



Sorca Clarke, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

20th April 2022

PQ: 18179/22

To ask the Minister for Health the criteria for which atropine 0.01% eye drops prescribed for myopia to limit the risk of damage to eyes and potentially detached retinas is not on licence and therefore not covered by the drug payment scheme (details supplied).-Sorca Clarke

Given that in one instance three siblings under 11 with myopia have been prescribed this treatment and the financial impact is placing the family in the position of potentially choosing between their children's eye sight and other bills.

Dear Deputy Clarke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 18179/22), which you submitted to the Minister for Health for response.

Atropine 0.01% eye drops are not licensed with the Health Products Regulatory Authority in Ireland. Only licensed medicines are added to the formal Reimbursement List in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

The HSE Medicines Management Programme (MMP) reviewed atropine 0.01% eye drops, to halt myopia progression, through exceptional arrangements under the Community Drug Schemes on behalf of PCRS last year. While there are many studies which highlight the benefits of atropine in slowing the progression of myopia, the optimum concentration of atropine has not been convincingly established. Effects of long-term use are still unknown and the potential for myopic rebound on discontinuation is not certain, although the effect is thought to be less likely with lower strengths. Furthermore, the majority of studies have been conducted in Asian populations and the benefits of atropine in a Caucasian population have not yet been demonstrated.

There are two clinical trials currently underway which are investigating atropine in Caucasian populations (MOSAIC and CHAMP). Atropine eye drops are available to Irish patients who have been enrolled in these clinical trials. Atropine eye drops for the reduction of myopia progression in children and adolescents between the ages of three and 18 years are currently the subject of a paediatric investigation plan (PIP) by the European Medicines Agency which is due for completion in January 2024.

The MMP were unable to recommend the reimbursement of the Exempt Medicinal Product, atropine 0.01% eye drops, at this time due to the lack of robust clinical evidence demonstrating the optimal strength, duration of treatment and efficacy in non-Asian populations.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Suzanne Doyle', written in black ink.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service