Implementation Examples of Reimbursement Prioritization Decisions in Türkiye

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I. INTRODUCTION

➢ All over the world, different interventions are made by the public decision-maker to effectively use limited resources in health economics. Restriction and prioritization decisions are aimed at equal distribution of fiscal resources and early access to medicine to target patient groups. Nevertheless, the scope of prioritized areas is expanded with reimbursement agreements with new proofs of efficacy and safety with time. Demographic pyramid, the incidence of disease, and health economics findings affect the scope of prioritization decision of new molecule.

➢In Türkiye, Licensing procedures are made by Türkiye Medicine and Medical Device Agency (TİTCK) and reimbursement decisions are made by Social Security Institution (SGK). Reimbursement Commissions of SGK decide positive list of medicines together with restrictions and prioritization rules. All positive decisions are published with the Healthcare Implementation Communique of SGK. Between 2015 and 2020, the number of drugs reimbursed and the addition of new indications for already reimbursed drugs increased. To prevent the unpredictable budget burden that such increases would cause, SGK made some restrictions.

➢The aim of this study, to compare selected original product reimbursement conditions between FDA, EMA region and Türkiye and evaluate on reimbursement decisions of Türkiye for recent years.

II. METHOD

➢In this study, the approved indications of selected medicines are web-based scanned EMA, FDA, TİTCK and SGK websites.

➢Oncology and hyperlidemia treatments have been determined as the study area since oncology and immunology treatment fields are forecasted to grow by 9-12% and 6-9% CAGR by 2026 (IQVIA).

➢Both healthcare issue has increased direct and indirect health expenditures.

➢The Regulations Regarding Some Specific Diseases and Drug Use section of Healthcare Implementation Communique (in Turkish) is assessed.

➢Nivolumab and Evolocumab were chosen as study medicines. Both molecules are monoclonal antibiotherapy.

III. RESULTS

➢There are 62 headlines for The Regulations Regarding Some Specific Diseases and Drug Use section in Healthcare Implementation Communique.

➢28 of them has regulated treatment conditions for specific diagnoses for reimbursement as mentioned in the example of Nivolumab and Evolocumab.

Nivolumab	FDA	EMA	Turkiye
Aproved incations (n)	11	10	7 (4 reimbursed)

Evolocumab	FDA	EMA	Turkiye
Aproved incations (n)	3	3	2 (1 reimbursed)

		FDA	EMA	Türkiye	
	Indications			**Approved**	**Reimbursed**
Nivolumab	Melanoma	12.2014	04.2015	04.2017	04.2018
	Non-small Cell Lung Cancer	09.2015	09.2015	07.2018	02.2022
	Renal Cell Carcinoma	11.2015	02.2016	04.2017	04.2018
	Classical Hodgkin Lenfoma	05.2016	10.2016	07.2018	04.2018
	Squamous Cell Carcinoma of the Head and Neck	11.2016	03.2017	07.2018	
	Urothelial Carcinoma	02.2017	04.2017		
	Colorectal Cancer	07.2017	05.2021	03.2019	
	Hepatocellular Carcinoma	09.2017			
	Esophageal Cancer	06.2020	10.2020	02.2022	
	Malignant Pleural Mesothelioma	10.2020	04.2021		
	Gastric Cancer	04.2021	09.2021		
		FDA	**EMA**	**Türkiye**	
	Indications			**Approved**	**Reimbursed**
Evolocumab	Hypercholesterolaemia and mixed dyslipidaemia	12.2017	05.2015		
	Homozygous familial hypercholesterolaemia	08.2015	05.2015	06.2016	08.2021
	Established atherosclerotic cardiovascular disease	08.2015	03.2018	06.2016	

➢We found out for Nivolumab, this delay averaged 1.94 years from FDA and 1.71 years from EMA.

➢Evolocumab has only one approved indication in Türkiye which was approved in Türkiye 10 months and 1.1 years after FDA and EMA, respectively.

➢ An indication for Nivolumab was reimbursed in Türkiye 2.3 and 2.1 years on average after it was approved by the FDA and EMA, respectively.

➢The only indication of Evolocumab approved in Turkey was reimbursed 5.98 and 6.24 years after it was approved by the FDA and EMA respectively.

IV. CONCLUSION

➢Certain patient groups have been prioritized with the restrictions made on such medicines, which have high budgetary expectations, and these patient's access to treatment has been facilitated. Further studies may conduct to evaluate access of new treatments and focus on potential benefit for patients' access to medicines.