMD)⁹

CONTROLLING MYOPIA PROGRESSION

- Eye care professionals now have the opportunity to slow myopia progression rather than just correct the visual symptoms
- Increased time outdoors can delay myopia's onset¹⁰ and may slow its progression¹¹
- Several myopia control therapies have shown efficacy of over 0.3 mm (around 0.75 D) over two to three years of treatment¹²⁻¹⁵

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ASSOCIATED RISKS OF MYOPIA

Myopia is associated with increased risks to eye health in adulthood. These risks include:

- Myopic macular degeneration (MMD)¹
- Staphyloma²
- Retinal detachment³
- Primary open-angle glaucoma⁴
- Cataracts⁵

Of these diseases, MMD and retinal detachment are the most devastating and have the strongest relationship to myopia and longer axial lengths (Table 1).⁶ Among people aged 75 years or older, cumulative risk of visual impairment (decimal VA 0.30 to 0.05 [approx. 20/60 to 20/400]) or blindness (decimal VA worse than 0.05 [20/400]) from all causes increases from 3.8% in eyes with an axial length less than 26 mm to 25% in eyes with an axial length of 26 mm or greater and more than 90% in eyes with an axial length of 30 mm or greater.⁷



Table 1: The increased likelihood (odds ratio) of a myopic person > 60 years developing eye disease versus an emmetrope by degree of myopia⁶

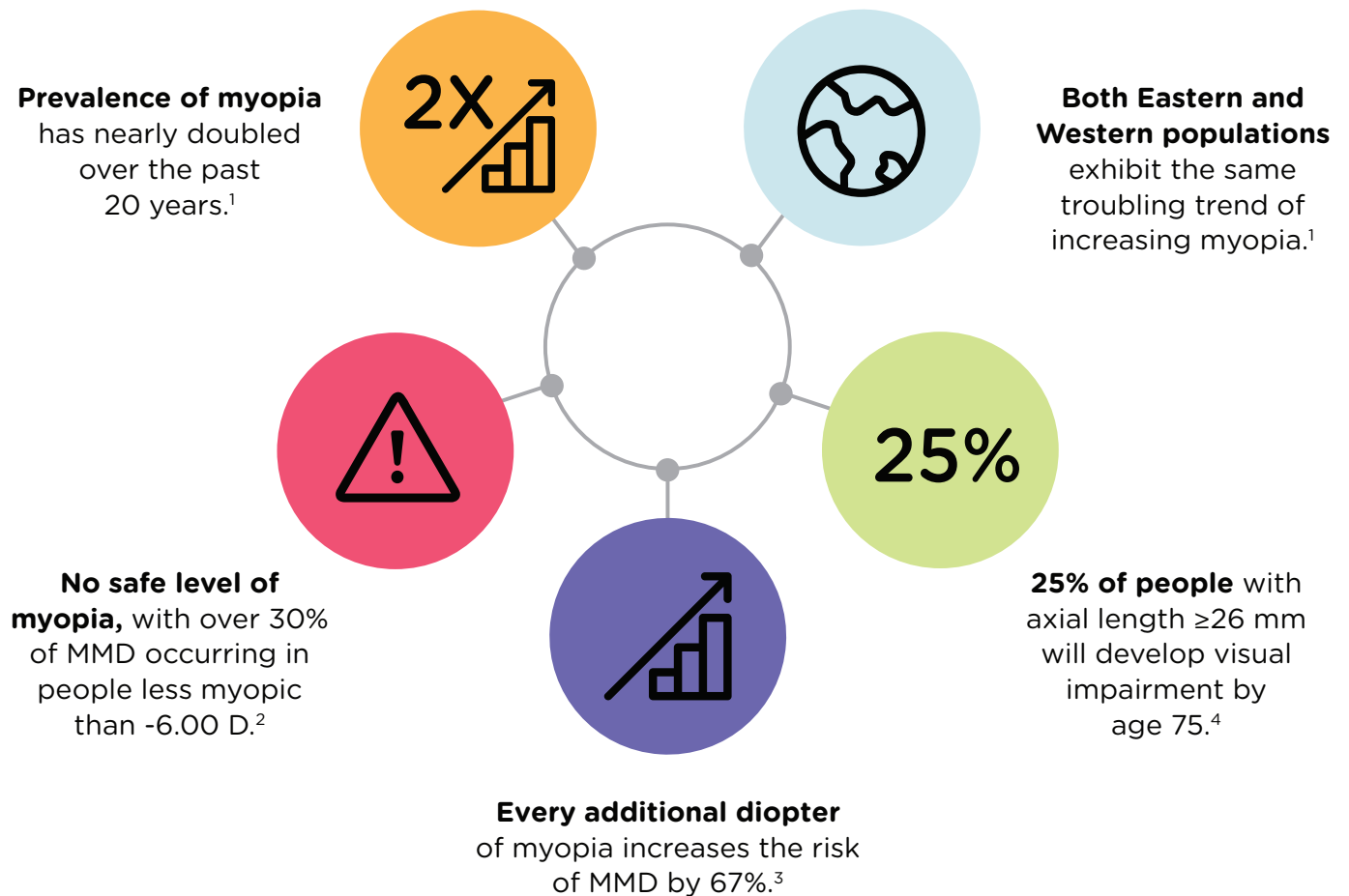
DEGREE OF MYOPIA			
	-0.50 to -3.00 D	-3.00 to -6.00 D	-6.00 D or more myopic
MMD	13.6	73	846
RETINAL DETACHMENT	3.2	8.8	12.6
VISUAL IMPAIRMENT [†]	0.9	1.7	5.5*

*Applies only to myopia of -6.00 to -10.00 D. Odds ratios are 7.8 for myopia of -10.00 to -15.00 D and 88 for myopia more than -15.00 D.
†Decimal visual acuity of 0.30 to 0.05 (approx 20/60 to 20/400).

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MYOPIA IS THE BIGGEST THREAT TO EYE HEALTH OF THE 21ST CENTURY

Eye care professionals should embrace new therapies treating children as soon as signs of myopia appear in order to reduce the risk of sight-threatening complications in later life.



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MANAGING MYOPIA IN CHILDREN: THE NEED FOR A NEW APPROACH

Myopia is a continuum of disease stages which should be assessed as early as possible. Myopia may continue to progress beyond the teenage years¹ and the associated disease risk increases exponentially with severity of myopia,^{2,3} making early diagnosis and treatment crucial to lifetime eye health.

Early myopia onset increases risk of high myopia

Myopia progresses more quickly in younger children.⁴ Because early onset implies more years of progression, myopes younger than 12 are at greater risk of developing high myopia. This is why it's essential to:

- Examine children at least once between the ages of 3-5 years to establish baseline measurements
- Examine all children at least annually until they reach 18 years old

Refractive error predicts myopia onset

Numerous risk factors can help predict myopia onset, but the best predictor is cycloplegic spherical equivalent refractive error at a given age. A child with low hypermetropic refraction for a given

age (Table 3) has greater than an 80% likelihood of myopia onset by age 13.⁵ This approach provides a simple clinical method to evaluate risk of myopia onset that is just as accurate as more complex algorithms.

Table 2: Classification of myopia by spherical equivalent refractive error⁵

	Emmetropia (Pre-Myopia if $\leq$ age 12) ⁶	Myopia ^{6,7}	High Myopia ⁷
REFRACTIVE ERROR	+0.75 to -0.49 D	-0.50 to -4.99 D	-5.00 D and more myopic

Table 3: Cycloplegic spherical equivalent autorefraction threshold by age, for children at high risk of becoming myopic by 8th grade⁸

AGE	6	7-8	9-10	11
REFRACTIVE ERROR	< +0.75 D	$\leq$ +0.50 D	$\leq$ +0.25 D	$\leq$ +0.00 D

REFERENCES 1. Pärssinen, Olavi, and Markku Kauppinen. "Risk factors for high myopia: a 22-year follow-up study from childhood to adulthood." *Acta Ophthalmologica* 97.5 (2019): 510-518. 2. Bullimore MA, Brennan NA. Myopia Control: Why Each Diopter Matters. *Optom Vis Sci* 2019;96:463-5. 3. Haarman AE et al. The complications of Myopia: A review and Meta-Analysis. *Investigative Ophthalmology & Visual Science* 2020 Apr 9;61:49. 4. Chua SY et al. Age of Onset of Myopia Predicts Risk of High Myopia in Later Childhood in Myopic Singapore Children. *Optical Physiol Opt* 2016;36:388-94. 5. World Health Organization - Brien Holden Vision Institute. The impact of myopia. In: The Impact of Myopia and High Myopia. Report of the Joint World Health Organization--Brien Holden Vision Institute Global Scientific Meeting on Myopia. Available at: https://www.visionuk.org.uk/download/WHO_Report_Myopia_2016.pdf. 6. Flitcroft DJ et al. IMI-Defining and classifying myopia: a proposed set of standards for clinical and epidemiologic studies. *Investigative ophthalmology & visual science*. 2019;60:M20-30. 7. World Health Organization - Brien Holden Vision Institute. The impact of myopia. In: The Impact of Myopia and High Myopia. Report of the Joint World Health Organization-Brien Holden Vision Institute Global Scientific Meeting on Myopia. Available at: https://www.visionuk.org.uk/download/WHO_Report_Myopia_2016.pdf. 8. Zadnik K et al. Prediction of Juvenile Onset Myopia. *JAMA Ophthalmol* 2015;133:683-9.

DECIDING WHEN AND HOW TO TREAT MYOPIA

Importance of early treatment: every diopter matters

- Progression is highly likely once a child is identified as pre-myopic or myopic.¹ The goal of myopia control is to restrict axial length and refraction as much as possible but certainly to keep axial length below 26 mm^{2,3} and less than 5 D of myopia.⁴
- Reducing myopia by 1.00 D reduces the likelihood of a patient developing myopic macular degeneration by about 40%⁵
- Begin clinical treatment for all myopic children 12 years of age or less and offer lifestyle guidance at a minimum for pre-myopic children

Risk factors for myopia

- Younger age⁶
- Refractive error (see Table 3)⁷
- Minimal time outdoors (< 2 hrs/day)⁸
- Near work for longer duration or at a shorter working distance^{9,10}
- Myopic parents¹¹

Lifestyle guidance

One evidence-based method to delay the onset of myopia in children is spending time outdoors.¹² Growing evidence supports that more time outdoors may also slow the progression of myopia.¹³ Increased outdoor time may benefit all children.

Table 4: Likelihood of myopia progression or onset and recommended clinical action by age and refractive status

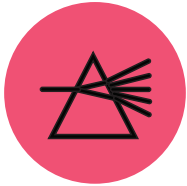
REFRACTIVE STATUS	Pre-myopia (≤ 12 yrs)	Myopia (≤ 12 yrs)	Myopia (13+ yrs)
PROBABILITY	Myopia onset highly likely	Progression highly likely	Progression possible
CLINICAL ACTION [†]	Close monitoring [‡]	Myopia control highly recommended	Present myopia control

[†]Lifestyle guidance is a suggested component of all myopia control therapy.

[‡]Treatment of pre-myopia is at the discretion of the parent/patient and clinician.

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EVALUATING PRE-MYOPIA AND MYOPIA



REFRACTIVE ERROR

- Primary method for diagnosing myopia and a routine measurement in every comprehensive eye examination¹
- Accuracy and repeatability improve with use of cycloplegia and objective measurements (autorefractometer)²
- Strongly correlated with axial length,³ but substantially less repeatable than optical biometry even with cycloplegia^{4,5}
- Misleading interpretation can occur with orthokeratology and/or atropine



AXIAL LENGTH (Optical Biometry)

- Primary metric for monitoring eye elongation
- Highly repeatable measurement
- Relates directly to the pathological processes in myopia
- Doesn't require cycloplegia
- Less susceptible to changes in the anterior optics of the eye which may occur over the course of treatment such as orthokeratology or atropine therapy



KEY POINTS FOR MONITORING

- Young myopes will progress, so set this as the expectation⁶
- Average treatment efficacy can be referenced from randomized clinical trials
- Monitor myopia control therapy use, acceptance, and maintenance every six months
- Evaluate progression using at least one (1) year of data to avoid seasonal changes and reduce measurement noise (even with optical biometry)
- Treatment efficacy cannot be determined for an individual patient because there is no way to know how that individual would have progressed if left untreated
- Refer to population-based normative data to assess progression (see Table 5)



REFERENCES 1. American Optometric Association, Comprehensive Pediatric Eye and Vision Examination. <https://www.aoa.org/AOA/Documents/Practice%20Management/Clinical%20Guidelines/EBO%20Guidelines/Comprehensive%20Pediatric%20Eye%20and%20Vision%20Exam.pdf>, accessed September 3, 2020. 2. Morgan, Ian G., et al. Cycloplegic refraction is the gold standard for epidemiological studies. *Acta Ophthalmologica* 93.6 (2015): 581-585. 3. Hou, Wei, et al. Axial elongation in myopic children and its association with myopia progression in the Correction of Myopia Evaluation Trial (COMET). *Eye & contact lens* 44.4 (2018): 248. 4. Buckhurst, Phillip Jonathan, et al. "A new optical low coherence reflectometry device for ocular biometry in cataract patients." *British Journal of Ophthalmology* 93.7 (2009): 949-953. 5. Bullimore, Mark A. et al. "The repeatability of automated and clinician refraction." *Optometry and Vision Science: Official Publication of the American Academy of Optometry* 75.8 (1998): 617-622. 6. Donovan L. et al. Myopia progression rates in urban children wearing single-vision spectacles. *Optom Vis Sci* 2012;89:27-32.



MONITORING AND EFFICACY

Expected progression without myopia control

Eye growth should be expected in all young patients, with even stable emmetropic eyes growing around 0.1 mm per year from age 6 to 14.¹ Younger myopes will progress faster on average, with average rate of progression in 7-year-old children nearly double that of 11-year-old children.² Individual progression near the mean values by age in Table 5 should not be considered normal or healthy, since any myopia progression will exponentially increase associated disease risk. Individual progression rates vary considerably across the population.³

Caution with myopia control calculators

Myopia control calculators offer reasonable estimates of normal progression without myopia control therapy. The calculated myopia control effect, however, extrapolates a few years treatment effect for up to 11 years, omitting that treatment effect decreases over time and misleading users with overly optimistic treatment expectations.⁴

Communicating myopia control efficacy

While “percentage treatment” effect is easy to understand, it leads to inconsistent representation across the progression range and fails to capture that myopia control efficacy slows over time. Myopia control treatment effect tends to be more of an absolute effect than a proportional effect.⁴ The best descriptor of myopia control efficacy is the cumulative absolute reduction in elongation or refractive error (e.g., total mm or D).

Table 5: Mean progression for myopic Asians and non-Asians by axial length and refractive error across age^{2,5}

	AGE	7	8	9	10	11	12
AXIAL LENGTH (mm)	Asian	0.52	0.46	0.41	0.36	0.32	0.28
	Non-Asian	0.35	0.31	0.28	0.25	0.22	0.20
REFRACTIVE ERROR (D)	Asian	-1.12	-0.94	-0.78	-0.66	-0.56	-0.50
	Non-Asian	-0.98	-0.82	-0.69	-0.56	-0.45	-0.35

REFERENCES 1. Mutti DO, Hayes JR, Mitchell GL et al. Refractive Error, Axial Length, and Relative Peripheral Refractive Error before and after the Onset of Myopia. *Invest Ophthalmol Vis Sci* 2007;48:2510-9. 2. Donovan L et al. Myopia progression rates in urban children wearing single-vision spectacles. *Optom Vis Sci* 2012;89:27-32. 3. Chua SY et al. Age of Onset of Myopia Predicts Risk of High Myopia in Later Childhood in Myopic Singapore Children. *Ophthalmol* 2016;123:388-94. 4. Brennan NA, Cheng X. Commonly Held Beliefs About Myopia That Lack a Robust Evidence Base. *Eye Contact Lens* 2019;45:215-25. 5. Brennan NA et al. Influence of Age and Race on Axial Elongation in Myopic Children. *Optom Vis Sci* 2018; 95: eAbstract 180072.

Average myopia control treatment effect

Numerous clinical studies provide cumulative myopia control effect for individual therapies in millimeters or diopters over a 2 to 3-year period, with multiple studies providing evidence of a 0.30 mm reduction in elongation (about 0.75 D).¹⁻⁴ Since the maximum effect observed to date is 0.44 mm (about 1.00 D) over a 7-year period,⁵ treatment should begin as early as possible. Combination therapy may enhance myopia control efficacy compared to a single treatment.⁶

Monitoring

Myopia control therapy use, acceptance, and maintenance should be frequently monitored following treatment initiation or modification and at least every six (6) months once treatment is established. Frequent monitoring helps reduce barriers to use, identify non-compliant or risky behaviors, and address any problems as early as possible, supporting safe and consistent use of the myopia control therapy. Axial length and cycloplegic refractive error may be measured at frequent intervals, but should be evaluated over at least one year before considering therapeutic changes or supplemental therapy because progression can vary seasonally.⁷ Knowing efficacy is similar across treatments, it is most critical that the treatment regimen fits the patient's lifestyle, expectations, motivation, and their abilities.

Stopping treatment

Once myopia control treatment has begun, myopia stabilization cannot be differentiated from an effective myopia control therapy. Because there is evidence for progression in some adults,⁸ myopia control can be continued beyond the teenage years if the treatment is well accepted. If not well accepted, an alternative myopia control therapy can be considered. Rebound after myopia control discontinuation may occur and regular monitoring should be continued after stopping therapy.

Sample myopia monitoring schedule Interim (6 months)

- Focused history including at a minimum:
 - Care and maintenance of therapy
 - Frequency and usage of therapy
 - Patient acceptance and satisfaction with therapy
- Visual acuity
- Binocular vision and accommodation (can be impacted by myopia control therapy)
- Measure axial length (if possible) and refractive error
- Assess therapy-related ocular health
- Additional testing as indicated by myopia control therapy

Annual (12 months)

- Comprehensive eye exam (w/cycloplegic refractive error if possible)
- Review myopia control therapy (as described above)
- Measure axial length (if possible)
- Review progression and compare to personalized goals



REFERENCES 1. Chamberlain, Paul, et al. "A 3-year randomized clinical trial of MiSight lenses for myopia control." *Optometry and Vision Science* 96.8 (2019): 556-567. 2. Lam, Carly Siu Yin, et al. "Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial." *British Journal of Ophthalmology* 104.3 (2020): 363-368. 3. Chua, Wei-Han, et al. "Atropine for the treatment of childhood myopia." *Ophthalmology* 113.12 (2006): 2285-2291. 4. Chen, Connie et al. "Myopia control using toric orthokeratology (TO-SEE study)." *Investigative Ophthalmology & Visual Science* 54.10 (2013): 6510-6517. 5. Santodomingo-Rubido et al. Long-Term Efficacy of Orthokeratology Contact Lens Wear in Controlling the Progression of Childhood Myopia. *Curr Eye Res* 2017;42:713-20. 6. Kinoshita et al. Efficacy of combined orthokeratology and 0.01% atropine solution for slowing axial elongation in children with myopia: a 2-year randomised trial. *Sci Rep* 10, 12750 (2020). 7. Gwiazda, Jane, et al. Seasonal variations in the progression of myopia in children enrolled in the correction of myopia evaluation trial. *Investigative Ophthalmology & Visual Science* 55.2 (2014): 752-758. 8. Pärssinen O, Kauppinen M. Risk factors for high myopia: a 22-year follow-up study from childhood to adulthood. *Acta Ophthalmol.* 2019;97:510-8.

PERSONALIZING MYOPIA CONTROL THERAPY

Treatments described here have been investigated in clinical studies for their safety and effectiveness. Efficacy and performance may vary significantly between products (e.g., for different brands) and it is important to note that some treatments are currently prescribed off-label. Choosing the right one will depend on the individual patient's lifestyle, age, maturity, and refractive error. This diagram can be helpful in guiding your conversation with patients and their parents.

Atropine Eye Drops

Allow complete parental control of treatment. Concentrations of 0.025 to 0.05% have demonstrated effective myopia control and limited side effects of photophobia and reduced accommodation.⁵ Atropine must be supplemented with glasses or contact lenses and could be combined with other myopia control therapies.⁶

Orthokeratology

Gas permeable lenses worn overnight to temporarily reshape the cornea, allowing clear vision during the day without correction. Preferred for athletics and water activities, also offering subjectively improved appearance and social self-perception compared to glasses.¹ Used overnight at home, allowing for parental oversight.

Clinical Considerations

Refractive error and astigmatism
Myopia control treatment history
Ocular health
Vision quality
Efficacy

Lifestyle Considerations

Sports/physical activity
Swimming or water activity
Patient responsibility/hygiene
Patient or parent preference
Desire for parental oversight

Soft Multifocal Contact Lenses*

The optics were originally designed to improve near vision in presbyopic patients, but some have been shown to slow myopia progression. Preferred for athletics, also offering subjectively improved appearance and social self-perception compared to glasses.² Younger children can wear these lenses³ and do not appear to be at increased risk of infection compared to older wearers.⁴

Myopia Control Spectacles

Optics specifically designed to slow myopia progression. Safe and easy option for a range of prescriptions; subject to non-compliant wear and loss/breakage. Optical designs and myopia control efficacy vary greatly.

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* Johnson & Johnson Vision does not currently have soft multifocal contact lens products approved for myopia control.

APPENDIX

MANAGING MYOPIA IN CHILDREN INTO EARLY ADULthood: QUICK GUIDELINES



COMPREHENSIVE EYE EXAMINATION¹

Care Process Includes:

- Visual acuity (OD/OS/OU Distance and Near)
- Objective and subjective refraction (with cycloplegia if possible)
- Binocular vision, ocular motility, and accommodation
- Color vision
- Pupil response
- Intraocular pressure
- Ocular anterior segment and adnexa
- Ocular posterior segment (internal eye)
- Supplemental testing as indicated based on clinical expertise

Identify children who have myopia or are at risk of myopia onset and discuss:

- Eye diseases associated with myopia
- Benefits of time outdoors
- Concept of myopia control therapy versus traditional vision correction
- The need for myopia control consultation and/or treatment initiation



MYOPIA CONTROL CONSULTATION, TREATMENT AND MONITORING

Consultation

- Perform baseline measurements as appropriate (e.g. refractive error, corneal topography, and axial length)
- Present personalized options for myopia control (if applicable) based on motivation, lifestyle, and ocular characteristics
- Discuss available treatment, expectations, potential adverse effects, and review consent for treatment
- Collaborate with parent to set goals, address potential barriers, and create an action plan

Treatment

- Train both child and parent to apply, remove, disinfect and care for the treatment (as applicable)
- Prescribe wearing schedule
- Provide emergency contact number, if applicable

Monitoring

- Monitor myopia control therapy use, acceptance, and maintenance frequently following treatment initiation and at least every six (6) months
- Evaluate progression using at least one (1) year of data to avoid seasonal changes and reduce measurement noise
- Treatment efficacy cannot be calculated for an individual patient because there is no way to know how an individual's myopia would have progressed untreated



While the regulatory requirements regarding myopia management vary across countries, practitioners should use this guidance in accordance with their local regulations. Johnson & Johnson Vision does not engage in the practice of medicine and this document is not intended as a substitute for appropriate medical education and training or for the exercise of independent medical judgment. Practitioners should use their own medical judgment when determining how to treat their patients.

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