



Louise O'Reilly, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

25th March, 2021

PQ: 12848/21

To ask the Minister for Health the existing treatments that are being provided for amyloidosis patients; the way in which these compare against patisiran; and the efficacy of these existing treatments in stopping the progression of amyloidosis. - Louise O'Reilly

Dear Deputy O'Reilly,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 12848/21), which you submitted to the Minister for Health for response.

There are currently no licensed treatments for amyloidosis approved for reimbursement in Ireland. Several pricing and reimbursement applications for drugs specifically licensed for the treatment of amyloidosis are currently being assessed by the HSE in line with the statutory legislation (Health [Pricing and Supply of Medical Goods] Act 2013), including an ongoing application for Patisiran.

The main evidence of efficacy for Patisiran submitted to the European Medicines Agency (EMA) to support the licensing of this medicine was from a randomised, double-blind, placebo-controlled study conducted in 225 patients with hATTR amyloidosis (APOLLO; Study ALN-TTR02- 004). The comparator arm of this study did not include any active treatment.

There are Health Technology Assessment (HTA) reports for Tafamidis and Patisiran, in which the National Centre for Pharmacoeconomics (NCPE) detail the comparative effectiveness data that is available for both of these medicines that are indicated for the treatment of amyloidosis. Summaries of these reports are available online:

<http://www.ncpe.ie/wp-content/uploads/2019/01/Technical-summary-document-patisiran-21.02.2020.pdf>

http://www.ncpe.ie/wp-content/uploads/2020/04/Tafamidis-Tech-Summary_NCPE-09_20.pdf

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie