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Pádraig Rice, T.D.
Dáil Éireann,
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23rd June 2025

PQ: 29980/25

To ask the Minister for Health the status of the commissioned managed access protocol necessary for the reimbursement of a severe asthma biologic medicine for patients with EOS level greater than 300 (Tezepelumab); the delivery timeline; and if she will make a statement on the matter. -Pádraig Rice

Dear Deputy Rice,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 29980/25), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(1) The health needs of the public,
(2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,

(3) The availability and suitability of items for supply or reimbursement,
(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and
(9) The resources available to the HSE

In terms of the specific details of the application for pricing and reimbursement of tezepelumab (Tezspire®):

The HSE received an application for pricing / reimbursement on the 9th May 2023 from AstraZeneca (the applicant) for tezepelumab (Tezspire®) indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 10th May 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 16th June 2023. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was not recommended and that tezepelumab (Tezspire®) not be considered for reimbursement at the submitted price.

- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessments of tezepelumab (Tezspire®) are available at https://www.ncpe.ie/tezepelumab-tezspire-hta-id-23025/.

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. The HSE CPU has met with the applicant to discuss this application.

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team. Tezepelumab (Tezspire®) for add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment was reviewed by the Drugs Group at the December 2023 meeting. The Drugs Group recommended in favour of reimbursement of tezepelumab (Tezspire®) in the T2-high population, subject to the commercial offer presented and the establishment of a managed access protocol. The Drugs Group considered there was insufficient evidence to support

a positive recommendation for the T2-low population (non-eosinophilic inflammation). The Group unanimously agreed that additional evidence was required to inform a recommendation for the T2-low population. Additional evidence that would be considered included a full HTA (https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-december-2023.pdf).

- The decision to support reimbursement for tezepelumab (Tezspire®) in the T2-high population is subject to a managed access protocol being put in place. As a condition of reimbursement, an individual patient approval system will be put in place by the HSE, to enable reimbursement for patients who meet the pre-defined criteria as per a HSE-devised managed access protocol.

- Following a request from the CPU, the HSE-Medicines Management Programme (MMP) has progressed the development of a HSE-Managed Access Protocol for medicines for the treatment of severe asthma. This outlines the criteria that must be met in order for reimbursement to be supported at an individual patient level for medicines for the treatment of severe asthma, including tezepelumab for the T2-high population.

- The processes necessary to implement this required managed access protocol for medicines for the treatment of severe asthma under High Tech arrangements, are currently being developed by the HSE. This includes the development and deployment of an online application system, to enable clinicians to submit applications for individual reimbursement approval for medicines for the treatment of severe asthma. The HSE cannot comment on the specific timeline for the HSE approval to be formalised while processes that involve a number of stakeholders and certain service development requirements to implement the managed access protocol are ongoing.

- The HSE commissioned a full HTA for tezepelumab (Tezspire®) in the T2-low population on the 1st February 2024 as per agreed processes.

- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act.

In summary:

- The systems necessary to implement the HSE-Managed Access Protocol for medicines for the treatment of severe asthma (including tezepelumab for the T2-high population) are currently being designed by the HSE.
- A HTA has been commissioned and is ongoing for the T2-low population. The HSE cannot make any comment on possible timelines from the ongoing process.

Yours sincerely,

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