



Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil  
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Health Service Executive, Primary Care Reimbursement Service  
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Denise Mitchell, T.D.  
Dáil Éireann,  
Leinster House,  
Kildare Street,  
Dublin 2.

10<sup>th</sup> July 2024

PQ: 28349/24:

**To ask the Minister for Health if consideration has been given to the adding of polycystic ovary syndrome to the HSE's PCRS in relation to a drug (details supplied); and if he will make a statement on the matter. -Denise Mitchell**

Dear Deputy Mitchell,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 28349/24), which you submitted to the Minister for Health for response.

Medicines are added to the formal Reimbursement List following detailed assessments which include assessment of the clinical evidence, the economic evidence and the budget impact of a decision to reimburse specific indications of a medicine. The Primary Care Reimbursement Service is required to reimburse in line with approved decisions of the HSE and the HSE is required to formally assess each medicines and each specific use of such medicines before reimbursing them.

Ozempic® (semaglutide) is licensed with the Health Products Regulatory Authority (HPRA) in Ireland and indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. Ozempic® was approved by the HSE for addition to the Reimbursement List for the treatment of Diabetes in 2018. Diabetes is one of the Long Term Illness (LTI) conditions for which eligible LTI persons can access their medicines to treat their Diabetes free of charge.

Controls are in place within the Primary Care Reimbursement Service scheme management systems (and are put in place and updated as required) on claiming processes to ensure that only HSE approved indications are reimbursed across a range of medicines. Controls are currently in place for Ozempic® to restrict reimbursement support to the HSE approved indication of Diabetes against a valid prescription.

Semaglutide (Ozempic®) currently does not have an EU marketing authorisation for the treatment of polycystic ovary syndrome (PCOS). Therefore, reimbursement support cannot be made available for an indication which is not licensed and has not gone through a pharmacoeconomic assessment.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle', written in a cursive style.

Suzanne Doyle  
Primary Care Reimbursement Service

**The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: [Oireachtas.pcrs@hse.ie](mailto:Oireachtas.pcrs@hse.ie)**