Applications for Tafamidis (Vyndaqel®) under a Managed Access Protocol in Ireland

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OBJECTIVE

Vyndaqel® (tafamidis) 61 mg capsules were reimbursed in Ireland under the High Tech Arrangement effective 1 March 2022, for the treatment of wild-type (wt) or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). Reimbursement is subject to a Health Service Executive (HSE)-Managed Access Protocol (MAP). This study provides an overview of applications for tafamidis (Vyndaqel®) reimbursement in the first year of the protocol.

METHODS

All applications submitted for reimbursement of tafamidis (Vyndaqel®) between 1 March 2022 and 28 February 2023 were analysed. Reimbursement claims data was extracted from the Primary Care Reimbursement Service (PCRS) reimbursement database. Data was complied and analysed in Microsoft Excel™.

RESULTS

In the first 12 months of reimbursement a total of 104 applications were received. Twenty (19.2%) applications were for patients with a confirmed hereditary diagnosis (hATTR-CM), and 79 (76%) had a confirmed diagnosis of wtATTR-CM. Genotype was not available for five applications (4.8%). The diagnosis of ATTR-CM was established by biopsy in 29 applications and by nuclear scintigraphy in 74. Further information in relation to diagnosis was still outstanding for one application.

Reimbursement was approved for 87.5% of applications received. Further information relating to 10 applications (9.6%) was still outstanding at the end of year one.

Three applications (2.9%) were not approved as the reimbursement criteria was not met. Two approved patients transferred to an alternative treatment (patisiran (Onpattro®)) and reimbursement for tafamidis was removed.

By March 2023, the HSE had approved 33 prescribers for tafamidis under this protocol and 80 patients were accessing treatment with tafamidis each month under the High Tech Arrangement. The majority (85%) of these patients were male, with a mean age of 76.4 years.

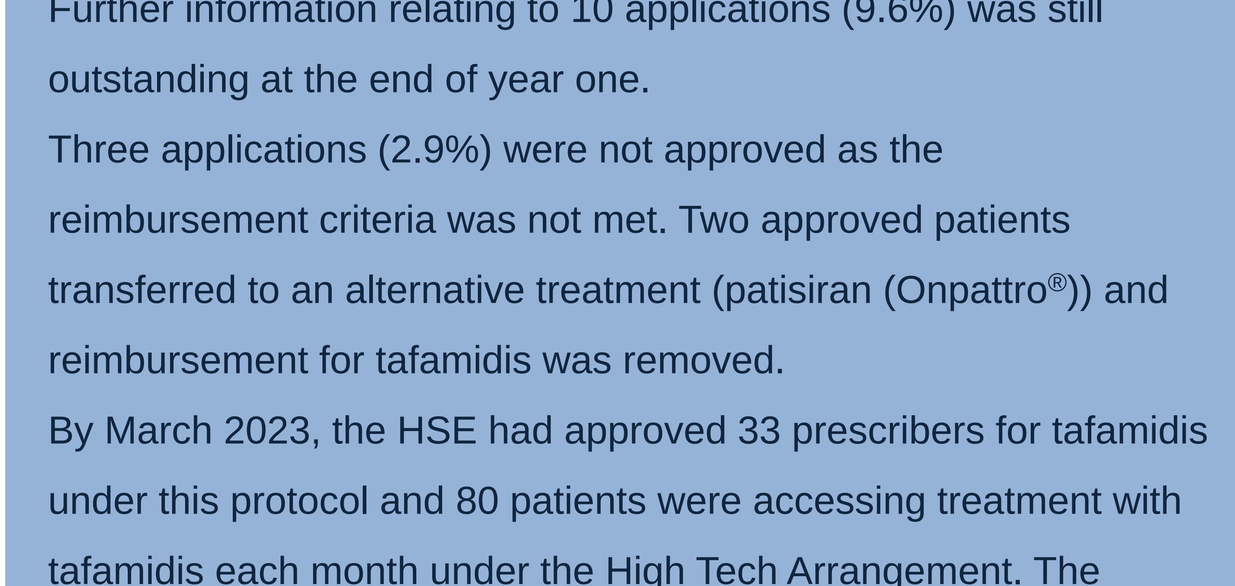

Figure 1: Number of patients in receipt of Vyndaqel® per month on the High Tech Arrangement, March 2022-February 2023

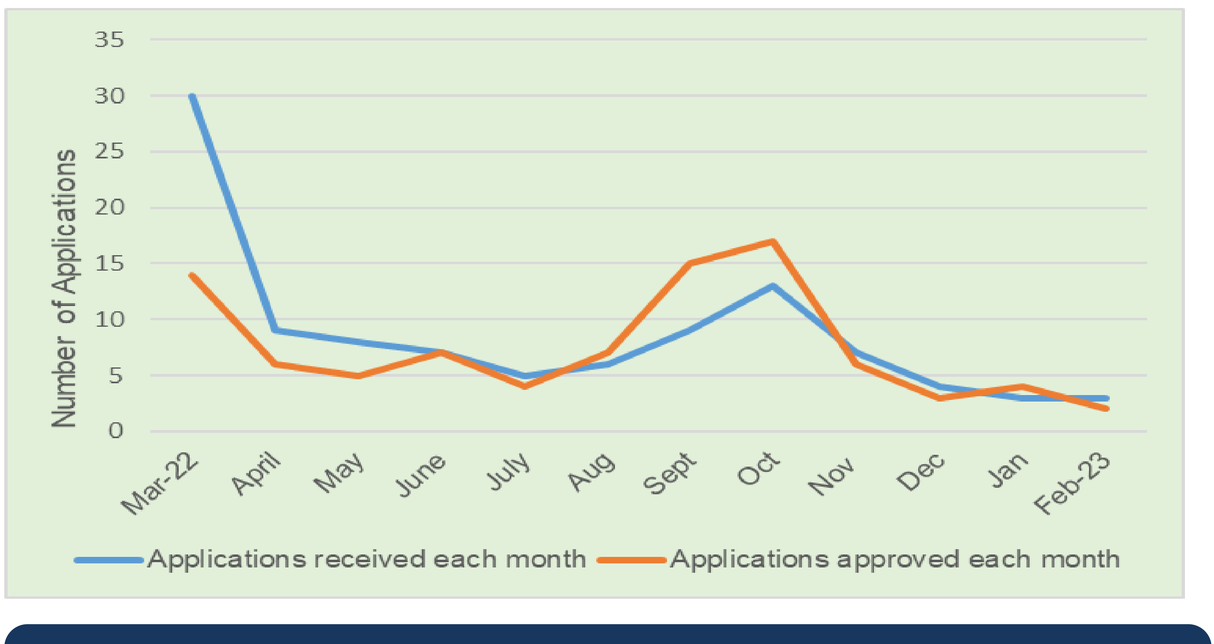

Figure 2: Number of applications received and approved for tafamidis per month, on the High Tech Arrangement, March-22 to February-23

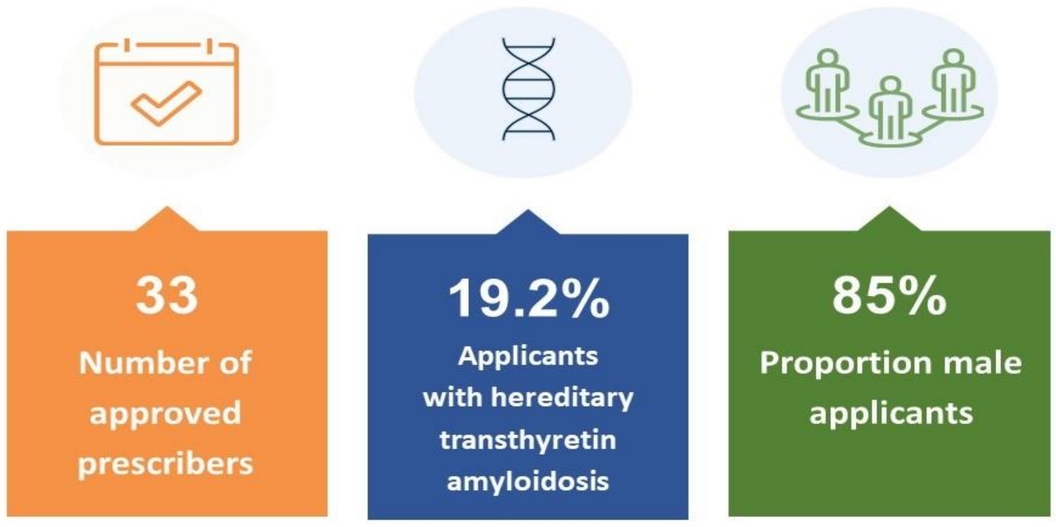

Figure 3: Data from applications following one year of reimbursement on the High Tech Arrangement

CONCLUSION

The introduction of a reimbursement application system for Vyndaqel® ensures reimbursement is confined to use for the licensed indication. The number of applications received in year one is double what was anticipated in the Health Technology Assessment (HTA) conducted by the National Centre for Pharmacoeconomics. The data collected may serve to inform future HTA and reimbursement decisions.

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