HTA Readiness for Tumor-Agnostic Therapies: Lessons From Analogues Across Major Markets

HTA189

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OBJECTIVE

Over the past decade, oncology therapy area has witnessed remarkable growth in the approval of drugs spanning multiple tumor types. Since Jan 2020, 9 molecules have been approved as tumor-agnostic drugs across global markets. This trend is reflected in the **evolving landscape of oncology clinical trials with 10-12% of phases 2, 2/3 and 3 trials being tumor-agnostic as of date**.

Given the current trajectory, we **explored how these therapies have been perceived by the global payers** specifically on their **willingness to attribute value to evidence** at launch and to **engage in constructive steps**.

METHOD

This research **was powered by Nuro, Access Infinity's proprietary data platform** along with secondary research.

HTA outcomes and payer perceptions were analysed for the identified analogues to **determine commonalities and differences in payer reviews** and **constructive suggestions provided to the manufacturers by the payers**.

Tumor-agnostic analogues considered:

KEYTRUDA (pembrolizumab), ROZLYTREK (entrectinib), VITRAKVI (larotrectinib)

In-scope markets:

RESULTS

HTA outcomes in the in-scope markets

	Rozlytrek (NTRK solid tumors)	Vitrakvi (NTRK solid tumors)	Keytruda (MSI-H/ d-MMR solid tumors)
DE	No added benefit		Not EMA approved
FR	SMR Insufficient	Mixed (SMR Moderate, ASMR V; SMR Insufficient)	
CA	Recommended	Not recommended	Recommended
AU	Not assessed	Recommended	Not assessed
UK	Recommended under Cancer Drug Fund (CDF)		Not MHRA approved

Payer Perceptions

Critical themes perceived by the global payers for the tumor-agnostic analogues:

Payer Concerns	Applicable Market	Applicable Analogue
Early clinical phase (Ph I/2 and/ or Ph 2)	*All*	*All*
Lack of comparative data	*All*	*All*
Small population size in clinical trial	*All*	*All*
Wrong population selection/ not generalisable to clinical practice	*DE, UK, AU*	*Rozlytrek, Vitrakvi*
Issues with trial end points	*All*	*All*

Constructive suggestions by the payers

Suggestion	Market	Applicable Analogue	Steps taken by the manufacturer	P&MA impact
Direct comparative data	DE, FR, CA	**Vitrakvi**	CA - Resubmission of clinical data for Vitrakvi with the real-world evidence done (4 real-world evidence studies with large sample sizes that supported the oncogenicity and mutual exclusivity of NTRK fusion in certain cancers)	Favorable decision (recommended) upon re-assessment
Setting-up of an exhaustive registry listing all the treated children	FR	**Vitrakvi**	No new data submitted by the MNF	No impact on the HTA outcome
Additional data collection from trials and RWE	UK	**Rozlytrek** and **Vitrakvi**	Data from additional trials and registry data such as Flatiron real-world data and Foundation Medicine genomic database, EURACAN registry	No meaningful impact due to data uncertainty and long time undertaken to collect data

CONCLUSIONS

- Tumor-agnostic therapies have **faced payer scrutiny** owing to **evidence issues** (e.g., lack of comparative data, small population size, etc.) however, there were **some signals that payers are willing to engage with manufacturers** to provide patient access even without a robust evidence package
- It is imperative for the manufacturers and the global market access teams to **adopt a tumor-agnostic approach in evidence generation**, such as **pooled analysis** of tumor types, providing an **indirect treatment comparison**, **real-world and registry data**, as applicable

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