Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Alan Kelly, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

22nd December 2021

PQ: 60463/21

To ask the Minister for Health when the new protocol for the distribution and prescribing of fremanezumab ajovy will be in place; the reason patients who are already registered on hospital medical databases are required to complete a manual re-registration process; the reason they the being denied the opportunity to privately avail of the drug as a direct result of actions by the HSE. -Alan Kelly

Dear Deputy Kelly,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 60463/21), which you submitted to the Minister for Health for response.

Fremanezumab (Ajovy®) was added to the High Tech Arrangement on 1st October 2021 following completion of the formal process for pricing and reimbursement of medicines under the Community Drug Schemes:

- Fremanezumab (Ajovy®) was assessed for value for money by the National Centre for Pharmacoeconomics (NCPE); they recommended that it should be considered for reimbursement for the prophylaxis of migraine in adult patients with chronic migraine who have failed three or more migraine-preventative treatments.
- The HSE-Drugs Group recommended reimbursement of fremanezumab in March 2021 for the prophylaxis of chronic migraine in adult patients who have failed three or more prophylactic treatments subject to an individual patient approval system being put in place to enable reimbursement for patients meeting predefined conditions via a managed access protocol in conjunction with the HSE-Medicines Management Programme.
- This recommendation was accepted by the HSE-Executive Management Team.

The Managed Access Protocol, which details the criteria that must be satisfied in order for a patient to be approved for reimbursement of fremanezumab under the High Tech Arrangement, is available on the website of the HSE-Medicines Management Programme: https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/managed-access-protocols/cgrp-mabs/hse-managed-access-protocol-cgrp-mabs.pdf

Approved prescribers are required to apply for reimbursement approval on an individual basis through the online application system. All reimbursement applications for CGRP MABs submitted are reviewed by the HSE-Medicines Management Programme. When a patient meets the criteria outlined in the Managed Access Protocol, they are approved for reimbursement of a CGRP MAB under the High Tech Arrangement.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service