



Ged Nash T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

23rd April, 2021

PQ: 19971/21

To ask the Minister for Health if he plans to extend the use of autoimmune drugs such as humira, neupogen and IVIG approved on the drugs payment scheme for the treatment of miscarriages caused by autoimmune issues in view of the case of a person (details supplied); and if he will make a statement on the matter. -Ged Nash

Dear Deputy Nash,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 19971/21), which you submitted to the Minister for Health for response.

Humira (adalimumab) and Neupogen (Filgrastim) are approved for reimbursement and available through the High Tech Arrangements for their licensed indications only. These products are not licensed for the treatment of miscarriages caused by autoimmune issues. Therefore, they are not approved under Community Drug Schemes for off-label usage. The HSE follows statutory processes around the addition of licensed medicines to the reimbursement list/schemes on foot of an application from a pharmaceutical company. Under those statutory processes, the HSE is legally required to consider a range of criteria which include unmet need, clinical evidence, economic evidence, budget impact and the resources available when making reimbursement decisions (i.e. add a medicine to the reimbursement list). The reimbursement decisions have to be in line with the relevant legislation, namely the Health (Pricing and Supply of Medical Goods) Act 2013.

Intravenous immunoglobulin (IVIG) therapy is not reimbursable under Community Drug Schemes. Intravenous immunoglobulin infusions are provided through the hospital setting and should be initiated and monitored under the supervision of a physician experienced in the treatment of immunodeficiency. Therefore, it is not a reimbursable product for community use under the statutory schemes.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle'.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service