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Eamon O'Cuiv, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

20th March, 2020

PQ: 3479/20

To ask the Minister for Health the reason a drug (details supplied) is not available under the GMS; the estimated number of patients that would potentially benefit from the drug; and if he will make a statement on the matter. -Éamon Ó Cuív

Osimertirib. Trade Name: Tagrisso which is a targeted cancer drug

Dear Deputy O'Cuiv,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 3479/20), which you submitted to the Minister for Health for response.

The HSE has statutory responsibility for medicine pricing and reimbursement, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013. The Act specifies the criteria for decisions on the reimbursement of medicines, which include unmet need, clinical evidence, economic evidence, budget impact and the resources available when making reimbursement decisions. The Minister for Health has no role or powers in relation to such matters.

The decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds by the HSE. The National Centre for Pharmacoeconomics (NCPE) conducts health technology assessments (HTAs) of medicinal products for the HSE, and makes recommendations on reimbursement to assist the HSE in its decision-making process. The NCPE uses a decision framework to systematically assess whether a drug is cost-effective as a health intervention.

The HSE also has a robust assessment and commercial negotiations process for all new medicines. These processes challenge inappropriate costings from applicant companies and deliver improved value for money around new medicines.

The HSE strives to reach a decision in as timely a manner as possible. However, because of the significant monies involved, it must ensure that the best price is achieved, as these commitments can be ongoing multi-million euro investments. Successful price negotiations also allow for more products to be approved within the finite budget available. If the HSE were not to challenge pharmaceutical companies pricing fewer medicines could be provided from the resources provided.

Despite the robust processes in place around new medicines which have resulted in significant reductions in the pricing demands, the HSE does face substantial challenges around the funding of new medicines. New medicines / new uses of new medicines continue (and will continue) to represent substantial funding challenges for the HSE and the Irish State.

The HSE has received pricing and reimbursement applications for the following indications (uses) for Osimertinib (Tagrisso):

1. The treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC)

2. The first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations

Information in relation to the position of Osimertinib (Tagrisso) for the treatment of EGFR T790M mutation-positive NSCLC within the assessment, commercial discussions and decision making processes is provided below:

The HSE received a Health Technology assessment (cost utility analysis) for this application in May 2018. A summary copy of that report is available on the NCPE website (www.ncpe.ie) @

http://www.ncpe.ie/drugs/osimertinib-tagrisso/

In this Health Technology Assessment, the National Centre for Pharmacoeconomics (NCPE) recommended that Osimertinib (Tagrisso) not be considered for reimbursement unless cost-effectiveness be improved relative to existing treatments. Following on from the assessment and after a number of rounds of commercial negotiations, a review by the HSE Drugs Group and a review by the HSE Senior Leadership Team, the HSE notified the applicant company in February 2019 that it was minded to not approve Osimertinib (Tagrisso) for the treatment of EGFR T790M mutation-positive NSCLC. Notwithstanding revised commercial terms, the HSE had concerns related to the high budget impact in the context of weak evidence submitted in relation to cost effectiveness.

Following a full review of this medicine, including representations received from the applicant company (and others), the HSE Drugs Group made a

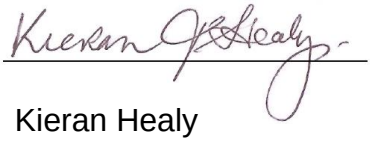
positive recommendation in May 2019 in relation to Osimertinib (Tagrisso) for the treatment of EGFR T790M mutation-positive NSCLC, notwithstanding the challenges in relation to value for money. Following the Drugs Group recommendation in relation to Osimertinib (Tagrisso) in May 2019, the application was subsequently discussed by the HSE Leadership Team. Following discussion at the HSE Leadership Team meeting in July 2019, the HSE Leadership Team was minded to approve Osimertinib (Tagrisso) for the treatment of EGFR T790M mutation-positive NSCLC in view of the clinical benefits and the Drugs Group positive recommendation. However, Osimertinib (Tagrisso) is an expensive medicine and the affordability issues are still being addressed before final decisions in relation to reimbursement can be announced.

In respect of the first-line indication, the HSE received a Health Technology assessment (cost utility analysis) for this application in August 2019. A summary copy of that report is available on the NCPE website (www.ncpe.ie) @

http://www.ncpe.ie/drugs/osimertinib-tagrisso-for-the-first-line-treatment-of-metastatic-nsclc/

Following assessment of the applicant's submission, the NCPE recommended that Osimertinib not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments. Once negotiations between the HSE and the applicant company are complete, this application must then be formally considered by the HSE Drugs Group.

Yours sincerely,



Kieran Healy
Primary Care Eligibility & Reimbursement Service