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Integrating healthcare system value into new medicine evaluations for timely and full patient access

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Introduction

Value assessment frameworks (VAFs) provide a structured approach to allow national payers to determine the overall worth of a new medicine for specific patient groups, conventionally assessing comparative clinical- and cost-effectiveness. As a tool, VAFs typically inform national reimbursement decisions. There is great heterogeneity in defining value, not least depending on the stakeholder type, and there is a well-published call to action for VAFs to capture patient-centered value.[1-2] The publication of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) value flower in 2018 was intended to highlight elements that may be overlooked or underappreciated in conventional drug value assessments [Fig. 1].[3-4]

Figure 1: Key elements of value depicted as the "ISPOR Value Flower" by the ISPOR Special Task Force

Adapted from Neumann et al (2022)

This moves some way toward expanding the value debate, recognizing there are wider determinants of value to evaluate patient access than those traditionally considered in VAFs. Here, we define patient access as:

> ***"Fully enabled in-market patient access, where a prescriber who wants to prescribe a medicine is fully enabled to do so in the healthcare system in which they operate."***

Critically, subnational payers, as a stakeholder group, consider value holistically in terms of healthcare system's impact on their local population. To ensure timely patient access, healthcare system value drivers such as service design and capacity planning, healthcare system risk, and impact on health inequalities must also be strategically planned for and evaluated.

Objective

Our objective was to understand if, and how, national payer value assessments guide subnational payers in evaluating a medicine's holistic value and enabling timely, fully enabled in-market patient access.

Methods

A targeted grey literature search of health technology assessment (HTA) reports and relevant publications examined value drivers in national assessments, focusing on frameworks used by HTA agencies and using CAR-T (chimeric antigen receptor T-cell) therapies as a case study.

Results

This literature search revealed that national assessments focused on value drivers at a national market access level, but not on the broader determinants of value considered operationally in the healthcare systems for decision-making, which are key to unlocking fully enabled in-market patient access [Fig. 2].

Figure 2: Current focus of national value assessments when evaluating CAR-T therapies

NICE[5-7]

Core assessment:
- Clinical need and treatment pathway
- Clinical evidence
- Economic model
- Severity (QALY)
- Cost-effectiveness estimates
- End of life

Other factors:
- Equality
- Innovation

HAS[8-10]

Core assessment:
- Clinical benefit
- Public health benefit
- Clinical added value
- Economic analysis

G-BA[11-12]

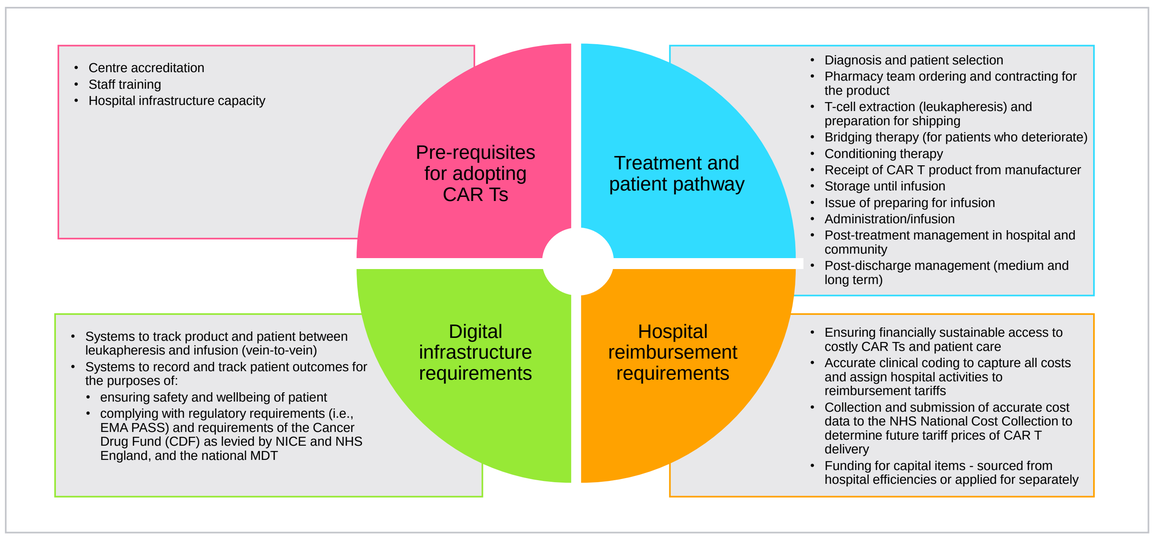
Core assessment:
- Clinical endpoints
- Quantity of patients eligible for treatment
- Requirements for quality-assured application
- Treatment costs

G-BA, Gemeinsamer Bundesausschuss; HAS, Haute Autorité de Santé; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year.

Therapies reviewed: NICE – axicabtagene ciloleucel, epcoritamab, loncastuximab tesirine; HAS – tisagenlecleucel, lisocabtagene maraleucel, axicabtagene ciloleucel; G-BA – tisagenlecleucel, axicabtagene ciloleucel.

The national assessments reviewed did not include subnational payer healthcare system value drivers which could influence the realization of CAR-T therapy benefits in the healthcare system. We utilized the successful adoption of CAR-T therapies in the UK healthcare system as a case study to demonstrate the disparity between VAFs employed by national payers versus the wider healthcare system, value drivers, that mean national market access can be translated into timely patient access [Fig. 3].[13]

Figure 3: Key drivers enabling patient access and uptake of CAR-T therapies at hospital level



Adapted from Catapult Cell and Gene therapy - White Paper (2021)

It is evident that subnational stakeholders consider the value of an asset not just in terms of clinical efficacy, safety, and cost but also in terms of wider societal determinants of value for their local health economy.
The complex requirements to enable timely adoption of CAR-T therapies required components of value that considered:

- Care pathway
- Clinical infrastructure
- Institutional readiness and skill of clinical staff
- Timely funding arrangements that were in place for hospitals to be appropriately reimbursed.

Conclusions

Despite calls to integrate patient and broader societal perspectives, we found insufficient evidence in national assessments to include broader healthcare system determinants of value that are crucial to payers operating within healthcare systems, with the potential to drive faster and more effective patient access. Advanced therapies such as CAR-Ts offer the potential to address significant and growing unmet healthcare needs, but timely and equitable patient access is only possible with early strategic planning in consideration of these wider healthcare system value drivers with subnational stakeholders.
These findings highlight how the consideration of value drivers to support both **national market access** and fully enabled-in market **patient access** are key for the full value of an asset to be realized and patients to achieve timely access.

Scan here for poster references

Poster presented at ISPOR EU, 17–20 November 2024, Barcelona, Spain