



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

22nd December 2021

PQ: 60507/21

To ask the Minister for Health further to Parliamentary Question No. 1852 of 21 April 2021, if the HSE has developed the individual patient approval system to enable reimbursement for patients who meet the pre-defined criteria as per the HSE Medicines Managed Programme which in March 2021 was in the development stage (details supplied); the system that has been implemented to date; the number of patients enrolled and informed of their status; if this is not the case, the stage at which this development has been completed to date; the protocols that have been established as a result of this managed programme; if his attention has been drawn to the fact that as a direct result of the delay in developing a managed programme patients with a debilitating, chronic illness are being forced to do without a drug which was approved in March 2021; the immediate steps he plans to take to ensure this vital drug will be available to patients; and the date from which it will be available. -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 60507/21), which you submitted to the Minister for Health for response.

From 1st October 2021, reimbursement of Fremanezumab, a calcitonin gene-related peptide (CGRP) monoclonal antibody (MAB) is supported under the High Tech Arrangement via a Managed Access Protocol overseen by the HSE-Medicines Management Programme.

Under the Managed Access Protocol for CGRP MABs, reimbursement of Fremanezumab is supported for the following subgroup of the licensed population:

- Prophylaxis of chronic migraine in adults who have failed three or more prophylactic treatments.

The Managed Access Protocol for CGRP MABs, in line with the recommendation of the HSE Drugs Group which was accepted by HSE Leadership, details the criteria that must be satisfied in order for a patient to be approved for reimbursement of Fremanezumab under the High Tech Arrangement. The Managed Access Protocol 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>

An approved prescriber must submit an online application for individual reimbursement approval for each patient. All reimbursement applications for CGRP MABs submitted are reviewed by the HSE-Medicines Management Programme. Patients who meet the criteria outlined in the Managed Access Protocol are approved for reimbursement of a CGRP MAB under the High Tech Arrangement.

As of 20th December 2021, 373 applications for CGRP MABs have been received; the majority of these applications have met the criteria outlined in the HSE-Managed Access Protocol and have been approved for reimbursement.

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service