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Reimbursement Recommendation

Seladelpar (Lyvdelzi)

Indication: For the treatment of primary biliary cholangitis, in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in adults unable to tolerate UDCA

Sponsor: Gilead Sciences Canada, Inc.

Final Recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Lyvdelzi?

Canada's Drug Agency (CDA-AMC) recommends that Lyvdelzi be reimbursed by public drug plans for the treatment of primary biliary cholangitis (PBC), in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in adults unable to tolerate UDCA if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

The Canadian Drug Expert Committee (CDEC) determined that Lyvdelzi demonstrates acceptable clinical value versus Iqirvo and Ocaliva in patients with PBC. Lyvdelzi, elafibranor (Iqirvo), and obeticholic acid (Ocaliva) are used in combination with UDCA in adults whose PBC has an inadequate response to UDCA alone or as monotherapy in adults with UDCA intolerance. This determination alone was sufficient for CDEC to recommend that Lyvdelzi be reimbursed. Given that Lyvdelzi is expected to be an alternative to Iqirvo or Ocaliva, acceptable clinical value refers to at least comparable value versus Iqirvo or Ocaliva.

Evidence from 1 clinical trial demonstrated that treatment with Lyvdelzi (in combination with UDCA in patients whose PBC has an inadequate response to UDCA or as monotherapy in those with UDCA intolerance) resulted in improved response to treatment (alkaline phosphatase [ALP] < 1.67 × upper limit of normal [ULN], normal total bilirubin level, and a decrease in ALP ≥ 15% from baseline) and improved pruritus after 1 year of treatment when compared with placebo. Although evidence from 1 indirect treatment comparison for Lyvdelzi versus Iqirvo or Ocaliva was associated with methodological limitations and showed imprecise results, CDEC felt the results did not demonstrate significant differences in outcomes comparing the treatments and found it reasonable to consider them similar in efficacy and safety.

Lyvdelzi meets some important patient needs by offering an additional treatment option that could improve treatment response and normalize ALP levels.

Which Patients Are Eligible for Coverage?

Lyvdelzi should only be covered to treat adult patients who have a diagnosis of PBC that has either not responded adequately to UDCA treatment after treatment for at least a year (with a stable dose maintained

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for a minimum of 3 months), or who have intolerance to UDCA treatment, and who have a total bilirubin level of no higher than 2 times the ULN. In addition, patients should have no history or current evidence of other liver diseases. Initial coverage for Lyvdelzi should not exceed 12 months.

What Are the Conditions for Reimbursement?

Lyvdelzi should only be reimbursed if prescribed by or in consultation with a specialist, such as a gastroenterologist, a hepatologist, or another physician with expertise in managing PBC. Lyvdelzi should be negotiated so that the drug program cost of Lyvdelzi does not exceed the drug program cost of treatment with the least costly relevant comparator for the same indication. For renewal after the initial authorization, Lyvdelzi should follow the same renewal criteria as Iqirvo and Ocaliva, in accordance with the reimbursement criteria of each public drug plan for treating PBC. For ongoing renewals, physicians must confirm that the patient's initial response to Lyvdelzi achieved during the first 12 months has been maintained. Renewal of coverage should be assessed on an annual basis.

Review Background

- **Disease background:** PBC is a rare, progressive autoimmune disease that damages the bile ducts in the liver. Over time, if left untreated, PBC can lead to permanent scarring of liver tissue (i.e., cirrhosis of the liver) and can cause liver failure or death. In Canada (excluding Quebec), the estimated prevalence of PBC is 17,316 individuals.
- **Indication and reimbursement request:** Seladelpar (Lyvdelzi) has been approved by Health Canada for the treatment of PBC in combination with UDCA in adults whose PBC has an inadequate response to UDCA alone or as monotherapy in adults with UDCA intolerance. The sponsor is seeking reimbursement for this patient population.
- **Drug under review:** Seladelpar is a peroxisome proliferator–activated receptor (PPAR) delta agonist. It is available as an oral capsule. The dosage recommended in the product monograph is 10 mg daily.
- **Treatment costs:** At the submitted price of $235.33 per 10 mg oral capsule, the annual cost of seladelpar is expected to be $85,955 per patient, based on the Health Canada–recommended dosage. Seladelpar is also indicated for use in combination with UDCA in adults whose PBC has an inadequate response to UDCA alone; the cost of this regimen is expected to be $86,485 to $86,624, depending on the dose of UDCA, per patient per year.

Highlights of Input From Interested Parties

The patient group Canadian PBC Society noted the following regarding impact of the disease, unmet needs, and important outcomes:

- PBC leads to unpredictable progression, persistent symptoms, and reduced quality of life. Even when disease markers improve, the burden of fatigue, itch, and cognitive fog continues to interfere with employment, daily function, and social connection.
- The patient group input indicated a need for effective and safe treatment options that can halt disease progression, alleviate symptoms such as pruritus, improve health-related quality of life (HRQoL), and reduce treatment side effects.

The clinician group Canadian Network for Autoimmune Liver Disease 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:

- The unmet needs of patients are new treatments that would control disease activity by normalizing ALP and bilirubin levels; improve PBC-related symptoms, including pruritus; and prevent end-stage liver disease or transplant.
- The anticipated place in therapy would be second-line treatment for patients whose PBC has an inadequate response or who have UDCA intolerance in first-line treatment with UDCA. The clinical experts noted that seladelpar could be used as an add-on therapy to UDCA in patients whose PBC has an inadequate response to UDCA or as monotherapy in patients with UDCA intolerance.

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

Recommendation

With a vote of 13 in favour to 0 against, the Canadian Drug Expert Committee (CDEC) recommends that seladelpar be reimbursed for the treatment of PBC in combination with UDCA in adults whose PBC has an inadequate response to UDCA alone or as monotherapy in adults with UDCA intolerance only if the conditions listed in Table 1 are met.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Treatment with seladelpar should be reimbursed when initiated in adults who have all the following: 1.1. A PBC diagnosis as demonstrated by at least 2 of 3 diagnostic factors: 1.1.1. ALP ≥ 1.67 × ULN for ≥ 6 months 1.1.2. positive AMA titre or presence of PBC-specific ANAs 1.1.3. liver biopsy consistent with PBC. 1.2. PBC has an inadequate response to UDCA after a prior UDCA trial of ≥ 12 months, and a stable dose for ≥ 3 months, or an intolerance to UDCA treatment. An inadequate response is defined as ALP ≥ 1.67 × ULN. 1.3. Total bilirubin level of ≤ 2 × ULN.	Evidence from the RESPONSE trial demonstrated that treatment with seladelpar resulted in a clinical benefit in patients with these characteristics. The majority of patients (approximately 94%) included in the RESPONSE trial were receiving UDCA at baseline. Therefore, there is limited evidence about the safety and efficacy of seladelpar for patients with UDCA intolerance.	CDEC noted that lack of response to UDCA should be assessed after at least 12 months of treatment. The clinical experts consulted by CDA-AMC noted that 6 months is an appropriate duration for a therapeutic trial of UDCA in patients with PBC. CDEC acknowledged clinical expert input but noted that the duration for a trial of UDCA outlined in condition 1.2 aligns with the characteristics of the trial population. The recommended dosage of UDCA for first-line use is 13 mg/kg to 15 mg/kg per day, according to the European Association for the Study of the Liver 2017 guidelines. There is no universal definition of UDCA intolerance, as per the clinical expert input. CDEC agreed with the clinical experts that the determination of intolerance to UDCA can be based on clinical judgment. In the RESPONSE trial, patients with intolerance to UDCA treatment must not have received UDCA for at least 3 months before screening. Seladelpar could be initiated similarly to elafibranor and obeticholic acid as per the reimbursement criteria for each public drug plan.
2. Patients must not have a history or presence of other concomitant liver diseases.	In the RESPONSE trial, patients with clinically important hepatic decompensation were excluded. There is also no evidence to support a benefit of seladelpar treatment in patients with a	—

Reimbursement condition	Reason	Implementation guidance
	history or presence of other concomitant liver diseases because this patient population was not included in the RESPONSE trial.	
3. The maximum duration of initial authorization is 12 months.	The RESPONSE trial assessed the primary and secondary end points at week 52.	—
Renewal		
4. For renewal after initial authorization, seladelpar should be renewed in a similar manner to elafibranor and obeticholic acid as per the reimbursement criteria for each public drug plan for the treatment of PBC.	There is no evidence that seladelpar should be held to a different standard than elafibranor and obeticholic acid when considering renewal.	The clinical experts noted to CDEC that in a scenario in which a patients' ALP level did not drop below 1.67 × ULN but there was still a 15% to 20% reduction from baseline, clinicians would consider these patients to have significantly benefited from seladelpar and would continue this treatment, even though meeting both criteria (ALP < 1.67 × ULN and a decrease in ALP ≥ 15%) is preferable. The clinical experts suggested that treatment should be continued if the reduction in ALP level from baseline was at least 15%; if the reduction in ALP level from baseline is not greater than 15% to 20%, patients should switch to another treatment.
5. For subsequent renewal, the physician must provide proof that the initial response achieved after the first 12 months of therapy with seladelpar has been maintained. Subsequent renewals should be assessed annually.	Annual assessments will help ensure the treatment is used for those benefiting from the therapy and would reduce the risk of unnecessary treatment.	—
Prescribing		
6. Seladelpar must be prescribed by, or in consultation with, a specialist such as a gastroenterologist, a hepatologist, or another clinician with expertise in managing PBC.	This is meant to ensure that seladelpar is prescribed to patients for whom it is appropriate and that AEs are managed in an optimized and timely manner.	Seladelpar could be prescribed similarly to elafibranor and obeticholic acid as per the reimbursement criteria for each public drug plan.
Pricing		
7. The drug program cost of seladelpar should be negotiated so that it does not exceed the drug program cost of treatment with the least costly relevant comparator for the same indication.[a]	Based on the committee's assessment of the evidence, seladelpar is expected to have comparable clinical value as elafibranor and OCA. Therefore, the drug program cost of seladelpar should be no more than elafibranor or OCA.	—
Feasibility of adoption		
8. The economic feasibility of adoption of seladelpar must be addressed.	At the submitted price, the incremental budget impact of seladelpar is expected	—

Reimbursement condition	Reason	Implementation guidance
	to be greater than $40 million in years 1, 2, and 3.	

AE = adverse event; ALP = alkaline phosphatase; AMA = antimitochondrial antibody; ANA = antinuclear antibody; CDA-AMC = Canada's Drug Agency; CDEC = Canadian Drug Expert Committee; PBC = primary biliary cholangitis; UDCA = ursodeoxycholic acid; ULN = upper limit of normal.

[a]CDEC noted that relevant comparators are treatments reimbursed as second-line therapies for PBC (e.g., obeticholic acid).

Rationale for the Recommendation

Clinical Value

Based on the totality of the clinical evidence, CDEC concluded that seladelpar demonstrates acceptable clinical value compared with appropriate comparators (elafibranor, obeticholic acid [OCA]) in adults with PBC in combination with UDCA in patients whose PBC has an inadequate response to UDCA alone or as monotherapy in patients with UDCA intolerance. Given that seladelpar is expected to be an alternative to elafibranor or OCA, acceptable clinical value refers to at least comparable value versus elafibranor or OCA.

Evidence from 1 double-blind, phase III, randomized controlled trial (RESPONSE; N = 193) demonstrated that treatment with seladelpar resulted in added benefit in biochemical response, ALP normalization, and improved pruritus compared with placebo in adults with PBC whose PBC has an inadequate response to intolerance to UDCA. CDEC considered the between-group difference in the proportion of patients with biochemical response and ALP normalization at 12 months and the change from baseline in the pruritus numerical rating score (NRS) (in patients with a baseline score > 4, indicating moderate to severe pruritus) at 6 and 12 months to be clinically important. However, for the HRQoL outcome, there appears to be little to no difference between groups at 12 months. The effect of seladelpar on clinical outcomes, such as progression to end-stage liver disease or transplant-free survival, is unknown. There are no notable safety concerns with seladelpar when compared to placebo. The committee considered that the harms associated with seladelpar appeared consistent with the known safety profile of this drug class.

No head-to-head comparisons between seladelpar and relevant comparators were submitted for review. Although the sponsor-submitted indirect evidence (1 network meta-analysis [NMA] and 1 anchored matched-adjusted indirect comparison [MAIC]) informing the comparison of seladelpar versus OCA and elafibranor was associated with methodological limitations and imprecisions, CDEC felt the results did not demonstrate significant differences in outcomes between the treatments and found it reasonable to consider them comparable in efficacy and safety.

Further information on the committee's discussion regarding 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 seladelpar. 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 the Distinct Social and Ethical Considerations domains in the Summary of Deliberation section.

Because CDEC recommended that seladelpar be reimbursed, the committee also deliberated 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. 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

- **Efficacy of seladelpar versus placebo:** Evidence from 1 double-blind, phase III, randomized controlled trial (RESPONSE) supported an improvement with seladelpar over placebo for biochemical response, ALP normalization, and improved pruritus in adults with PBC that has an inadequate response or intolerance to UDCA. For the proportion of patients with a biochemical response and ALP normalization at 12 months, the estimated between-group differences were 41.7% (95% confidence interval [CI], 27.7% to 53.4%) and 25.0% (95% CI, 18.3% to 33.2%), respectively. For pruritus NRS (in patients with a baseline score > 4) at 6 and 12 months, the between-group difference in least squares mean change from baseline was −1.5 (95% CI, −2.5 to −0.5) and −1.8 (95% CI, −3.0 to −0.6), respectively. There appears to be little to no difference between groups in HRQoL, as assessed by the PBC-40 QoL total score, at 12 months. CDEC discussed that there was limited evidence on the effect of seladelpar in patients with UDCA intolerance (6.2% of enrolled patients). Additionally, the long-term extension (LTE) study (ASSURE) of the RESPONSE trial did not include efficacy results in the submitted interim analysis; therefore, the longer-term efficacy of seladelpar beyond 52 weeks is unknown.
- **Clinical importance of treatment effects**: Controlling disease activity, improving symptoms and HRQoL, reducing treatment side effects, and preventing progression to end-stage liver disease or transplant are important outcomes to patients and clinicians, based on the input received for this review. CDEC noted that, based on the evidence, treatment with seladelpar, compared to placebo, may result in a clinically meaningful improvement in pruritus, a common symptom that can be debilitating according to patients. CDEC further discussed that meaningful clinical outcomes

for patients with PBC, such as survival or disease progression to fibrosis or cirrhosis, were not evaluated in the RESPONSE trial. CDEC discussed the clinical importance of the primary outcome of biochemical response at 12 months (defined as ALP < 1.67 × ULN, a decrease in ALP ≥ 15%, and total bilirubin ≤ 1.0 × ULN) in the trial. Although this biochemical response is not validated, it has been used in clinical trials for patients with PBC as surrogate markers to predict the benefit of treatment in the absence of data on hard clinical outcomes. CDEC considered the improvement in biochemical response and ALP normalization to be clinically meaningful when comparing seladelpar versus placebo. However, CDEC highlighted that the correlation between the biomarkers and long-term clinical outcomes remains unknown, and that the clinical relevance of normalizing ALP in terms of longer survival, slower disease progression, and improved HRQoL in the long term still needs to be demonstrated for seladelpar.

- **Certainty of the evidence:** CDEC discussed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) assessment of selected outcomes from the RESPONSE trial and noted that the certainty of the outcomes of biochemical response and ALP normalization were considered high, while the certainty of pruritus NRS scores were considered moderate at 6 months and low at 12 months due to concerns with small sample size and low completion rates. The HRQoL outcome was considered low at 12 months due to concerns with imprecision.
- **Harms findings versus placebo:** CDEC noted that evidence from the RESPONSE trial suggested that seladelpar may result in similar treatment-emergent adverse events (TEAEs), serious TEAEs, and TEAEs of special interest (e.g., liver-, muscle-, pancreatic-, and renal-related toxicities) when compared with placebo. There is uncertainty in comparative long-term safety due to the open-label design and lack of a comparator group in the LTE study (ASSURE) of the RESPONSE trial.
- **Efficacy and harms findings versus OCA and elafibranor:** CDEC noted that elafibranor and OCA are appropriate comparators for seladelpar in the target population. Direct evidence for seladelpar versus OCA and elafibranor was not submitted. CDEC discussed the sponsor-submitted NMA and MAIC, which indirectly compared seladelpar with OCA and with elafibranor, respectively, in patients with PBC in a second-line setting. CDEC noted that the indirect evidence from the MAIC was insufficient, mostly due to serious imprecision and heterogeneity, to definitively conclude whether treatment with seladelpar differs from elafibranor in terms of biochemical response, ALP normalization, improvement in symptoms of pruritus (as an adverse event [AE]), TEAEs, or the risk of all-cause study discontinuation. CDEC noted that the results of these outcomes were also insufficient in the MAIC, except seladelpar may be related to fewer occurrences of pruritus (as an AE and of any severity) compared to OCA 10 mg. CDEC noted there was uncertainty in the treatment effect estimates from the NMA, mostly attributed to serious imprecision and heterogeneity, due to limitations of the available indirect evidence.
- **Clinical value:** Based on the submitted indirect evidence, seladelpar may be related to fewer occurrences of pruritus as an AE compared to OCA; however, there was uncertainty associated with the results due to limitations in both the NMA and MAIC, mostly attributed to serious imprecision. Notwithstanding limitations of the indirect evidence, CDEC felt the results did not demonstrate

significant differences in efficacy outcomes between the treatments and found it reasonable to consider them comparable in efficacy. Considering all the clinical evidence, CDEC accepted that seladelpar likely has at least comparable clinical value with elafibranor and OCA.

Unmet Clinical Need

- **Input on unmet clinical need in PBC:** Clinical experts consulted by CDA-AMC indicated that, although many patients with PBC respond to first-line treatment with UDCA, approximately one-third of patients treated with UDCA have PBC that inadequately responds to UDCA or have UDCA intolerance. Clinicians and patients noted that currently available second-line treatments are limited in efficacy and poorly tolerated, and that there is a need for more effective and safe treatment options that can halt disease progression; alleviate symptoms, such as pruritus; and improve HRQoL.
- **Severity of the disease:** CDEC acknowledges input from patients and clinicians that PBC is a rare, progressive, autoimmune disease associated with significant symptoms (e.g., fatigue, itch) that impact daily function and HRQoL. Disease progression typically follows a path from cholestasis to hepatic inflammation, fibrosis, cirrhosis, and potentially liver failure or hepatocellular carcinoma.
- **Place in therapy and availability of treatment options:** CDEC discussed the place in therapy of seladelpar for the treatment of PBC and noted that seladelpar can be used as a second-line treatment for patients whose PBC does not respond or inadequate responses or those who have UDCA intolerance in first-line treatment with UDCA. CDEC noted that, currently, elafibranor and OCA are relevant comparators for seladelpar, and that these drugs are available treatment options as second-line therapy in patients with PBC. Input received indicated that OCA has modest biochemical benefit, often worsens pruritus, and is contraindicated in advanced liver disease; elafibranor had inconsistent effects on pruritus relief in clinical trials and is associated with significant gastrointestinal upset.
- **Use in combination with elafibranor or OCA:** CDEC noted that there is no available data on the efficacy or safety of combining elafibranor or OCA with seladelpar; therefore, seladelpar should not be reimbursed when used in combination with elafibranor or OCA.

Distinct Social and Ethical Considerations

- **Input on unmet nonclinical need:** CDEC acknowledged the caregiver burden, psychological impact, and occupational impact of PBC despite available treatments identified by patients and clinicians.
- **Equity considerations:** The clinical experts noted that severe PBC is more prevalent, and the risk of poor outcomes is higher, among Indigenous populations and among males. CDEC discussed that the RESPONSE trial patient population lacked substantive sex and ethnic or racial diversity, particularly very few Indigenous participants; therefore, the findings of the trial may not be generalizable to these populations. Additionally, CDEC discussed that Canadian jurisdictions generally have access to all necessary diagnostics. Treatment with seladelpar requires no special laboratory assessments before

treatment or for monitoring, which reduces barriers to equitable access to care across Canadian jurisdictions and populations.

Economic Considerations

- **Health impacts of seladelpar versus relevant comparators:** Due to methodological limitations and imprecision associated with the sponsor's NMA and MAIC, CDA-AMC could not draw definite conclusions on the relative efficacy and safety of seladelpar compared to OCA and to elafibranor. Based on the NMA, seladelpar may be related to fewer occurrences of pruritus as an AE compared to OCA; however, this finding is highly uncertain. Definite conclusions about the comparative harms and impact on Global HRQoL could not be made because these outcomes were not assessed in the ITCs.
- **Cost of seladelpar versus relevant comparators:** Based on the sponsor's submitted economic evaluation, seladelpar is expected to increase health care system costs if reimbursed by public drug plans. Drug acquisition costs were the primary driver of incremental costs between seladelpar and comparators. Although pruritus was identified as an important outcome for patients with PBC, the sponsor's analysis indicated that pruritus management did not contribute meaningfully to incremental costs between treatments.
- **Key findings of the economic evaluation:** The cost-effectiveness of seladelpar compared to elafibranor and to OCA is uncertain. Based on evidence reviewed for this submission, there is no robust evidence to suggest that seladelpar provides greater health benefit than elafibranor or OCA. If there are no differences in health outcomes between seladelpar and OCA or elafibranor, then the total cost of seladelpar to the health system should not exceed that of OCA or elafibranor for the treatment of adult patients with PBC, either in combination with UDCA or as monotherapy.
    - The cost-effectiveness of seladelpar with or without UDCA compared to UDCA monotherapy in patients with UDCA intolerance and to best supportive care in patients with UDCA intolerance is uncertain due to lack of long-term evidence on the impact of seladelpar on pruritus, HRQoL, transplant-free survival, and overall survival. However, UDCA monotherapy and best supportive care alone may not be the most appropriate comparators for this indication.
- **Certainty of the evidence:** The sponsor-conducted MAIC and NMA used to compare seladelpar with elafibranor and with OCA did not demonstrate significant differences in efficacy outcomes between the treatments. Additionally, the lack of direct evidence on the effect of seladelpar on long-term outcomes, such as transplant-free and overall survival, introduced additional uncertainty in the predicted benefit of seladelpar compared to elafibranor or OCA.
- **Other considerations:** CDEC noted that availability of elafibranor for the treatment of PBC is uncertain. Elafibranor received a positive reimbursement recommendation for the treatment of PBC in combination with UDCA in adults whose PBC has an inadequate response to UDCA or as monotherapy in adults with UDCA intolerance. It is currently in active pCPA negotiations.

Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimated that, by year 3 of reimbursement, 8,066 patients would be eligible for treatment with seladelpar with or without UDCA, of whom 4,033 are expected to receive seladelpar with or without UDCA. It is estimated that the budget impact of reimbursing seladelpar with or without UDCA for use in the indicated population will be $770 million over the first 3 years compared to the amount currently spent on comparators. The expenditure on seladelpar with or without UDCA over this period is predicted to be $785 million. The estimated budget impact was driven by market share assumptions and the estimated population of eligible patients, both of which were highly uncertain. Market share assumptions represent a key source of uncertainty in this budget impact analysis due to uncertainty in elafibranor listing status. The economic feasibility must be addressed because the incremental budget impact of reimbursing seladelpar with or without UDCA is predicted to be greater than $40 million in year 1, year 2, and year 3, and the magnitude of uncertainty in the estimated budget impact.

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 seladelpar (refer 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, Canadian PBC Society (refer to the Patient and Clinician Group Input document)
- input from 1 clinician group, Canadian Network for Autoimmune Liver Disease (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 PBC 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, Dr. 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: November 26, 2025

Regrets: Three expert committee members did not attend.

Conflicts of interest: None

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Questions or requests for information about this report can be directed to Requests@CDA-AMC.ca.