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2nd April 2025

Deputy Pádraig Rice, TD
Dáil Éireann
Leinster House
Kildare Street
Dublin 2

RE: PQ 13245/25

To ask the Minister for Health if her Department will provide additional resources and equipment for the neurology assessment and nerve conduction study testing for amyloidosis; if she is aware of the current issues regarding the wait list for a drug (details supplied); and if she will make a statement on the matter

Dear Deputy Rice,

The Health Service Executive has been requested to reply directly to you in relation to the above parliamentary question, which you submitted to the Minister for Health for response. I have consulted with the National Clinical Programme for Neurology and Medicines Management Programme (MMP) on your question and have been informed that the following outlines the position.

Hereditary TTR amyloidosis (ATTRv) is a rare inherited disease that occurs when a protein called TTR amyloid builds up in organs, which typically predominantly affects the nerves and heart. ATTRv can lead to severe end-organ sequelae (heart failure, neuropathy leading to immobility) and death, usually within 10 years of symptom onset. The symptoms may mimic other diseases and affected patients may attend many different doctors before the diagnosis of amyloidosis is made, experiencing significant delays.

Vutrisiran is authorised by the European Medicines Agency (EMA) for the treatment of ATTRv in adult patients with stage 1 or 2 polyneuropathy. Nerve conduction tests are required to establish that the treatment is appropriate for the patient in accordance with the licensed treatment indication.

Vutrisiran is available in the HSE under hospital pricing approval, subject to a managed access protocol (MAP), for adult patients with ATTRv with stage 1 or 2 polyneuropathy. The MAP, which details the criteria that must be satisfied for funding of a medicine used in ATTRv in adult patients with stage 1 or stage 2 polyneuropathy (e.g. Vutrisiran [Amvuttra®]), is available on the website of the HSE-Medicines Management Programme:
https://www.hse.ie/eng/about/who/cspd/medicines-management/managed-access-protocols/vutrisiran-amvuttra-/vutrisiran-amvuttra-.html

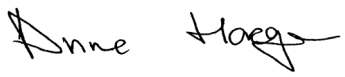
Under the MAP for medicines used in ATTRv in adult patients with stage 1 or stage 2 polyneuropathy, funding of Vutrisiran is supported in line with the licensed indication, as authorised by the European Medicines Agency. Nerve conduction tests are required to establish that the treatment is appropriate for the patient as per the product license and to establish eligibility for funding under the MAP.

When individual patient applications for funding are submitted, they are reviewed by the clinical team in the HSE-MMP, with reimbursement recommendations provided within a number of days.

Applications for reimbursement approval of Vutrisiran are considered from consultants with experience in the diagnosis and management of ATTRv in specialist centre(s) in Ireland, who are registered with the Irish Medical Council, have agreed to the terms of the MAP and who have been approved by the HSE. There are currently three consultants approved to submit applications for funding approval for Vutrisiran.

I trust this information is of assistance to you.

Yours sincerely



Anne Horgan
General Manager