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Reimbursement Recommendation

Tezepelumab (Tezspire)

Indication: As an add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled by systemic corticosteroids and/or surgery

Sponsor: AstraZeneca Canada Inc.

Final recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Tezspire?

Canada's Drug Agency (CDA-AMC) recommends that Tezspire be reimbursed by public drug plans as an add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled by systemic corticosteroids and/or surgery if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

The Canadian Drug Expert Committee (CDEC) determined that Tezspire demonstrates acceptable clinical value compared with appropriate comparators dupilumab and mepolizumab. Given that Tezspire is expected to be an alternative to dupilumab, omalizumab, and mepolizumab, acceptable clinical value refers to an at least comparable value versus 1 or more of these drugs. Evidence from a clinical trial showed that Tezspire with intranasal corticosteroids for 52 weeks reduced the size and burden of nasal polyps in patients with severe CRSwNP inadequately controlled by oral corticosteroids and/or surgery. Evidence from an indirect comparison suggests that treatment with Tezspire and dupilumab results in similar improvements in symptoms and overall disease burden. Compared with mepolizumab, Tezspire was associated with further reductions in disease burden as well as a lower need for surgery or systemic corticosteroids. However, the indirect comparisons were very uncertain because of methodological limitations, differences between trials, and uncertainty in the overall results, which make definitive conclusions challenging. Also, there was no comparison between Tezspire and omalizumab.

CDEC noted that there are unmet clinical needs with existing treatments and challenges with accessing them. Dupilumab requires additional monitoring for potential safety issues and injection every other week, which may be burdensome to patients. It was also not yet available on the public drug plans at the time of the committee meeting. Mepolizumab is publicly available but requires prior polyp surgery. A biosimilar version of omalizumab is available for CRSwNP in some jurisdictions, but its use can be impractical because it requires an immunoglobulin E level assessment. With acceptable clinical value and potentially simpler requirements, Tezspire could address current unmet needs.

Which Patients Are Eligible for Coverage?

Tezspire should only be covered for patients with severe CRSwNP who are taking intranasal corticosteroids and have persistent symptoms despite

Summary

recent treatment with oral corticosteroids and/or with a history of nasal polyp surgery.

What Are the Conditions for Reimbursement?

Tezspire should only be reimbursed if prescribed by physicians with experience in managing biological treatment and expertise with severe CRSwNP, the patient is not receiving another biologic for CRSwNP, and the drug program cost of Tezspire does not exceed the drug program cost of treatment with the least costly biologic reimbursed for this indication.

Important budget impact considerations must be addressed for health systems to be able to adopt Tezspire.

Review Background

- **Disease background:** CRSwNP is an inflammatory condition of the upper airways with noncancerous epithelial projections (nasal polyps). It has a high symptom burden of nasal obstruction, discharge, facial pain, and loss of smell, all of which have a big impact on health-related quality of life. In Canada, chronic rhinosinusitis affects approximately 5% of the population, and CRSwNP comprises 25% to 30% of these cases.
- **Indication and reimbursement request:** Tezepelumab (Tezspire) has been approved by Health Canada as an add-on maintenance treatment along with intranasal corticosteroids in adult patients with severe CRSwNP that is inadequately controlled by systemic corticosteroids and/or surgery. The sponsor is seeking reimbursement for this patient population.
- **Drug under review:** Tezepelumab is a human monoclonal antibody and thymic stromal lymphopoietin inhibitor. It is available as a 210 mg single-use prefilled syringe or pen (110 mg/mL solution) administered by subcutaneous injection, and the dosage recommended in the product monograph is 210 mg (1 syringe or pen) every 4 weeks.
- **Treatment costs:** At the submitted price of $2,027.63 per prefilled syringe or pen, the annual cost of tezepelumab is expected to be $26,450 per patient, based on the Health Canada–recommended dosage.

Highlights of Input From Interested Parties

The patient group (Asthma Canada) noted the following regarding impacts of the disease, unmet needs, and important outcomes:

- CRSwNP symptoms can disrupt daily activities, sleep, and social engagement, and they are associated with emotional distress as well as financial strain that includes related, out-of-pocket costs for treatment that are not uniformly covered by health insurance. The condition has a big impact on quality of life for patients and caregivers and can limit a patient's social life.
- Current treatments often provide only partial relief, require frequent administration, and cause side effects like sinus infections and sleep disturbances.
- Important goals of treatment include improved breathing, restored smell and taste, reduced frequency of infections, improved sleep, lower recurrent polyps requiring surgery, and improved overall quality of life.

The clinician group (Canadian Rhinologic Society) and the clinical experts consulted by CDA-AMC noted the following regarding unmet needs arising from the disease and the place in therapy for the drug under review:

- Access to surgery differs across the country, and surgery often needs to be repeated. Access to biologics varies, partly due to inconsistencies in health insurance coverage (for dupilumab) and also because mepolizumab can only be used after surgery.

- There are people whose symptoms do not respond to mepolizumab or dupilumab. Mepolizumab may not always be effective at olfactory recovery or in maintaining symptom control over time. Dupilumab is increasingly stopped for side effects, including eosinophilia and arthralgias, and the biweekly injection is burdensome for some patients.
- Tezepelumab offers a broader approach to targeting inflammation than other biologics and may be particularly useful for people with mixed or noneosinophilic disease. It may be more appealing than dupilumab because it requires less frequent administration (every 4 weeks).

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

Recommendation

With a vote of 13 for to 0 against, the Canadian Drug Expert Committee (CDEC) recommends that tezepelumab be reimbursed as an add-on maintenance treatment for CRSwNP inadequately controlled by systemic corticosteroids and/or surgery only if the conditions listed in Table 1 are met.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Patients must have all of the following: 1.1. severe CRSwNP, confirmed endoscopically or by CT, with documented bilateral nasal polyps 1.2. tolerance and ability to continue use of an INCS but have refractory symptoms despite use of an optimized INCS for at least 3 months 1.3. persistent symptoms despite adequate recent treatment with systemic corticosteroids (within past 24 months) and/or any history of nasal polyp surgery, or with contraindications or intolerance to either.	Evidence from the WAYPOINT study demonstrated that treatment with tezepelumab as an add-on to INCS resulted in added clinical benefit in patients with these characteristics. These criteria align with those of dupilumab, and there is no evidence that tezepelumab should be held to a different standard than dupilumab when considering the requirement for these baseline values to support renewal criteria.	Jurisdictions may consider initiation criteria for tezepelumab that align with the criteria for dupilumab or mepolizumab used by each of the public drug plans. Jurisdictions should consider additional implementation guidance as provided for dupilumab: Condition 1.1: Severe CRSwNP is defined as patients with bilateral sinonasal polyposis that persisted despite prior treatment with an SCS within the past 2 years; and/or had a medical contraindication to SCSs; and/or had prior sinonasal surgery for nasal polyps, and had baseline endoscopic bilateral NPS of at least 5 out of a maximum score of 8 (at least a score of 2 in each nostril) and had 1 of the following: • ongoing symptoms of nasal congestion and/or blockage with moderate or severe severity (NC score of at least 2 on a scale of 0 to 3) and a weekly average severity of at least 1, and

Reimbursement condition	Reason	Implementation guidance
		• another symptom such as loss of smell or rhinorrhea (anterior and/or posterior) for at least 8 weeks. The guidelines suggest that diagnosis of severe CRSwNP can be confirmed by CT documentation of bilateral nasal polyps along with the previously identified clinical symptoms, as an alternative to endoscopic bilateral NPS. Condition 1.2: In the setting in Canada, the optimized INCS option is mometasone furoate nasal spray, two 50 mcg sprays in each nostril twice daily or equivalent, where tolerated. Condition 1.3: Lack of response to nasal polyp surgery is demonstrated within 3 months from surgery; hence, treatment with dupilumab should not be initiated if the patient has undergone nasal polyp surgery within the past 3 months.
2. The prescribing clinician must submit a baseline score for SNOT-22 or endoscopic NPS.	This criterion aligns with those of dupilumab and mepolizumab, and there is no evidence that tezepelumab should be held to a different standard than dupilumab or mepolizumab when considering the requirement for these baseline values to support renewal criteria.	—
3. Duration of initial reimbursement should be 52 weeks.	Patients in the WAYPOINT study were treated for 52 weeks.	—
Renewal		
4. Patients must exhibit a clinically meaningful response on the SNOT-22 or endoscopic NPS relative to their baseline score. 4.1. Response to treatment should be assessed every 52 weeks.	The WAYPOINT trial demonstrated a clinically meaningful change from baseline between-group difference in total NPS and SNOT-22. These criteria align with those of dupilumab and mepolizumab, and there is no evidence that tezepelumab should be held to a different standard than dupilumab or mepolizumab when considering renewal.	A clinically meaningful response on the SNOT-22 is a decrease in score from baseline of at least 8.9 points or greater. A clinically meaningful response for NPS is a decrease in score from baseline of at least 1 point or greater. Jurisdictions may consider renewal criteria for tezepelumab that align with the criteria for dupilumab and/or mepolizumab used by each of the public drug plans.
Prescribing		
5. Tezepelumab should be prescribed by physicians with experience in managing biological treatment and expertise with severe CRSwNP.	This is meant to ensure the accurate diagnosis and management of patients with CRSwNP and that tezepelumab is prescribed for patients for whom it is appropriate.	Jurisdictions may consider prescribing criteria for tezepelumab that align with the criteria for dupilumab and/or mepolizumab used by each of the public drug plans.

Reimbursement condition	Reason	Implementation guidance
6. Tezepelumab should not be prescribed in conjunction with other biologics indicated for the treatment of CRSwNP.	There is no evidence that combination biologic therapy is safe and effective in the treatment of CRSwNP.	—
Pricing		
7. The drug program cost of tezepelumab should be negotiated so that it does not exceed the drug program cost of treatment with the least costly biologic reimbursed for this indication.	Based on the committee's assessment of the evidence, tezepelumab is expected to have comparable clinical benefits and harms compared with dupilumab, and uncertain clinical benefits and harms compared with other biologics. Therefore, the drug program cost of tezepelumab should be no more than the least costly biologic reimbursed for this indication.	—
Feasibility of adoption		
8. The economic feasibility of adoption of tezepelumab must be addressed.	At the submitted price, the incremental budget impact of tezepelumab is expected to be greater than $40 million in year 3. The magnitude of uncertainty in the budget impact must be addressed to ensure the feasibility of adoption, given the difference between the sponsor's estimate and the CDA-AMC estimate(s).	—

CDA-AMC = Canada's Drug Agency; CRSwNP = chronic rhinosinusitis with nasal polyps; INCS = intranasal corticosteroids; NC = nasal congestion and/or obstruction; NCS = nasal congestion score; NPS = nasal polyp score; SCS = systemic corticosteroid; SNOT-22 = 22-item Sino-Nasal Outcome Test.

Rationale for the Recommendation

Clinical Value

Based on the totality of the clinical evidence, CDEC concluded that tezepelumab demonstrates acceptable clinical value compared with appropriate comparators dupilumab and mepolizumab in patients with severe CRSwNP inadequately controlled by systemic corticosteroids and/or surgery. Given that tezepelumab is expected to be an alternative to dupilumab, omalizumab, and mepolizumab, acceptable clinical value refers to at least comparable value versus 1 or more of these drugs.

The WAYPOINT trial demonstrated that treatment for 52 weeks with tezepelumab plus INCS resulted in added clinical benefit for patients with severe CRSwNP inadequately controlled by systemic corticosteroids and/or surgery compared with placebo plus INCS in nasal polyp score. The trial showed that tezepelumab likely resulted in added clinical benefit in 22-item Sino-Nasal Outcome Test (SNOT-22) score, proportion with SNOT-22 response, and need for nasal polyp surgery compared with placebo.

Evidence from 1 network meta-analysis (NMA) suggested similar effects in several outcomes, including symptom scores and disease burden, when comparing tezepelumab with dupilumab, and an improvement

in several outcomes, including disease burden and use of surgery or systemic corticosteroids, when tezepelumab and mepolizumab were compared. However, the NMA results were very uncertain because of sparse networks, study heterogeneity, and wide credible intervals, which make definitive conclusions about relative efficacy challenging. Also, no conclusions could be made about harms and health-related quality of life or about the comparative efficacy with omalizumab, because these were not included in the sponsor-conducted NMA. Given the uncertainty in the NMA and gaps in the evidence, there is insufficient evidence to conclude that tezepelumab provides added benefit versus appropriate comparators.

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

Developing the Recommendation

The determination of acceptable clinical value was sufficient for CDEC to recommend reimbursement of tezepelumab. As part of the deliberation on whether to recommend reimbursement, the committee also considered unmet clinical need, unmet nonclinical need, and health inequity. Information on this discussion is provided in the Unmet Clinical Need and Distinct Social and Ethical Considerations domains in the Summary of Deliberation section.

Because CDEC recommended that tezepelumab be reimbursed, the committee also deliberated on whether reimbursement conditions should be added to address important economic considerations, health system impacts, or social and ethical considerations, or to ensure clinical value is realized. The resulting reimbursement conditions, with accompanying reasons and implementation guidance, are stated in Table 1.

Summary of Deliberation

CDEC 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 Canada's Drug Agency.

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

Clinical Value

- **Appropriate comparators:** CDEC considered dupilumab, mepolizumab, and omalizumab to be the most appropriate comparators in the present review.
- **Efficacy versus placebo:** One randomized controlled trial (WAYPOINT; N = 410) demonstrated that tezepelumab resulted in a significantly improved nasal polyp score (mean change from baseline −2.078; 95% confidence interval [CI], −2.399 to −1.757]), nasal congestion score (mean change from baseline: −1.039; 95% CI, −1.214 to −0.865), and SNOT-22 score (mean change from baseline −27.441; 95% CI, −32.512 to −22.370) compared with placebo at 52 weeks. The study also

demonstrated that tezepelumab increased the proportion of patients with a SNOT-22 response (odds ratio 9.49; 95% CI, 4.77 to 18.87) and decreased the probability of requiring nasal polyp surgery (hazard ratio = 0.02; 95% CI, 0.00 to 0.09) or systemic corticosteroids (hazard ratio = 0.11; 95% CI, 0.04 to 0.25) compared with placebo in the same time period. However, CDEC acknowledged that there may be some bias because of the high numbers of people treated with placebo who stop treatment because of a lack of efficacy, including some who dropped out of the study. However, the direction or impact of this bias is unknown.

- **Clinical importance of treatment effects:** CDEC noted that outcomes considered important to patients highlighted in the patient group input — symptom management (such as improved breathing, restored smell and taste, improved sleep), enhanced overall quality of life, improved long-term outcomes (such as “reoccurring polyps”), and fewer infections — were assessed in the WAYPOINT trial. CDEC considered the improvement in nasal polyp, symptom scores, disease burden, or quality of life, and the reduction in surgery with tezepelumab compared to placebo were clinically meaningful. This was based on generally accepted minimally important differences for these outcomes and clinical input. Whereas there were improvements in the use of systemic corticosteroids with tezepelumab compared with placebo, it was less clear if the results were clinically meaningful.
- **Certainty of the evidence:** Using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for the comparison between tezepelumab and placebo, the certainty of evidence for the impact on nasal polyp score was high, whereas the other outcomes were either moderate or low. The lower uncertainty for other outcomes was because of a risk of bias from imbalanced missing outcome data between arms, possible unblinding from the lack of efficacy in the placebo arm, which may have influenced the measurement of subjective outcomes, and imprecision in the results. However, longer-term efficacy and safety beyond 52 weeks are unknown, an important gap given that tezepelumab can be taken for a prolonged period, if not indefinitely. For the comparisons between tezepelumab and other treatments (refer to the next points), there was uncertainty associated with the lack of direct evidence.
- **Efficacy versus dupilumab:** CDEC noted that the network meta-analyses showed tezepelumab had similar efficacy outcomes to dupilumab, except that tezepelumab was favoured over dupilumab for the proportion of patients having surgery. The committee noted the considerable uncertainty with network meta-analyses because of sparse networks, clinical and methodological heterogeneity (questioning the transitivity assumption), and wide credible intervals, which make definitive conclusions about relative efficacy compared with dupilumab challenging.
- **Efficacy versus mepolizumab:** CDEC noted that the network meta-analyses showed that tezepelumab was statistically favoured over mepolizumab for most efficacy outcomes. However, the committee noted the same uncertainties from the comparison with dupilumab applied to the comparison with mepolizumab.
- **Efficacy versus omalizumab:** There was no evidence presented to inform the comparative efficacy of tezepelumab compared with omalizumab.

- **Safety of tezepelumab:** No new safety signals were identified in the WAYPOINT trial compared to what has been seen in clinical practice. However, the certainty of the evidence on serious adverse events compared with placebo was low because of low event rates. It was not possible to draw conclusions on safety against other comparators because safety was not assessed in the NMA.
- **Clinical value:** Based on the preceding considerations, CDEC determined that there was comparable or similar clinical value compared with dupilumab and mepolizumab, and added clinical value compared with placebo.

Unmet Clinical Need

- **Input on unmet clinical need:** CDEC noted that the patient input highlighted partial relief and side effects like sinus infections and sleep disturbances with current treatments as unmet clinical needs. Both clinician and patient input noted the burden associated with surgery, which often needs to be repeated, and the serious risks of long-term use of oral corticosteroids. Clinical experts also noted that access to surgery varies and wait times can be very long in some areas. Clinical experts noted that dupilumab requires additional monitoring for arthralgia, rash, and eosinophilia, and its injection every 2 weeks may be burdensome for some patients. They also noted that omalizumab is often not used and is impractical because it requires weight-based dosing and immunoglobulin E level assessment.
- **Severity of the disease:** CDEC acknowledged the patient group input, which highlighted that CRSwNP is a chronic disease with a high symptom burden, including nasal obstruction, discharge, facial pain, and loss of smell. The input also noted the big impact on quality of life, including sleep disturbance, social life limitations, emotional distress, and financial strain. CDEC acknowledged that despite the burden associated with CRSwNP, it is not life-threatening, seriously debilitating, or both serious and chronic in nature.
- **Availability of treatment options:** In terms of biologics, CDEC noted that mepolizumab is widely available in public drug plan formularies but requires prior surgery. They note that patients who are not suitable for surgery may not be able to access mepolizumab, and this can disproportionately impact some equity-deserving groups. Dupilumab was not yet available in public drug plans at the time of the committee meeting but has received a conditional reimbursement recommendation from CDA-AMC. A biosimilar version of omalizumab was available for CRSwNP in some public drug plan formularies at the time of the meeting.

Distinct Social and Ethical Considerations

- **Input on unmet nonclinical need:** CDEC acknowledged that access to ear, nose, and throat specialists and surgery varies in Canada and wait times can be long. The patient group also highlighted that surgery is burdensome, anxiety-provoking, and temporary. Patients also highlighted the substantial impact of the disease on their quality of life and job functioning, as well as that of their

families. Clinical experts note that a dupilumab injection given every 2 weeks can be burdensome to patients.

- **Equity considerations:** CDEC acknowledged that CRSwNP disproportionately impacts people with comorbid asthma and chronic pulmonary lung diseases, which are more prevalent in some systematically disadvantaged and equity-deserving populations. For example, there are poorer asthma outcomes in lower socioeconomic populations, such as more hospitalizations. Also, severe asthma is more prominent in women with low income. Additionally, asthma is more prevalent in First Nations, Inuit, and Métis people, and this is further compounded by other difficulties within some Indigenous communities, including accessing regular health care providers and safe housing. Difficulties accessing primary care can lead to delays in diagnosis, which can delay treatment. Barriers to accessing ear, nose, and throat specialists, endoscopy services, and CT scans may be greater in areas that are more rural or remote, which can delay diagnosis and treatment, and pose challenges for monitoring response to treatment.

Economic Considerations

- **Health impacts of tezepelumab versus relevant comparators:** Tezepelumab plus standard of care (SOC) is likely to improve clinical outcomes compared with placebo plus SOC, including the proportion of patients experiencing a response based on SNOT-22 scores or improvement in SNOT-22 scores from baseline, and the proportion of patients needing nasal polyp surgery after 52 weeks. As there was no direct comparison of tezepelumab plus SOC with dupilumab plus SOC and with mepolizumab plus SOC, clinical efficacy was informed by a sponsor-submitted NMA. The NMA results suggested no statistically significant differences between tezepelumab plus SOC and dupilumab plus SOC for change in SNOT-22 scores and SNOT-22 response; but tezepelumab plus SOC was statistically favoured for change in SNOT-22 scores, whereas SNOT-22 response showed no statistically significant difference compared to mepolizumab plus SOC. However, the CDA-AMC clinical review noted that the NMA was associated with methodological limitations, which made definitive conclusions about the relative efficacy challenging.
- **Cost of tezepelumab versus relevant comparators:** At the submitted price for tezepelumab and public list prices of all other treatments, tezepelumab is more costly than dupilumab and less costly than mepolizumab per year of treatment.
- **Key findings of the economic evaluation:** If decision-makers determine there are no differences in health outcomes between tezepelumab plus SOC and other biologics, then the total cost of tezepelumab plus SOC to the health system should not exceed that of the least costly biologic as an add-on maintenance treatment in adult patients with severe CRSwNP inadequately controlled by systemic corticosteroids and/or surgery.
- **Certainty of the evidence:** The sponsor's assumptions regarding extrapolation of short-term trial evidence over the modelled time horizon, improved survival, and limitations with the modelling approach further limit the validity of the results of the economic model. Given limitations with the

clinical evidence informing the economic model, the cost-effectiveness of tezepelumab plus SOC compared with relevant comparators is uncertain.

Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimated that by year 3 of reimbursement, 15,627 patients would be eligible for tezepelumab plus SOC. Of these, 2,084 patients are expected to receive tezepelumab plus SOC. The estimated incremental budget impact of reimbursing tezepelumab plus SOC is predicted to be approximately $61.7 million over the first 3 years, with an expected expenditure of $136.7 million on tezepelumab plus SOC. The actual budget impact will depend on the number of people eligible for treatment and market share assumptions.

Sources of Information Used by the Committee

To make its recommendation, the committee 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 tezepelumab (refer to the main report and Supplemental Material document)
- the sponsor’s comments on the draft report and the CDA-AMC responses
- patients' perspectives gathered by 1 patient group, Asthma Canada (refer to the Patient and Clinician Group Input document)
- input from 1 clinician group, Canadian Rhinologic Society (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 2 clinical experts with expertise in the management of CRSwNP, consulted by CDA-AMC.

CDEC Information

Members of the Committee

Dr. Peter Jamieson (Chair), Dr. Kerry Mansell (Vice-Chair), Sally Bean, Daryl Bell, Dan Dunsky, Dr. Ran Goldman, Dr. Trudy Huyghebaert, Dr. Dennis Ko, Dr. Christine Leong, Alicia McCallum, Dr. Srinivas Murthy, Dr. Nicholas Myers, Dr. Krishnan Ramanathan, Dr. Marco Solmi, Carla Velastegui, Dr. Edward Xie, and Dr. Peter Zed.

Meeting date: March 25, 2026

Regrets: Three expert committee members did not attend.

Conflicts of interest: None

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