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pricing, reimbursement
& market access

CADTH issues its first CAR-T assessment

The Canadian Agency for Drugs and Technologies in Health (CADTH) issued its first assessment of a chimeric antigen-receptor T-cell therapy (CAR-T) in January,[1] recommending Kymriah (tisagenlecleucel) for pediatric/young adult acute lymphoblastic leukemia (ALL) and adult diffuse large B-cell lymphoma (DLBCL), conditional on discounts to the list price.

Cost-effectiveness analysis indicates that the discount expected for ALL is minor, but for DLBCL could be in the range of 50–70%. CADTH also has significant concerns over budget impact, capacity constraints of the limited network of potential treatment centers, and travel costs and issues of equality of access for patients without a treatment center in their province.

For these reasons, the panel recommended the development of clear and transparent patient selection criteria and interprovincial agreements to provide access to all eligible patients across provinces. Collection of real-world evidence through a Canada-wide registry was also recommended, to assess long-term safety, effectiveness, and cost-effectiveness.

The key findings of the assessment were as follows:

- The cost per quality-adjusted life-year was $212,000 for DLBCL and $53,000 for ALL.
- Budget impact concerns are focused on DLBCL, for which the 3 year incremental cost is $400 million, compared with $25 million for ALL.
- Only five provinces currently have FACT-accredited centers, leaving a further five provinces and all three territories without any CAR-T treatment centers.
- CADTH evaluated scenarios where capacity constraints were assumed to lead to only 70% of eligible patient demand being met for ALL and less than 25% for DLBCL.
- Cross-province billing and capacity planning will be required to address issues of equality of access.
- Out-of-country treatment in the US is considered an option to address short-term capacity issues.
- In the longer term, treatment may move to outpatient centers and centers without Foundation for the Accreditation of Cellular Therapy (FACT) accreditation.

The launches of Yescarta and Kymriah in the US and Europe are generating important learnings for developers of the next wave of products, and PRMA Consulting continues to monitor this area closely.

The understanding we have of these latest developments, combined with our deep, global expertise in the area of oncology, allows us to support our clients and help them achieve future market access and commercial success. Our tailored services include strategic market access, landscape assessments, payer and KOL engagement, value propositions, GVDs, evidence generation, real-world evidence, and pricing and reimbursement strategy. We are always happy to have an informal, confidential chat and help you re-think your market access challenges.

References

1. CADTH (2019) Tisagenlecleucel (Kymriah) for Pediatric Acute Lymphoblastic Leukemia and Diffuse Large B-Cell Lymphoma. Accessed 15 January 2019. Available at: www.cadth.ca/tisagenlecleucel-kymriah-pediatric-acute-lymphoblastic-leukemia-and-diffuse-large-b-cell-lymphoma

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