



Sean Sherlock, T.D.  
Dáil Éireann,  
Leinster House,  
Kildare Street,  
Dublin 2.

23<sup>rd</sup> April, 2021

PQ: 20202/21

**To ask the Minister for Health if medications including humira, neupogen and IVIG, which are currently available for certain autoimmune conditions, will be approved on the drug payment scheme for the treatment of miscarriage arising from immune issues. -Sean Sherlock**

Dear Deputy Sherlock,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 20202/21), 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