

SUBMITTED ELECTRONICALLY

June 24, 2025

Washington Prescription Drug Affordability Board
Washington State Health Care Authority
PO Box 42716
Olympia, WA 98504-2716

Re: Inclusion of Epclusa on Affordability Review Shortlist

Dear Members of the Prescription Drug Affordability Board (“the Board”):

I am writing on behalf of Gilead Sciences, Inc. (“Gilead”), in response to the Board’s recent inclusion of EPCLUSA® on the shortlist of medicines for potential selection for affordability review. Epclusa is a prescription medicine used to treat adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1-6 infection with or without cirrhosis (compensated), or with decompensated cirrhosis for use in combination with ribavirin.¹ Left untreated, chronic hepatitis C can cause serious health problems including liver disease, liver failure, liver cancer, and even death. Chronic hepatitis C is a leading cause of liver cancer and the leading cause of liver transplants in the United States.² Washington has a goal to end the state’s HCV epidemic by 2030³ and Epclusa, which offers a 98% overall cure rate in studies of genotype 1-6 patients without cirrhosis or with compensated cirrhosis,⁴ plays a role in helping to reach that goal. We are concerned that the Board has identified Epclusa for possible affordability review based on limited data that is not representative of actual experiences of patients and Washington state. These data lead to inaccurate conclusions about the affordability of Epclusa and the potential impacts of any affordability reviews to be completed. Such a review could have unintended consequences for patients, including disrupting access to medicines on which they rely.

Gilead is a research-based biopharmaceutical company that discovers, develops, and provides innovative medicines in areas of unmet medical need. We endeavor to transform and simplify care for people with life-threatening illnesses around the world. Our portfolio of products and pipeline of investigational medicines includes treatments for liver diseases, human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), cancer, inflammatory and respiratory diseases, and cardiovascular conditions. We are committed to ensuring that people have access to our medicines through our pioneering patient support and access programs.

¹ https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf

² <https://www.cdc.gov/hepatitis-c/about/index.html>

³ <https://doh.wa.gov/sites/default/files/2023-05/2023HepCFreeWaProgressReportQ1.pdf>

⁴ Gilead data on file

The following comments expand on these three points:

1. The published data dashboard overestimates the number of patients in Washington who use Epclusa.
2. The published data dashboard overlooks the many ways in which Epclusa is affordable, overestimates spending on Epclusa, and does not acknowledge other, existing Washington programs that help patients with HCV.
3. The Board’s Advisory Group did not recommend reviewing Epclusa and, according to the statute, input from the Advisory Group must be considered.

The Board’s published data overestimates how many people were treated with Epclusa in Washington and HCV treatment costs have already been substantially reduced via the state’s prior actions and through market competition. Accordingly, Gilead respectfully submits that conducting an affordability review of Epclusa would not be a good focus of the Board’s resources and could lead to disrupted access and other unintended consequences for the few patients accessing Epclusa in Washington.

1. The published data dashboard overestimates the number of patients in Washington who use Epclusa.

The number of Washington patients using Epclusa in 2022 as reported on the PDAB’s public dashboard exceeds both Gilead’s internal data as well as reasonable estimates from publicly available literature, raising concerns about the validity of the dashboard data. Compared to data on file at Gilead and publicly available literature, it appears that the dashboard overestimates actual patient counts of Epclusa by up to a factor of four, substantially misleading the public and the PDAB about the potential impact of an affordability review.

Table: Number of Washington State Patients Using Epclusa, 2022

Source	Count
PDAB Dashboard	1,262 individuals
Gilead Internal Data	~320 individuals
Public Literature Analysis	~350-530 individuals

Below, we walk through estimates of the number of patients using Epclusa in Washington based on publicly available literature. These modeling calculations are also described in the attached table.

- Washington state reported approximately 3,400 newly diagnosed HCV patients in 2022.⁵ Three in five newly diagnosed individuals were enrolled in Medicaid, and 65% of those newly diagnosed Medicaid enrollees received HCV treatments.⁶
- Among Medicaid enrollees, most receive AbbVie’s Mavyret for HCV treatment. As part of its contracted payment model for HCV medications, Washington selected Mavyret as the preferred medicine for HCV treatment and does not impose any prior authorization requirements for its preferred medicine.⁷ Non-preferred HCV medications, including Epclusa, are covered only when medically necessary and are considered on a case-by-case basis when treatment with Mavyret is not indicated.⁸ Furthermore, requests for brand-name medications that also have a generic equivalent available, like Epclusa, must meet certain additional criteria.⁹ As a result, few Medicaid enrollees in the state use Epclusa.¹⁰ Indeed, when Epclusa is prescribed, it is often the best medical option based on the patient’s specific circumstances.
- For non-Medicaid enrollees, it is estimated that 910-1,400 newly diagnosed individuals received HCV treatment in 2022. Given the availability of generics, authorized generics, and other branded competitors for HCV treatment, only a fraction of these patients receive Epclusa. Using a national market share estimate, which itself is likely a high estimate of Epclusa market share given the implementation of the state’s contracted payment model, between 340-520 non-Medicaid enrollees are estimated to have used Epclusa in the State in 2022, far below the number put forward by the state.

2. The published data dashboard ignores the many ways in which Epclusa is affordable, overestimates spending on Epclusa, and does not acknowledge other, existing Washington programs that help patients with HCV.

The published dashboard’s cost estimates overstate actual Epclusa costs for several reasons. To start, the dashboard reports spending amounts that do not reflect actual cost burdens. For example, plan-paid amounts represent amounts paid by the plan or PBM to pharmacies and do not account for manufacturer rebates that are paid to the plan at a later point in time and reduce the plan’s total cost for the medicine. Moreover, member paid amounts (“out-of-pocket costs”) ignore secondary payers and other sources of financial assistance, such as patient assistance programs offered by manufacturers or other third parties. Patient assistance programs may help reduce or even eliminate a patient’s cost-sharing burden, depending on the program and the

⁵ Assessment Unit, Office of Infectious Disease, Washington State Department of Health. Hepatitis C Data Snapshot: Washington State 2022. <https://doh.wa.gov/sites/default/files/2025-02/150307-HepatitisC-DataSnapshotWashingtonState2022.pdf>

⁶ Washington State Health Care Authority. Washington Apple Health Hep C Free Treatment Dashboard. <https://hca-tableau.watech.wa.gov/t/51/views/HepCFreeTreatmentDashboard/TreatmentDashboard>

⁷ Washington State Health Care Authority (2019). Antivirals – Hepatitis C Treatment. <https://www.hca.wa.gov/assets/billers-and-providers/antiviral-hepatitis-C.pdf>

⁸ Washington State Health Care Authority (2019). Antivirals – Hepatitis C Treatment. <https://www.hca.wa.gov/assets/billers-and-providers/antiviral-hepatitis-C.pdf>

⁹ Washington State Health Care Authority (2025). Brands with Biosimilars or A-rated Generics. <https://www.hca.wa.gov/assets/billers-and-providers/NC-0001-MultisourceBrands.pdf>

¹⁰ Gilead data on file.

patient’s eligibility. As a result, the published amounts overestimate actual health system and patient spending on Epclusa.

Other data sources show that net costs per HCV treatment are significantly lower than figures reported in the PDAB dashboard. Milliman estimates that, by mid-2020, the average net cost of HCV treatment was between \$11,500 and \$17,000.¹¹ Greater competition among treatments and the introduction of authorized generics have lowered treatment costs by as much as 86% over a seven-year period.¹² For example, since 2019, an authorized generic version of Epclusa has been available at a substantially lower wholesale acquisition cost, expanding patient access and affordability.¹³ The dashboard does not provide enough transparency to understand how it arrives at its figures, and thus, such data integrity issues may lead to misguided conclusions for affordability review.

Importantly, Washington state has developed programs to help make HCV treatment more affordable to Washingtonians, and has already made progress in reducing HCV medication costs. In 2019, the state launched a contracted “subscription” model that guarantees access to HCV medications while reducing the financial burden on the state.¹⁴ Given that three in five newly diagnosed HCV patients in the state are Medicaid beneficiaries who already benefit from the State’s contracted pricing model—and many others access the same pricing in state facilities or as public employees—few Washington residents could potentially experience a change in their costs as a result of an affordability review of Epclusa.¹⁵ Given the state’s progress to date and the many other resources available in Washington for patients with HCV, the PDAB should exclude Epclusa from affordability review.

3. The Board’s Advisory Group did not recommend reviewing Epclusa and, according to the statute, input from the Advisory Group must be considered.

The PDAB statute lists three factors that must be considered when selecting medicines for an affordability review.¹⁶ One of those factors is “[i]nput from the relevant advisory groups.”¹⁷ As provided at the January 2025 PDAB meeting, none of the advisory group members recommended reviewing Epclusa.¹⁸ The Advisory Group’s recommendation is well considered given the affordability of Epclusa in Washington, the programs that exist to help patients with HCV, and the specific nature of HCV treatment. In light of the statutory requirement to consider

¹¹ Susan Silseth & Hans Shaw, Milliman (2021). Analysis of Prescription Drugs for the Treatment of Hepatitis C in the United States. <https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states>

¹² Susan Silseth & Hans Shaw, Milliman (2021). Analysis of Prescription Drugs for the Treatment of Hepatitis C in the United States. <https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states>

¹³ Gilead (2018). Gilead Subsidiary to Launch Authorized Generics of Epclusa and Harvoni for the Treatment of Chronic Hepatitis C.

¹⁴ Washington State Health Care Authority (2019). Eliminating Hepatitis C in Washington State. <https://www.hca.wa.gov/assets/program/HCA-HCV-elimination-breif.pdf>

¹⁵ Washington State Health Care Authority. Washington Apple Health Hep C Free Treatment Dashboard. <https://hca-tableau.watech.wa.gov/t/51/views/HepCFreeTreatmentDashboard/TreatmentDashboard>

¹⁶ See RCW § 70.405.040(1)

¹⁷ *Id.* 70.405.040(1)(b)

¹⁸ <https://www.hca.wa.gov/assets/program/advisory-group-and-ICER-drug-selection-summary.pdf>



input from the Advisory Group, it would be improper for the Board to disregard the Advisory Group's unanimous conclusion that Epclusa should not be selected for an affordability review.

The net cost of HCV treatment has declined dramatically over time due to new entrants like Asegua Therapeutic's authorized generic for Epclusa, along with increased market competition leading to large rebates. Washington has further lowered costs in the state by implementing a contracted payment model for a specific HCV medicine. Affordability reviews for HCV medications like Epclusa are unlikely to help – and could actually hinder – the state from achieving its goals to end the HCV epidemic by 2030. In fact, such a review could have unintended consequences for patients, including disrupting access to medicines on which they rely. For these reasons, we urge the Board not to select Epclusa for affordability review. If you have any questions or wish to notify Gilead about future PDAB actions, please do not hesitate to contact Abra Yeh at abra.yeh@gilead.com.

Sincerely,

Rekha Ramesh
Vice President, U.S. Policy
Government Affairs
Gilead Sciences, Inc.

Attachment: Estimates of Patients Using Epclusa in Washington State, 2022

Parameter	Estimate	Source	Notes
1. Number of patients diagnosed with HCV	3,400	Washington State Department of Health ¹⁹	Includes newly diagnosed acute and chronic HCV patients
2. Number of patients with HCV enrolled in Medicaid	2,000	Washington State Health Care Authority ²⁰	
3. Number of patients with HCV enrolled in Medicaid who received treatment	1,300	Washington State Health Care Authority ²	
4. HCV treatment rate for Medicaid enrollees	65%	Calculation	Row 3 divided by Row 2
5. Number of patients with HCV enrolled in Medicaid who received Epclusa	~10	Gilead claims data	Mavyret is preferred in Medicaid
6. Number of non-Medicaid patients with HCV	1,400	Calculation	Row 1 minus Row 2
7. HCV treatment rate for non-Medicaid enrollees	65%-100%	Assumption	Assume low estimate equivalent to HCV treatment rate for Medicaid enrollees
8. Number of non-Medicaid patients with HCV who received treatment	910-1,400	Calculation	Row 7 multiplied by row 6
9. Epclusa market share for HCV medications	~37%	Literature ²¹	Assume Epclusa market share for non-Medicaid enrollees in WA is equivalent to national all-payer market share.
10. Number of non-Medicaid HCV patients who received Epclusa in WA	340-520	Calculation	Row 8 multiplied by row 9
11. Total number of HCV patients who received Epclusa in WA	350-530	Calculation	Row 5 plus row 10

¹⁹ Assessment Unit, Office of Infectious Disease, Washington State Department of Health. Hepatitis C Data Snapshot: Washington State 2022. <https://doh.wa.gov/sites/default/files/2025-02/150307-HepatitisC-DataSnapshotWashingtonState2022.pdf>

²⁰ Washington State Health Care Authority. Washington Apple Health Hep C Free Treatment Dashboard. <https://hca-tableau.watech.wa.gov/t/51/views/HepCFreeTreatmentDashboard/TreatmentDashboard>

²¹ Susan Silseth & Hans Shaw, Milliman (2021). Analysis of Prescription Drugs for the Treatment of Hepatitis C in the United States. <https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states>