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Costs of Extended Drug Treatment Duration in Multiple Diseases

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ABSTRACT

Brand drugs are generally expensive. At present, there are no limitations on duration of therapy. Costs multiply with extended drug use. We plan to focus on cost of drug use over 1-3 years in multiple diseases.

Results: Annual costs of the immune check point inhibitors Pembrolizumab 1-year $168,000 cost, 2-year were $336,000 and 3-year $504,000. Atezolizumab, Durvalumab and Nivolumab also multiplied after 2–3-year use. Similarly, 2-year costs of Semaglutide used for diabetes mellitus and obesity was $2,200, increasing to $3,300 at 3-years. Evolocumab annual $6,864 cost for Alzheimer multiplied with 2-3-year use. In contrast, the proposed 9-month Ivonescimab 9-month cost for advanced/metastatic non-small cell lung carcinoma (a/m-NSCLC), was $188,000.

Conclusion: Extended drug treatment is rather expensive rendering prior disclosure of treatment costs necessary.

Abbreviations: a/m-NSCLC: Advanced/ Metastatic Non-Small-Cell Lung Cancer; ALK: Anaplastic lymphoma Kinase; ROS 1: C-Ros oncogene 1; EGFR: Epidermal Growth Factor Receptor; ICI: Immune Check Point Inhibitors; Pembro: Pembrolizumab; GLP-1: Glucagon Like Peptide; PD-1: Programmed Cell Death Protein-1; VEGF: Vascular Endothelial Growth Factor; TT: Target Therapy

INTRODUCTION

Drug value [1,2] is simply defined as its worth in monetary fund. Admittedly, prices are widely variable and largely negotiable. Only few medical journals tackle such a sensitive subject. Pembrolizumab (Pembro) was the 1st- immune checkpoint inhibitor (ICI) approved in advanced/metastatic non-small cell lung cancer (a/d-NSCLC) in 2015 [3,4]. Outcomes are dependent on a 50% program death receptor-1 (PD-1) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic alterations. Other ICIs later followed including Nivolumab, Atezolizumab, Durvalumab and Cemiplimab. Prices were set close for competitive reasons.

Identification of molecular aberrations paved the way towards target therapy (TT) [5] discovery and wide use. At present, there are at least, 9 molecular markers with the number still counting.

Osimertinib is currently the most widely TT utilized. It is used as neoadjuvant, adjuvant and in advanced/metastatic lung cancer [6]. Osimertinib plus chemotherapy was recently reported to significantly prolongs the overall survival in EGFR-mutated in a/d-NSCLC [7].

Except for Ivonescimab [8-10], all the drugs analyzed in our study are approved and utilized in the United States (US), European nations and Canada.

In **Table 1**, costs of ICIs, Glucagon like peptides (GLP-1) and Evolocumab were compared with the proposed 9-month $188,000 cost of Ivonescimab [8-10].

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Table 1. Costs of ICIs, Glucagon like peptides (GLP-1) and Evolocumab were compared with the proposed 9-month $188,000 cost of Ivonescimab [8-10].

Drug	Class	Disease	1-year Cost	2-yr Cost	3-yr Cost
Pembrolizumab * (Pembro)	Programmed death-ligand 1 (PD-L1)	Multiple	$168,000	$336,000	$504,000
Atezolizumab	"	"	$120,000	$240,000	$360,000
Durvalumab	„	‘’	$114,000	$228,000	$342,000
Nivolumab	‘’	‘’	$125,800	$251,600	$377,400
Ivonescimab [8-10	Bispecific	Lung cancer	9-month $188,000	unwarranted	
Semaglutide po 3.5-14mg Injectable, 0.5 -2 mg subcutaneous (sq) q-week	Glucagon like peptide-(GLP-1)**	Diabetes, Mellitus, Obesity, Addiction	$1,100 $1,618	$2,200 $3,236	$3,300 $4,854
Tirzepatide, 5-15 mg sq q-week	GLP-1**	Diabetes Mellitus Obesity Addiction	$1,100	$2,200	$3,300
Evolocumab 140 mg sq, q-2 weeks, lowers LDL and risks of heart attacks	Anti-Plaque	Alzheimer	$673	$1,346	$2,019

Pembro, Atezolizumab, Durvalumab and Nivolumab are PD-L1 or immune checkpoint inhibitors (ICI).*

***GLP-1 is a naturally occurring hormone that plays a role in regulating blood sugar levels in diabetes mellitus and promoting weight loss. It stimulates insulin secretion, controls blood sugar levels in diabetes mellitus, slows gastric emptying, reduces suppress appetite and promotes weight loss.*

Target Therapy Costs

Almost all TT listed drugs were approved after 2-3-year testing. Hence, their 2-3 years use was the norm rather than the exception **(Table 2)**.

Table 2. Target Therapy Costs.

Drug	1-year cost	2-yr Cost	3-yr Cost
Osimertinib 80mg daily, Inhibits Epidermal growth factor receptor (EGFR) [6,7]	$180,000	$360,000	$540,000
Alectinib 600mg bid, inhibits Anaplastic Lymphoma Kinase) (ALK)	$130,000	$260,000	$390,000
Crizotinib 250mg bid, Inhibits ALK and c-ros oncogene (ROS1)	$138,000	$276,000	$414,000
Entrectininb 600mg bid, inhibits Tropomyosin receptor Kinase (TRK), ROS1 and ALK fusion	$258,720	$517,440	$776,160
Larotrectinib 100mg bid, I-inhibits TRK	$140,688	$281,376	$422,064

DISCUSSION

Pembro discovery paved the way to 4 more ICI introduction, each with similar and/or additional therapeutic triumph over disease. Ivonescimab, of the Bispecific class, was later discovered and approved in China. Its prolongation of disease-free survival at proposed 9- months $188,000 was indeed worthy and justified [8-10].

The ICI costs are, in general, relatively high. Pembro, the 1st ICI member discovered, has over 15 approved indications in early and later-stage cancers. It has paved the way to other ICI discovery but with lesser number of indications. The Impact and duration of use of ICI and TT on cost in lung cancer has been previously discussed [5]. Costs have since changed and some drugs have become generics.

TT family members are similarly expensive. The low incidence of targetable markers essentially rationalizes their relatively high costs. Ret fusion was extensively studied. Its prevalence in NSCLC is 1-2% but relatively higher in papillary thyroid and salivary gland cancer.

The incidence of EGFR in lung cancer is associated with adenocarcinoma histology and increases with smoking. It is 15% in the US, 10-15% and Europe, and 40% in Asia. In California, Orange County US, EGFR incidence is 20% compared with 15% in Los Angeles (LA), approximately 20 miles apart. The LA area has a higher number and percentage of smokers.

Over the last 10 years since our 1st publication 2015 [5] on approaches to control drug costs e.g. imposing caps and/or 37.5% cost reduction have been suggested [6]. To lessen the impact of the drug heavy financial burden [11-13], it has become clear over the last few years that the best cost-cutting approach would entail direct face to face negotiation between government and pharma.

In summary, the wide variation in drug costs could in part reflect on the number of potential eligible patients. The total duration of therapy is costly and needs to be scrutinized, if not limited. Future drugs need to be effective, safe and if possible, with well-defined and controlled treatment duration.

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