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Reimbursement Recommendation

Toripalimab (Loqtorzi)

Indication: As a single agent, for the treatment of adults with recurrent unresectable or metastatic nasopharyngeal carcinoma with disease progression on or after a platinum-containing chemotherapy

Sponsor: Apotex Inc.

Final recommendation: Do not reimburse

Summary

What Is the Reimbursement Recommendation for Loqtorzi?

Canada's Drug Agency (CDA-AMC) recommends that Loqtorzi not be reimbursed by public drug plans for the treatment of adults with recurrent unresectable or metastatic nasopharyngeal carcinoma (NPC) with disease progression on or after a platinum-containing chemotherapy.

Why Did CDA-AMC Not Recommend Reimbursement?

The pan-Canadian Oncology Drug Review Expert Review Committee (pERC) concluded that Loqtorzi does not demonstrate acceptable clinical value compared with appropriate comparators such as chemotherapeutic agents in patients with previously treated NPC. Given that Loqtorzi is expected to be an alternative to chemotherapy, acceptable clinical value refers to at least comparable value versus drugs such as capecitabine, taxanes, or carboplatin that are currently used in Canada.

The committee reviewed 1 phase II trial (POLARIS-02); however, this study did not compare Loqtorzi to any other drugs and therefore was not designed to demonstrate that treatment resulted in similar or better clinical benefit relative to any treatment. In this trial, patients treated with Loqtorzi had their cancer worsen within a median of 1.9 months and survived for a median of 15.7 months. Additionally, 20.9% of patients had their tumour shrink, a response that lasted a median of 14.9 months. Health-related quality of life (HRQoL), which is important to patients, was not assessed in the trial.

The key limitation of the trial is that Loqtorzi was not compared to another drug, and this prevents any conclusion of the relative clinical value of Loqtorzi versus drugs usually prescribed to the target patient population. Additionally, no indirect treatment comparison was submitted to inform relative efficacy or safety of Loqtorzi compared to other drugs. In the absence of comparative evidence, the committee was unable to conclude that Loqtorzi provides clinical value for patients who have been previously treated.

The committee considered whether the drug would address significant unmet clinical or nonclinical needs. The committee acknowledged needs for additional therapies in the context of an aggressive disease and broader needs for support of patients and caregivers, especially in underserved groups. However, the committee did not judge that Loqtorzi could address these needs with an acceptable level of certainty. Based on

Summary

all the preceding considerations, pERC recommended that Loqtorzi not be reimbursed.

Review Background

- **Disease background:** NPC is a rare cancer of the uppermost part of the throat, which tends to be detected at a more advanced stage (stage III or IV) and therefore can be difficult to treat.
- **Incidence:** The incidence of NPC is 0.5 to 1 per 100,000, although it is more common in certain populations, including people of Asian descent and Inuit.
- **Indication and reimbursement request:** Toripalimab (Loqtorzi) has been approved by Health Canada for use "as a single agent, for the treatment of adults with recurrent unresectable or metastatic nasopharyngeal carcinoma with disease progression on or after a platinum-containing chemotherapy." The sponsor is seeking reimbursement for this patient population.
- **Drug under review:** Toripalimab is a PD-1 inhibitor. It is available as a solution that is administered by IV infusion and the dosage recommended in the product monograph is 3 mg/kg per body weight every 2 weeks.
- **Treatment costs:** At the submitted price of $8,800 per vial, the cost of toripalimab is expected to be $8,800 per patient per 14-day cycle, based on the Health Canada–recommended dosage. When considering a 28-day cost, the cost of toripalimab is expected to be $17,600 per patient.

Highlights of Input From Interested Parties

Patient groups (Canadian Organization for Rare Disorders, the Canadian Cancer Survivor Network, and the Canadian Cancer Society) noted the following regarding impacts of the disease, unmet needs, and important outcomes:

- Patients report that NPC has a significant impact on their quality of life (QoL), including their social interactions, food intake, work, or daily activities and that the current treatments cause significant side effects including pain, hearing loss, radiation burns, and loss of taste.
- Patients report significant side effects from currently available treatments and would prefer to use less interventions that they perceive to be less toxic.

The clinician group (Ontario Health's [Cancer Care Ontario] Head and Neck Cancer Drug Advisory Committee) and the clinical experts consulted by CDA-AMC noted the following regarding unmet needs arising from the disease and place in therapy for the drug under review:

- The clinician group and clinical experts noted that patients will eventually progress after multiple courses of chemotherapy and therefore more treatment options are needed for patients with NPC.
- The clinician group and clinical experts also noted that there are currently no approved treatments for those patients in the second line setting who have progressed on standard chemotherapy.
- The clinician group and clinical experts believe that toripalimab monotherapy will change the treatment paradigm for those in the second line.

The participating public drug programs raised potential implementation issues related to considerations for initiation and prescribing of therapy and the generalizability of trial populations to broader populations.

Person With Lived Experience

A person with lived experience shared his treatment journey living with stage 4 metastatic NPC, initially thought to be a lingering cold. After using virtual care due to lack of a family physician, a CT scan and biopsy confirmed the diagnosis, and that the cancer had spread to his liver, lungs, and stomach. His oncologist gave him an initial prognosis of a few months, and he began chemotherapy with cisplatin and gemcitabine within a week, later adding an immunotherapy through a clinical trial. Within a month of adding an immunotherapy, his scans showed no trace of cancer in his head, lungs, or stomach, and only a small spot remained on his liver, which he described as a major turnaround from the multiple lesions at diagnosis. His main treatment priorities were longevity, symptom relief, and QoL, and despite side effects like fatigue, neuropathy, and hair loss he felt the treatment was worth it. Support from family, health care teams, and a positive outlook were pivotal to his recovery. He also noted the distinct burden of having a disease associated with his ethnicity, a connection that intensified feelings of isolation and prompted concerns about disparities in treatment access depending on geographic location. He emphasized the emotional and financial burdens of living with NPC and going through treatment, and the importance of making immunotherapy a standard of care for patients.

Disclaimer: The perspectives shared by people with lived experience who present to the committee reflect their individual experiences and are not necessarily representative of all people with the same condition or course of treatment. Their insights provide valuable context about what a patient, support person, or caregiver might go through with this condition or treatment, helping to inform the committee's deliberations. These narratives complement other forms of evidence and input and should be considered as 1 element contributing to a broader understanding of the condition and treatment under review.

Recommendation

With a vote of 11 to 4, pERC recommends that toripalimab not be reimbursed for previously treated NPC.

Rationale for the Recommendation

Clinical Value

Based on the totality of the clinical evidence, pERC concluded that toripalimab does not demonstrate acceptable clinical value compared with appropriate comparators such as chemotherapeutic agents in patients with previously treated NPC. Given that toripalimab is expected to be an alternative to chemotherapy, acceptable clinical value refers to at least comparable value versus drugs such as capecitabine, taxanes, or carboplatin that are currently used in Canada.

One noncomparative single-arm phase II trial (POLARIS-02) did not demonstrate that treatment resulted in similar or better clinical benefit for patients with previously treated NPC relative to any comparator drug. At data cut-off of February 19, 2020, after a median follow-up of 12 months, patients treated with toripalimab

had a median overall survival of 15.7 months (95% confidence interval [CI]: 5.6 months to not estimable) and a progression-free survival of 1.9 months (95% CI, 1.8 months to 3.5 months). The independent review committee-assessed objective response rate was 20.9% (95% CI, 15.1% to 27.8%) and the median duration of response was 14.9 months (95% CI, 10.3 months to not estimable).

HRQoL was not assessed in the trial, and no indirect evidence was submitted. The key limitation of the trial is the single-arm, noncomparative design with precludes any conclusion of the relative clinical value of toripalimab versus drugs usually prescribed to the target patient population. Additionally, no indirect treatment comparison was submitted to inform relative efficacy or safety of toripalimab.

In the absence of comparative evidence, pERC was unable to make an evidence-informed recommendation for the use of toripalimab in second line. Further information on the committee's discussion around clinical value is provided in the Summary of Deliberation section.

Considering Significant Unmet Clinical Need

Based on clinician and patient input, pERC established that there was a significant unmet clinical need for effective and safe treatments in patients with previously treated recurrent or metastatic NPC. These patients have aggressive disease and there are no approved second-line therapies, leaving drugs offered in clinical trials or palliative chemotherapy as the only options. Currently available treatments offer poor survival outcomes and cause significant toxicity, while the disease severely impacts QoL through pain, functional limitations, and emotional distress.

However, even when taking the significant unmet clinical need into account, it remained uncertain if the drug addresses any of these needs. Thus, pERC was unable to conclude that there was an acceptable level of certainty in the clinical value of toripalimab.

Further information on the committee's discussion around unmet clinical need is provided in the Summary of Deliberation section.

Considering Significant Unmet Nonclinical Need or Health Inequity

pERC considered that although the disease is rare in Canada, it disproportionally affects Indigenous populations (such as Inuit) and people who have recently immigrated from countries where the disease is endemic (e.g., East Asia and South Asia) who may experience language or cultural barriers, or access to health care issues. Language and cultural challenges can hinder timely diagnosis and treatment. Patients in rural or remote regions may also face long travel times and limited local expertise. Additionally, there is a need for better psychosocial support, as NPC imposes significant emotional and mental health burdens on patients and caregivers.

However, the committee could not conclude that toripalimab would address any of these needs in a meaningful way.

Further information on the committee's discussion around unmet nonclinical need is provided in the Distinct Social and Ethical Considerations subsections in the Summary of Deliberation section.

Developing the Recommendation

Due to the uncertainty in clinical value, pERC could not recommend whether to reimburse toripalimab or not based on clinical value alone. Whether toripalimab addressed a significant unmet clinical need with an acceptable level of certainty in clinical value, was also considered. pERC was not able to recommend reimbursement even after taking this into account. Finally, they considered whether toripalimab addresses a significant unmet nonclinical need or health inequity. pERC was unable to conclude that toripalimab addresses a significant unmet nonclinical need or health inequity to a degree that overcomes the uncertainty in clinical value and potential risks. Based on all of the preceding considerations, pERC recommended that toripalimab not be reimbursed.

Because pERC recommended that toripalimab not be reimbursed, further deliberation was not required on whether reimbursement conditions should be added to address important economic considerations, health system impacts, social and ethical considerations, or to ensure clinical value is realized.

Summary of Deliberation

pERC considered all domains of value of the deliberative framework before developing its recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, refer to Expert Committee Deliberation at CDA-AMC.

The committee considered the following key discussion points, organized by the 5 domains of value.

Clinical Value

- **Appropriate comparators:** pERC considered that the appropriate comparators for second-line treatment with toripalimab in NPC would be alternative chemotherapeutic agents such as taxanes, platinum rechallenge (if eligible), or capecitabine. Other PD-1 inhibitors or clinical trials may be accessed by patients in this setting on a case-by-case basis but are not considered comparators from a public drug program perspective.
- **Efficacy versus trial comparator:** As stated previously, the POLARIS-02 trial was a noncomparative study that assessed clinical response and survival outcomes in patients with NPC who were previously treated with 1 or more lines of therapy and then exposed to toripalimab. There was no direct or indirect evidence relative to appropriate comparators cited previously.
- **Clinical importance of treatment effects**: In the absence of a comparator, the committee was uncertain about how meaningful the treatment effects were. Overall survival, progression-free survival, and tumour response were outcomes of relevance to clinicians. However, the committee could not conclude whether the observed absolute effects would address the needs for improvement in these outcomes. HRQoL was not measured in the POLARIS-02 trial, precluding any conclusion on this aspect. Patients highlighted the need for treatments with minimal added toxicity. Safety was

assessed in the POLARIS-02 trial but could not be compared with that of other treatments. No major safety concerns were identified by the committee.

- **Certainty of the evidence**: Certainty of single-arm, noncomparative evidence is considered very low for any outcome according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework. The magnitude of the absolute effects was not considered sufficiently high to increase certainty in the results. No other factors were identified that would increase confidence in the results.
- **Clinical value:** Based on all of the preceding considerations, the committee determined there was no measurable clinical value versus appropriate comparators (i.e., alternate second-line chemotherapy).

Unmet Clinical Need

- **Input on unmet clinical need**: According to patients and clinicians, there are no drugs currently approved for use in second line or beyond for recurrent or metastatic NPC. Patients often seek out clinical trials as their best option, and other options include traditional chemotherapy. The intent of currently available treatments in recurrent or metastatic NPC is mainly palliative and not curative. There is an unmet clinical need for effective therapies in the second line with less side effects and lasting HRQoL impacts.
- **Severity of the disease**: According to the patients and clinicians, NPC is a severe disease often diagnosed at advanced stages, leading to poor long-term outcomes and limited curative options. It causes significant physical symptoms such as pain, difficulty swallowing, and hearing loss, and negatively impacts QoL, including work, sleep, and emotional well-being. Many patients experience anxiety, depression, and social isolation, compounded by treatment-related side effects and access barriers.
- **Availability of treatment options**: As previously mentioned, publicly available options for recurrent NPC are limited to chemotherapies. Similar to toripalimab, these treatments are administered with palliative intent. Experimental or unapproved options may be accessed on a case-by-case basis.
- **Significant unmet clinical need**: Overall, pERC determined there was significant unmet clinical need in the population under review due to high symptoms burden, poor prognosis, and limited treatment options. However, the committee remained uncertain as to whether toripalimab could address these needs given the limitations of the evidence.
- **Considerations for evidence generation**: Although NPC is considered rare in Canada (less than 1 per 100,000 person-year), it is significantly more common in endemic countries. Therefore, pERC did not believe the rarity of the condition would preclude generation of comparative clinical evidence of sufficiently high quality. pERC noted that this has been realized in the first-line setting (JUPITER-02 trial) and in the phase III KEYNOTE-122 trial comparing pembrolizumab to chemotherapy in patients with previously treated NPC. However, pERC acknowledged that PD-1 inhibitors are moving to the first-line setting. With such a lack of equipoise, future trials are unlikely to be conducted in the second-line setting.

Distinct Social and Ethical Considerations

- **Input on unmet nonclinical need:** pERC acknowledged nonclinical needs for patients with NPC. The disease presents challenges regarding access to diagnostic and treatment resources, imposing burden on patients and caregivers (time and expense for travel, absence from work, removed from social network). A similar situation prevails for those who have immigrated and their families (availability for support, translation, transportation).
- **Equity considerations:** pERC noted that NPC tends to disproportionately impact people of Asian descent, Indigenous Peoples, and Inuit, who face barriers to care due to language, proximity to large cancer centres, or due to distrust of the medical system. First Nations, Inuit, and Métis patients and caregivers face additional burden from travel to cancer centres from rural or remote locations. pERC remarked that toripalimab is an IV treatment that does not address the latter access barrier.
- **Significant unmet nonclinical need or health inequity:** While pERC identified some unmet nonclinical needs and equity issues, it did not deem them to be significant enough to justify recommending toripalimab for reimbursement. pERC did not consider that the drug could address these needs and issues in any meaningful way, or that it could accept a higher level of uncertainty because of these needs.
- **Deliberation on social and ethical implications**: The committee considered social and ethical implications of toripalimab; however, the recommendation not to reimburse meant that further deliberation on measures to address these implications was not required.

Economic Considerations

Deliberation on economic considerations: The committee reviewed the economic considerations for toripalimab; however, the recommendation not to reimburse meant that further deliberation on the considerations was not required.

Impacts on Health Systems

Deliberation on impacts on health systems: The committee considered the impacts on health systems when implementing toripalimab; however, the recommendation not to reimburse meant that further deliberation on measures to address these impacts was not required.

Sources of Information Used by the Committee

To make its recommendation, the committee and subcommittee considered the following information (links to the full documents for the review can be found on the project webpage):

- the CDA-AMC review of the clinical and pharmacoeconomic evidence submitted by the sponsor, as well as relevant ethical issues related to toripalimab (refer to the Main Report and Supplemental Material document)

- the sponsor’s comments on the draft report and the responses by CDA-AMC
- patients' perspectives gathered by 3 patient groups, the Canadian Organization for Rare Disorders, the Canadian Cancer Survivor Network, and the Canadian Cancer Society (refer to the Patient and Clinician Group Input document)
- input from a person with lived experience who delivered a brief presentation and answered questions from the committee (refer to the Person with Lived Experience section)
- input from 1 clinician group, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Committee (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the Supplemental Material document)
- input from 3 clinical experts with expertise in the management of NPC consulted by CDA-AMC.

Special thanks: CDA-AMC extends our special thanks to the individual who presented directly to pERC, and to the patient organizations representing the community of those living with NPC, including the Canadian Cancer Society, the Canadian Organization for Rare Disorders, and the Canadian Cancer Survivor Network.

General note: CDA-AMC makes every attempt to engage with people with lived experience as closely to the indication under review as possible; however, at times, CDA-AMC is unable to do so and instead engages with individuals with similar treatment journeys to ensure lived experience perspectives are included and considered in Reimbursement Reviews. CDA-AMC is fortunate to be able to engage with individuals who are willing to share their treatment journeys with CDEC and pERC.

pERC Information

Members of the Committee

Dr. Catherine Moltzan (Chair), Dr. Kelvin Chan (Vice-Chair), Paul Agbulu, Dr. Phillip Blanchette, Dr. Matthew Cheung, Dr. Michael Crump, Annette Cyr, Dr. Jennifer Fishman, Dr. Jason Hart, Terry Hawrysh, Dr. Yoo-Joung Ko, Dr. Aly-Khan Lalani, Amy Peasgood, Dr. Anca Prica, Dr. Michael Raphael, Dr. Adam Raymakers, Dr. Patricia Tang, Dr. Pierre Villeneuve, and Danica Wasney.

Meeting date: December 3, 2025

Regrets: Two expert committee members did not attend.

Conflicts of interest: One expert committee member did not participate due to considerations of conflict of interest.

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