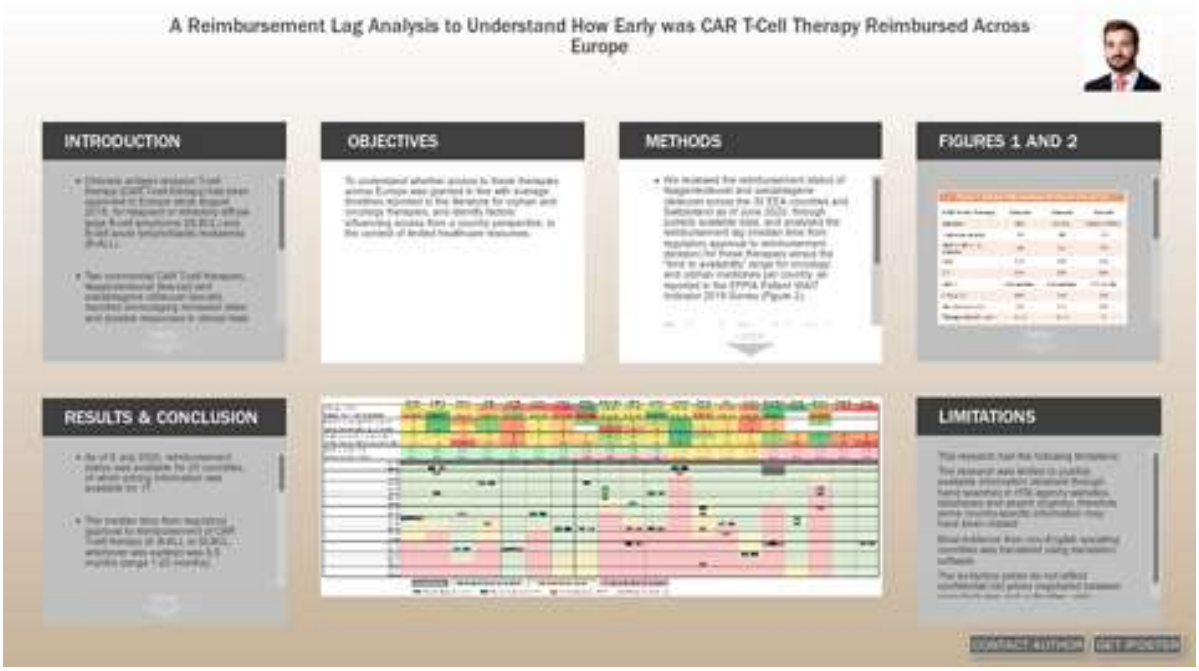
A Reimbursement Lag Analysis to Understand Whether CAR T-Cell Therapy was Reimbursed as Expected Across Europe



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PRESENTED AT:

INTRODUCTION

- Chimeric antigen receptor T-cell therapy (CAR T-cell therapy) has been approved in Europe since August 2018, for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and B-cell acute lymphoblastic leukaemia (B-ALL).

- Two commercial CAR T-cell therapies, tisagenlecleucel (tisa-cel) and axicabtagene ciloleucel (axi-cel), reported encouraging remission rates and durable responses in clinical trials and fulfil an unmet need for patients with limited alternatives (Figure 1).

- However, fragmentation of the European payer landscape may result in reimbursement lags and delayed patient access across countries, aggravated by the high costs of treatment.

OBJECTIVES

To understand whether access to these therapies across Europe was granted in line with average timelines reported in the literature for orphan and oncology therapies, and identify factors influencing access from a country perspective, in the context of limited healthcare resources.

METHODS

- We reviewed the reimbursement status of tisagenlecleucel and axicabtagene ciloleucel across the 30 EEA countries and Switzerland as of June 2020, through publicly available data, and analysed the reimbursement lag (median time from regulatory approval to reimbursement decision) for these therapies versus the “time to availability” range for oncology and orphan medicines per country, as reported in the EFPIA Patient WAIT Indicator 2019 Survey (Figure 2).

- We also analysed the ex-factory list price and GDP per capita in each country, to identify potential impact on reimbursement. The list prices and GDP per capita data were obtained from national pricing databases or HTA appraisals and Eurostat, respectively.

FIGURES 1 AND 2

Figure 1. Clinical data summary for tisa-cel and axi-cel

CAR T-cell Therapy	Tisa-cel	Tisa-cel	Axi-cel
Indication	ALL	DLBCL	DLBCL/PMBCL
Evaluable patients	79	99	101
Median follow-up (months)	4.8	9.4	7.9
ORR	83%	50%	72%
CR	63%	32%	51%
mDOR	Not reached	Not reached	9.2 months
CRS ≥ G3	48%	23%	13%
Neurotoxicity ≥ G3	13%	11%	31%
Therapy-related deaths	None	None	4
Regulatory approval	EEA: Aug 2018 CH: Oct 2018	EEA: Aug 2018 CH: Oct 2018	EEA: Aug 2018 CH: Apr 2019

EEA: European Economic Area; CH: Switzerland

Figure 2. Illustrative method for estimating expected reimbursement lag

Median time to availability of:	Oncology medicines	Orphan medicines
Sweden	≈7 months	≈14 months

*As tisa-cel and axi-cel are orphan and oncology medicines, the "as expected" interval was defined as the timeframe between the median time to availability of oncology medicines and orphan medicines.

RESULTS & CONCLUSION

- As of 8 July 2020, reimbursement status was available for 20 countries, of which pricing information was available for 17.

- The median time from regulatory approval to reimbursement of CAR T-cell therapy (in B-ALL or DLBCL, whichever was earliest) was 8.5 months (range 1-22 months).

- When analysed versus the time to availability for oncology and orphan drugs, access was granted earlier than expected for B-ALL in 55% of countries (median 8 vs 12 months) and for DLBCL in 35% of countries (median 10 vs 12 months).

- While list price was aligned across Europe, four countries granted reimbursement earlier than expected in both B-ALL and DLBCL despite lower than average GDP per capita (Spain, Greece, Czechia, Croatia).

- In opposite, three countries took longer than expected or still had not reimbursed CAR T-cell therapy despite a higher than average GDP per capita (Denmark, Ireland, Switzerland).

- In conclusion, despite wide variability across European countries, in general CAR T-cell therapy reimbursement was granted earlier or in line with expected timelines, suggesting a consensus on the perceived added value brought by CAR T-cell therapy in addressing treatment unmet needs.

LIMITATIONS

The authors note the following limitations in this research:

- The research was limited to publicly available information obtained through hand searches in HTA agency websites, databases and search engines, therefore some country-specific information may have been missed

- Most evidence from non-English speaking countries was translated using translation software

- The ex-factory prices do not reflect confidential net prices negotiated between manufacturers and authorities, which may have influenced the time to reimbursement

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- Poland: AOTMiT (Agencja Oceny Technologii Medycznych I Taryfikacji)
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