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Duncan Smith, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

24th February, 2021

PQ: 9741/21

To ask the Minister for Health the status of the plans his Department and the HSE have with regard to licensing the drug dupilumab for use by patients with severe eczema as of February 2021 given the HSE drugs group met on 12 January 2021; and if he will make a statement on the matter. -Duncan Smith.

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 9741/21), which you submitted to the Minister for Health for response.

The HSE has a standard assessment process in place for pricing and reimbursement approval of new drugs and new indications for existing drugs. This process is intended to arrive at decisions on the funding of drugs that are clinically appropriate, fair, consistent and sustainable. The reimbursement process is underpinned by the Framework Agreement on the Supply and Pricing of Medicines (2016) and the Health (Pricing and Supply of Medical Goods) Act 2013.

The decision making authority in the HSE is the HSE Executive Management Team (EMT). The HSE EMT has supported reimbursement of Dupilumab under the High Tech arrangements subject to a managed access programme being implemented and that reimbursement is restricted to a defined subgroup of the full licensed indication i.e. moderate-to-severe atopic dermatitis in refractory adults and adolescents 12 years and older for whom immunosuppressant treatment has failed, or is not tolerated or is contraindicated.

As part of the National Service Plan 2021 and budgetary process, the HSE has worked closely with the Department of Health to secure a significantly enhanced budget of €50m for new medicines in 2021. Funding of Dupilumab will be from this allocation.

As a condition of reimbursement an individual patient approval system will now be implemented by Primary Care Reimbursement Services (PCRS) to enable reimbursement for patients who meet the pre-defined criteria as per the Medicines

Management Programme (MMP) devised managed access protocol that is currently in development.

The HSE cannot comment on the timeline for the HSE approval to be formalised as the processes required to implement the managed access programme are currently ongoing.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service