

Manufacturer Information Submission Form for Affordability Review: [Drug Name]

**Washington State Health Care Authority
Prescription Drug Affordability Board (PDAB)**

Cherry Street Plaza
626 8th Avenue SE
Olympia, WA 98501
Phone: 360-725-0944
Email: hca_wa_pdab@hca.wa.gov
hca.wa.gov

[Month Day Year]

Table of Contents

Instructions	4
I: Background Information	5
1. Generic Name (optional)	5
2. Brand Name (optional)	5
3. Drug Class (optional)	5
4. National Drug Code(s) (NDC)	5
5. Indications and Approval Date by the Food and Drug Administration (FDA) (optional)	5
6. Orphan Drug Approval Status (optional)	6
7. Drug Shortage Status (optional)	6
8. Manufacturer Contact Information	6
II: Drug Efficacy and Safety (optional)	7
1. Efficacy and Safety	7
Indication 1: [Indication]	7
Indication 2: [Indication]	7
2. Summary Table of Efficacy and Safety	8
III: Drug Price Information	9
1. Wholesale Acquisition Cost (WAC) (optional)	9
2. National Average Drug Acquisition Cost (NADAC) (optional)	9
3. Average Manufacturer Price (AMP)	9
4. The Most Current WAC for a Therapy Duration	9
5. Discounts	9
6. Rebates	10
7. Other Price Concessions (if applicable)	10
8. Manufacturer Net Price of Drug Purchases After All Discounts, Rebates, and Other Price Concessions	10
IV: Manufacturing, Delivery, and Administration Cost	11
1. Cost of Research and Development (R&D)	11
R&D Funding Sources	11
R&D Cost Descriptions	11
2. Recurring Cost of Drug Manufacturing	12
3. Cost of Delivering the Drug to Patients (if applicable)	12
4. Cost of Administering the Drug to Patients (if applicable)	13
5. Other Administrative Costs (if applicable)	13
V: Price Effect on Consumers' Access to the Drug in WA	14
1. Prevalence and Incidence of Indicated Condition(s) in the State	14

2. Sales Volume in the Nation vs. the State	14
VI: Manufacturer Patient Assistance Program and Coupons.....	15
1. Patient Assistance Program (PAP) Availability and Patient Eligibility	15
2. PAP-Approved Product Quantity and Dollar Value	15
3. Coupon Availability	15
4. Coupon Limitations	15
VII: Therapeutically Equivalent Drugs (if applicable).....	16
VIII: Price and Availability of Therapeutic Alternatives	17
1. Therapeutic Alternatives.....	17
Indication 1: [Indication]	17
Indication 2: [Indication]	19
2. Same-Class Drug Not Considered Therapeutic Alternative.....	20
IX: Cost-Effectiveness Analysis.....	21
1. Cost-Effectiveness Analysis	21
Indication 1: [Indication]	21
Indication 2: [Indication]	22
2. Interactive Model for the Cost-Effectiveness Analysis.....	22
X: Additional Information from the Drug Manufacturer	24
1. Exclusivity and Patent Expiration Date (if applicable)	24
2. Relevant Information on Exclusivity and the Patent Expiration Date (if applicable):	24
3. Life-Cycle Management.....	24
4. Market Information	24
Indication 1: [Indication]	24
Indication 2: [Indication]	28
5. Interactive Model for the Budget Impact Analysis.....	31
6. Additional Information for Drug Pricing (if applicable).....	33
XI: Off-Label Usage of the Drug (if applicable).....	34
1. Summary Table for Off-Label Usage	34

Instructions

The manufacturer is required to submit all requested information unless a section is marked “optional.” For “optional” sections, you may provide the requested information or choose to have the Agency extract and interpret information from public-facing sources, such as FDA websites, First Databank and/or MediSpan drug database. A checkbox is available for the manufacturer to indicate the choice under each “optional” section.

If the manufacturer is unable to submit any information in a section not marked “optional,” please specify the information you are omitting and include a reasonable justification for omitting the requested information under the applicable section(s). Information should be omitted only if the submitter does not have the information and if the manufacturer has no way to collect, gather and/or estimate the information; the Agency may make its own estimates if information is omitted.

Details of requested information are listed under each section in italics. Certain sections require submission of data with accompanying excel template sheets; please review detailed instructions listed under each section heading for completing the data submission. A separate data submission guide is also available to assist with the formatting of the data.

Action items are highlighted in yellow for the submitter throughout this form. Remove the highlights once the actions are completed.

Provided tables on this form should be used to fill in the requested information. Provided tables can be modified by adding or deleting rows as necessary on this form.

If a selected drug for the affordability review has only one approved indication, extra parts for “Indication 2” can be deleted. If a selected drug for the affordability review have more than two approved indications, additional sections should be created by copying the formatting of “Indication 2” to provide information on all approved indications. Similarly, bullet points can be removed or added as needed to provide all requested information.

I: Background Information

1. Generic Name (optional)

Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

[generic name]

2. Brand Name (optional)

Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

[brand name (this “Brand Name” subsection can be omitted if the selected drug for affordability review is a generic drug)]

3. Drug Class (optional)

- List all drug classes if the drug belongs to multiple therapeutic classes, based on FDB HIC3 in the context of a Clinical Formulation ID (GCN_SEQNO).

Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

- [Class 1]
- [Class 2]

4. National Drug Code(s) (NDC)

- List all applicable NDCs for the PDAB Affordability Review

- Include information on dosage, formulation, package size, and the approximate share of revenue that each NDC represents relative to total revenue from sales of the drug in the United States over the most recent 12-month period for each NDC.

- [NDC 1]: [dosage, formulation, package size, approximate share of revenue]
- [NDC 2]: [dosage, formulation, package size, approximate share of revenue]

5. Indications and Approval Date by the Food and Drug Administration (FDA) (optional)

- List FDA-approved indications of the drug and the FDA approval date(s).

- List indications(s) for which the manufacturer is currently seeking approval. In this case, write “under review” if the manufacturer is currently seeking approval.

Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

- [Indication 1]: [approval date, MM/DD/YYYY]
- [Indication 2] (Write “under review” if the manufacturer is currently seeking approval.)

6. Orphan Drug Approval Status (optional)

- List of indications with orphan drug approval status if any.

Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

- [Orphan Indication 1]: [orphan status approval date, MM/DD/YYYY]
- [Orphan Indication 2] (Write “under review” if the manufacturer is currently seeking approval.)

7. Drug Shortage Status (optional)

- Provide information on drug shortage status in the provided table, based on the list published by the FDA, as well as any additional information available to the manufacturer.

Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

NDC	Formulation	Strength	Estimated Shortage Duration	Related Information	Shortage Reason

8. Manufacturer Contact Information

- Provide the name and contact information of an individual who will be able to answer questions regarding the information submitted to the Health Care Authority by filling in the provided table.

Contact Information	
Name of Manufacturer	
Contact Name	
Contact Title	
Email Address	
Telephone Number	
Street Address	
City	
State	
Zip	
Washington (WA) Drug Price Transparency (DPT) Number (if applicable)	

II: Drug Efficacy and Safety (optional)

- This section is intended to give the Board and the public general background information on the reviewed drug by succinctly summarizing what outcomes were measured for the drug approval, how well the medication works, and what safety concerns exist.
 - Include information for each indication if the drug has multiple indications.
 - Word limit is 1000 words per indication. Any additional details can be submitted as supplemental information if desired by manufacturers.
 - Include in-text numbering citations and a list of full reference information, using an AMA format.
 - Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.
- Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

1. Efficacy and Safety

Indication 1: [Indication]

Clinical Efficacy

- Briefly describe treated condition and the outcome measures.
- Describe clinical efficacy. Summarize data from clinical trials and real-world evidence (RWE) to describe the drug efficacy. Please explicitly list the measured outcomes.
- Do not include any interim data, preliminary data analyses, and publications without a full description of methodology to assess the study quality and potential bias (e.g. preliminary reports, conference posters). Summary of preliminary data analyses is permissible for an ongoing study as an exception.

[Response]

Safety Profile

- Describe drug safety. Common adverse drug reactions (ADR with $\geq 10\%$ frequencies in clinical trials); ADRs observed with statistical significance in clinical trials, any notable signals from RWE, post-market surveillance concerns, as well as any black-box warning, should be summarized.

[Response]

Indication 2: [Indication]

Clinical Efficacy

[Response]

Safety Profile

[Response]

2. Summary Table of Efficacy and Safety

Indication	Efficacy	Safety

References:

[References]

III: Drug Price Information

1. Wholesale Acquisition Cost (WAC) (optional)

- Provide data from the last five years or the five most recent price changes, whichever is longer.
 - **Submit via the template excel sheet "WAC."**
- Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

2. National Average Drug Acquisition Cost (NADAC) (optional)

- Provide data from the last five years.
 - **Submit via the template excel sheet "NADAC."**
- Check this box if the submitter chooses to have the Agency extract and interpret information from public-facing sources.

3. Average Manufacturer Price (AMP)

- Provide data from the last five years or the five most recent price changes, whichever is longer.
- **Submit via the template excel sheet "AMP."**

4. The Most Current WAC for a Therapy Duration

- For the drug indicated for acute condition(s), provide 1) calculated number of drug units and 2) current WAC for a course of treatment via the excel template sheet.
- For the drug indicated for chronic condition(s), provide 1) calculated number of drug units and 2) current WAC for a year of treatment (i.e. 365 days of therapy) via the excel template sheet.
- If a drug has multiple indications with varying therapy duration, calculation for each indication is requested.
- Each indication should be listed on separate rows of the template excel sheet.
- **Submit via the template excel sheet "WAC for Therapy Duration."**
- Describe rationale behind the estimates and any assumptions for the calculation, including but not limited to the number of units per dose, the number of doses per day, the number of days for the duration (or 365 if chronic), how weight-based or BSA-based dosing was calculated, how loading vs maintenance dose was incorporated. (500-word max).

[Response]

5. Discounts

- Provide data from the last five years or the five most recent price changes, whichever is longer.
- Include pricing information for the Federal Supply Schedule (FSS), BIG4 [the Department of Veterans Affairs (VA), the Department of Defense (DOD), U.S. Coast Guard, the Public Health Service (PHS)], VA National Contracts (NC) price, the 340B ceiling price, and the Medicare maximum fair price.
- All discount types listed above are required.
- If no discounted pricing available, type "0.00" for the "Discount Amount Per Unit" column of the template.
- **Submit via the template excel sheet "Discounts."**
- Submit a narrative to supplement information in the data table, such as any relevant contract term (e.g. how long the current discount is in effect) (500-word max).

[Response]

6. Rebates

- Provide data from the last five years or the five most recent price changes, whichever is longer.
- Submit via the template excel sheet "Rebates."
- Submit a narrative to clarify how estimates are made for different NDCs when rebates are offered as a bundle for multiple products) (500-word max).

[Response]

7. Other Price Concessions (if applicable)

- Provide data from the last five years or the five most recent price changes, whichever is longer.
- Submit via the template excel sheet "Other Price Concessions."

8. Manufacturer Net Price of Drug Purchases After All Discounts, Rebates, and Other Price Concessions

- Provide data from the last five years or the five most recent price changes, whichever is longer.
- For the "Entity," both discounted entities mentioned on earlier section (e.g. VA, Medicare) and commercial payers are requested.
- Submit via the template excel sheet "Manufacturer Net Price."
- Submit a narrative to describe how the net price was calculated (500-word max).

[Response]

IV: Manufacturing, Delivery, and Administration Cost

1. Cost of Research and Development (R&D)

R&D Funding Sources

- **List any external funding sources, grants, and/or tax credits** (e.g. any federal and/or state government-related grants, funding from non-profit organizations, public and private foundations), associated with the process of bringing the drug to the market including research, discovery, clinical trials, and the FDA review and approval process, with amounts in a provided table. Include whether any FDA priority review voucher was received and, if sold, the revenue generated from the voucher's sale.
- If the drug candidate was purchased from another organization or institution during the R&D process, the original funding sources should be identified (e.g. academic funding, federal funding supporting the original developer) as much as possible.

Source	Year	Value (USD)

R&D Cost Descriptions

- Describe and provide data on the R&D costs (i.e. costs incurred for the discovery, clinical trials, and the FDA review and approval process).
- 1000-word limit for the narrative (any additional details can be submitted separately as supplemental information if desired by the manufacturer).
- No need to include cost information submitted under separate sections (e.g. manufacturing costs etc. will be submitted to the separate sections; no need to include this information under the R&D section)
- If the drug was purchased from another company, organization, or institution after approval, include the purchase amount in a provided table.
- **Include a comment on whether the R&D cost was recovered from the drug market.** If the R&D cost has not been recovered yet, estimate the remaining percentage, as well as the rate of recovery in the future years. Include details on how the numbers are estimated (e.g. any adjustments made for inflation, discounting).
- Provide a summary table to illustrate the breakdown of R&D costs, specifying the attributes, dates, and amounts (this table does not count toward the 1000-word limit; the table should be formatted to effectively communicate the breakdown of the R&D costs to the Board).
- Describe how the costs were estimated or calculated as part of the requested narrative.

[Response]

Acquisition Cost

Requested Information	Response
Name of entity from which you acquired the drug	
Acquisition date	
Estimated acquisition cost for the drug (USD)	

Description of the methodology used to calculate the above estimate for the drug

Acquisition Details (e.g. whether the drug was acquired through the merger with or acquisition of another entity and/or if any other drugs or assets were acquired by your organization from the entity)

R&D Summary Table

Attribute	Date (MM/DD/YYYY)	Amount (USD)

2. Recurring Cost of Drug Manufacturing

- Provide data on recurring drug manufacturing costs from the last five years. This section asks for information on recurring costs needed to supply the drug (e.g. raw materials, factory labor and overheads). Any costs related to the research and development will be asked under a separate section and should not be included under this section.
- **Submit via the template excel sheet "Manufacturing Recurring Cost."**
- Describe the breakdown of the manufacturing costs with amounts for the most recent year.
- Include a narrative of how variable the production cost has been between years (e.g. manufacturing site transition, new technology adaptation, shortage of raw materials). Any additional insights to supplement the data table would be helpful.
- Include a narrative of what changes are expected in the future if any.
- Include projected future manufacturing costs if any significant change is expected in the manufacturing costs.
- The narrative/descriptions are limited to 1000 words. (Any additional details can be submitted separately as supplemental information if desired by the manufacturer.)

[Response]

3. Cost of Delivering the Drug to Patients (if applicable)

- Provide data on delivery costs if patients need to have the drug delivered via a special mechanism from the manufacturer, resulting in any costs to patients.
- Include yearly averages of the total drug delivery cost for completion of therapy duration from the last five years.
- For the drug indicated for chronic condition(s), the cost should be calculated for a 365-day therapy.
- For the drug with multiple indications, information is requested for each indication.
- Each indication should be listed on separate rows of the template excel sheet.

PDAB Affordability Review: [Drug Name]
[Month Day Year]

- **Submit via the template excel sheet “Delivering Cost.”**
- Describe what items are included as drug delivery cost as a narrative.
- Include what changes are expected in the future if any.
- For the narratives, the word limit is 500 words.

[Response]

4. Cost of Administering the Drug to Patients (if applicable)

- Provide data on patients’ cost related to drug administration if patients require any additional supplies to administer the drug (e.g. syringes, separate solution vials).
- Information from the last five calendar years is requested.
- For the drug indicated for chronic condition(s), the cost should be calculated for a 365-day therapy.
- For the drug with multiple indications, information is requested for each indication.
- Each indication should be listed on separate rows of the template excel sheet.
- **Submit via the template excel sheet “Administering Cost.”**
- Describe what items are included as administration cost as a narrative.
- Include what changes are expected in the future is requested if any.
- For the narratives, the word limit is 500 words.

[Response]

5. Other Administrative Costs (if applicable)

- Provide data on any other costs related to the production and delivery of the drug.
- Include yearly averages of the other costs for completion of therapy duration from the last five calendar years.
- **Submit via the template excel sheet “Other Admin Costs.”**
- Describe what items are included as other administrative costs as a narrative.
- Include how the cost is calculated or estimated.
- Include what changes are expected in the future is requested if applicable.
- For the narratives, the word limit is 500 words.

[Response]

V: Price Effect on Consumers' Access to the Drug in WA

1. Prevalence and Incidence of Indicated Condition(s) in the State

- Provide the prevalence and incidence data of the indicated condition(s) in the State during the previous five calendar years.
- Submit data via the template excel sheet "Prevalence and Incidence."
- Submit an estimate for the most recent year if studies providing exact numbers are not available. If making an estimate, describe the method (500-word limit).
- Include a reference(s) in the AMA style.

[Response]

Reference:

[Reference]

2. Sales Volume in the Nation vs. the State

- Provide data on drug sales volume for WA and the national from the most recent year.
- Provide estimates of the number of patients receiving the drug if available.
- Provide estimates of patients' OOP cost for the treatment duration if available.
- For chronic conditions, estimates should be made for one-year therapy.
- Submit via the template excel sheet "Nation vs WA."
- Describe the method for the estimates. (1000-word limit).

[Response]

VI: Manufacturer Patient Assistance Program and Coupons

1. Patient Assistance Program (PAP) Availability and Patient Eligibility

- Provide data on the patient assistance program (PAP). (Any information related to coupons is collected under a later section, so do not include coupon-related data under this current section.)
- Data is requested for the previous five calendar years.
- For the drug indicated for chronic condition(s), therapy duration is considered 365 days.
- For the drug with multiple indications, information is requested for each indication.
- Each indication should be listed on separate rows of the template excel sheet.
- **Submit data via the template excel sheet "PAP Eligibility."**
- Submit any supplemental narrative (500-word limit).

[Response]

2. PAP-Approved Product Quantity and Dollar Value

- Provide data on total numbers of drugs requested to and approved by the PAP from the last five calendar years.
- Provide data on dollar values equivalent to cover the number of drug units requested to and approved by the PAP from the last five calendar years.
- **Submit data via the template excel sheet "PAP Qty & Dollar."**
- Submit any supplemental narrative (500-word limit).

[Response]

3. Coupon Availability

- Submit data on coupons from the last five calendar years. (Any information related to the PAP is collected under an earlier section, so do not include PAP-related data under this current section.)
- For the drug indicated for chronic condition(s), the therapy duration is considered 365 days.
- For the drug with multiple indications, information is requested for each indication.
- Each indication should be listed on separate rows of the template excel sheet.
- **Submit data via the template excel sheet "Coupon."**
- Submit any supplemental narrative (500-word limit).

[Response]

4. Coupon Limitations

- List limitations to use coupons.
- Include all limitations existing for use of coupons, such as any patient ineligibility (those enrolled in Medicare, Medicaid, or other government insurance), the number of refills or days of supply. (500-word limit)

[Response]

VII: Therapeutically Equivalent Drugs (if applicable)

- Based on WAC 182-52-0010, "Therapeutic equivalent" means a drug product of the identical base or salt as the specific drug product prescribed with essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.
- Provide data on availability of generic or biosimilar drugs for a brand drug based on FDA orange or purple book respectively.
- Submit generic drug information via the template excel sheet "Orange Book." (if applicable)
- Submit biosimilar drug information via the template excel sheet "Purple Book." (if applicable)

VIII: Price and Availability of Therapeutic Alternatives

1. Therapeutic Alternatives

- Based on WAC 182-52-0010, "Therapeutic alternative" means a drug product that may contain a different chemical or biological structure than the drug prescribed and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to individuals in a therapeutically equivalent dose.
- Describe all drugs considered a therapeutic alternative. All drugs within the same therapeutic class, as well as drugs from different therapeutic classes evaluated within guidelines for treating the same disease and the same severity, should be evaluated under this section.
- For the "Guideline recommendations," all guidelines considered current and intended for the US population should be included.
- For the "Comparison of Cost," WAC cost should be estimated for a therapy duration, not including any rebates and discounts. For chronic conditions, the cost should be calculated for a 365-day therapy. The cost estimation methodology should be applied to all therapeutic alternatives under this section.
- For the "Comparison of Efficacy," descriptions of comparative data are requested based on head-to-head trials if any. If no head-to-head trials exist, data derived from individual clinical studies conducted in a similar patient population are requested. Data from clinical trials and real-world evidence (RWE) can be used. However, any interim data, preliminary data analyses, and publications without a full description of methodology to assess the study quality and potential bias are not to be included (e.g. preliminary reports, conference posters).
- For the "Comparison of Safety," create a table listing common side effects from clinical trials and RWE, black-box warning, and any concerning post-market surveillance signals with individual expected rate of occurrences.
- Summarize information from domestic and foreign Health Technology Assessment (HTA) organizations and systematic reviews published in peer-reviewed journals, as part of the following "Summary Tables of Therapeutic Alternatives" section (i.e. summary table is requested). If the review from the ICER is available, the summary of reviews from other HTA organizations abroad is optional.
- The word limit for each therapeutic alternative is 1000 words. Inclusions of tables and/or diagrams are recommended to illustrate the information effectively (and the tables/diagrams do not count toward the word limit).
- Include in-text numbering citations and a list of full reference information, using an AMA format.
- Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.

Indication 1: [Indication]

Therapeutic Alternative 1

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

PDAB Affordability Review: [Drug Name]
[Month Day Year]

Therapeutic Alternative 2

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Summary Tables of Therapeutic Alternatives for Indication 1

Generic/ Biosimilar Name	Brand Name	Place in Therapy	Comparison of Guideline Recommendations To Therapy Drug	Cost Comparison To Reviewed Drug	Efficacy Comparison To Reviewed Drug	Safety Comparison To Reviewed Drug

Institution/ Organization	Clinical Effectiveness Conclusion	Reference Number
Cochrane Library		
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

References:

[References]

Indication 2: [Indication]

Therapeutic Alternative 3

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Therapeutic Alternative 4

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Summary Tables of Therapeutic Alternatives for Indication 2

Generic/ Biosimilar Name	Brand Name	Place in Therapy	Comparison of Guideline Recommendations To Therapy Drug	Cost Comparison To Reviewed Drug	Efficacy Comparison To Reviewed Drug	Safety Comparison To Reviewed Drug

Institution/ Organization	Clinical Effectiveness Conclusion	Reference Number
Cochrane Library		
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

References:

[References]

2. Same-Class Drug Not Considered Therapeutic Alternative

- If drugs from the same class are not listed above with the same indication, describe why they are not considered to be therapeutic alternatives.
- List of NDCs: character string format. List 11-digit NDCs by separating them with semicolons (;).

Generic/ Biosimilar Name	Brand Name	List of NDCs (11-digit)	Description Of Why Not Considered Therapeutic Alternative
		11111111111; 22222222222; 33333333333	

IX: Cost-Effectiveness Analysis

- Based on RCW 70.405.050, the board must not use quality-adjusted life years that take into account a patient's age or severity of illness or disability.
- Based in RCW 70.405.050, for the drug that extends life, cost-effectiveness should not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition.
- Submit summary descriptions of cost-effectiveness analyses. Information from domestic and foreign HTA organizations should be included (e.g. peer-reviewed publications, reports from Cochrane Library, ICER, NICE, CADTH, IQWiG, INAHTA, NCHI). If the review from the ICER is available, the summary of reviews from other HTA organizations abroad is optional.
- If the drug has multiple indications, information for each indication is requested.
- Include descriptions of study population, comparison groups, and outcomes of interest with the results. Limitations of each study/analysis should also be identified.
- Any interim data, preliminary data analyses, and publications without a full description of methodology to assess the study quality and potential bias are not to be included (e.g. preliminary reports, conference posters). Summary of preliminary data analyses is permissible for an ongoing study as an exception.
- Include in-text numbering citations and a list of full reference information, using an AMA format.
- Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.

1. Cost-Effectiveness Analysis

Indication 1: [Indication]

Available Cost-Effectiveness Analysis Data

Summary Tables:

Study	Study Population	Comparison Groups	Measured Outcomes	Results	Limitations	Reference Number

HTA Organization (Country)	Cost Effectiveness Conclusion	Reference Number
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

References:

[References]

Indication 2: [Indication]

Available Cost-Effectiveness Analysis Data

Summary Tables:

Study	Study Population	Comparison Groups	Measured Outcomes	Results	Limitations	Reference Number

HTA Organization (Country)	Cost Effectiveness Conclusion	Reference Number
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NCHI (Netherlands)		
INAHTA (international)		

References:

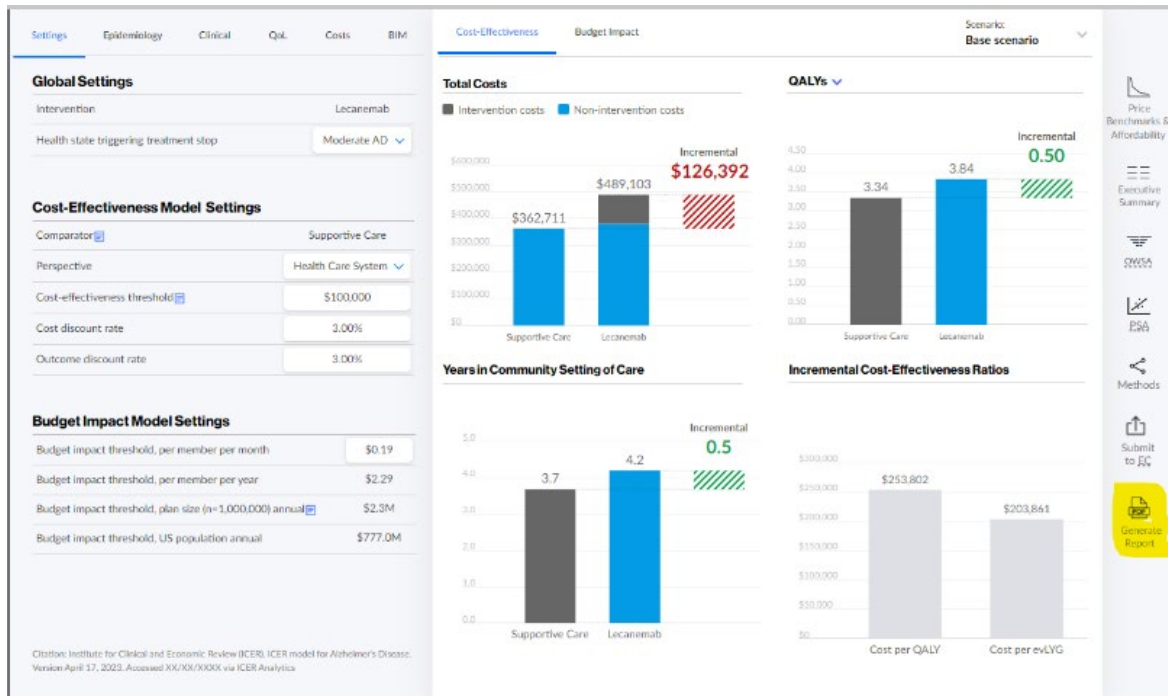
[References]

2. Interactive Model for the Cost-Effectiveness Analysis

- *Submission of a cost-effectiveness analysis model is strongly recommended by using the ICER Analytics Interactive Modeler, if the stakeholder subscribes to this model and/or if there is any relevant model published already. In this case, please submit any parameter specifications that need to be adjusted from the base scenario with supporting documents and justifications for the adjustments.*
- *Fill in a table under this section to compare between ICER original values and updated values with a list of citations. Include in-text numbering citations and a list of full reference information, using an AMA format. Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.*
- *Additionally, use the “Generate Report” option to download your model from the ICER Analytics as a PDF file. The Interactive Modeler allows user data not to be saved to the platform, which should address any concerns with putting non-public information in the platform.*

Parameters Changed	ICER Value	Manufacturer Alternative Value	Source/Citation

References:
 [References]



- Alternatively, a copy of the in-house model file for cost-effectiveness analysis in an Excel file can be submitted. A detailed description or a manual explaining the model, the parameters, and assumptions are requested, so that the HCA staff can verify and make adjustments if needed for the Board's requests.

X: Additional Information from the Drug Manufacturer

- If the drug has multiple indications, information for each indication is requested.
- Include in-text numbering citations and a list of full reference information, using an AMA format.
- Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.

1. Exclusivity and Patent Expiration Date (if applicable)

- Concisely list exclusivities and patents with the expiration dates (100-word limit).

[Response]

2. Relevant Information on Exclusivity and the Patent Expiration Date (if applicable):

- Describe an earliest date a generic/biosimilar product can enter the market. If there is any additional information related to the exclusivity and patent expiration, potentially resulting in delays in generics/biosimilars entering the market, relevant information is requested (500-word limit).

[Response]

3. Life-Cycle Management

- Describe current work related to the reviewed drug (500-word limit). This may include but is not limited to reformulation of the product and ongoing clinical studies for potentially a new indication in the future.
- If any specific formulation of the drug is expected to have patent protection longer than others, this information is requested.

[Response]

4. Market Information

Indication 1: [Indication]

Market Competition and Context

- Provide a narrative on market competition and context with a description of how the market share is defined (500-word limit).

[Response]

Uptake and Market Share Table

- Provide percentages of market share in the provided table.

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Eligible WA Population	X	X	X	X	X	X
Reviewed Drug	X%	X%	X%	X%	X%	X%

PDAB Affordability Review: [Drug Name]
[Month Day Year]

[Therapeutic Alternative 1]	X%	X%	X%	X%	X%	X%
[Therapeutic Alternative 2]	X%	X%	X%	X%	X%	X%

Past Revenue

- Provide revenue information on the current year and the past five years.

	Year -5	Year -4	Year -3	Year -2	Year -1	Current Year
Reviewed Drug						
[Therapeutic Alternative 1]						
[Therapeutic Alternative 2]						

Projected Revenue

- Provide revenue projection for the next five years.

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Reviewed Drug						

Budget Impact Analysis

- Include in-text numbering citations and a list of full reference information, using an AMA format.

- **Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.**

a) Reviewed Drug

- Complete the template table, including details of the treatment regimen and method of administration.
- Specify the sources of information and data used to complete the table, for example the prescribing information or trial data.

Optimization of population	Provide details of any optimization of the population (compared to the indicated population in the state of Washington), or state if no optimization is proposed.	
	Descriptions	Source
Acquisition cost (USD)*		
Method of administration		
Dosage		
Average length of a course of treatment		
Average interval between courses of treatments		
Anticipated number of repeat courses of treatments		
Dose adjustments		
* When the reviewed drug is recommended in combination with other treatments in the Prescribing Information, the price of each intervention should be presented.		

b) Health Condition and Position of the Drug in the Treatment Pathway

- Present the clinical pathway of care that shows the context of the proposed use of the drug within the pathway. This information should be summarized in a diagram.
- Describe established clinical practice for the population eligible for treatment with the reviewed drug.
- State the line of treatment the reviewed drug will be used in, for example, 'second-line treatment' or 'second-line and third-line treatment.'
- Explain how the new technology may change this existing pathway including any impacts on subsequent treatments.
- State the comparator technologies being considered.
- Where benefits/savings are achieved, show these per each relevant year.
- Provide details of other clinical guidelines which are considered current and targeting the US population.
- Describe any issues relating to current clinical practice, including any variations or uncertainty about established practice.

[Response]

c) Eligible Population

- Briefly describe the incidence and prevalence of the condition and life expectancy for people with the condition.
- State how many people are eligible for treatment with the drug in the state of Washington and for any subgroups considered. Include data for the next 10 years.
- Provide details of any assumptions used and include all steps taken to calculate the eligible population.

[Response]

d) Resources Necessary for Use of the Reviewed Drug and Therapeutic Alternatives

- Describe disease-related expenditure.
- Describe inclusive treatment costs (e.g. drug acquisition, diagnostic, administration, monitoring, side effect treatment). Identify use of resource to the Washington payers associated with the reviewed drug.
- State whether any concomitant therapies are required by the Prescribing Information or were administered in the key clinical trials (for example, for managing adverse reactions) with the drug.
- State if and to what extent the reviewed drug affects patient monitoring, compared with established clinical practice in the US.
- Provide a table that clearly sets out all relevant costs for the drug.
- This table should include the costs of administration, monitoring, managing adverse events, and any other costs that should be taken into account when assessing the budget impact of the drug.
- Provide information (source data, calculations, basis for assumptions) on the unit costs used.
- Provide a table that clearly sets out the relevant costs for the therapeutic alternatives or current standard of care. This should include all costs and the information described for the reviewed drug.

[Response]

e) Summary Table of Annual Budget Impact

- Provide a summary table. The suggested table format can be modified to fit the analyzed elements for the 10-year time horizon.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Eligible WA Population for Treatment with Reviewed Drug										
WA Population Expected to Receive Reviewed Drug										
Budget of Treatment Without Reviewed Drug										
Budget of Treatment with Reviewed Drug										
Net Budget Impact										

f) Uncertainty Analysis

- Describe uncertainty (uncertainty analysis) (1000-word limit).
- If conducting one-way sensitivity analysis, include a tornado diagram.

- Include different scenarios if applicable.
- Include a sensitivity analysis with 100% adherence to the drug regimen, if the adherence level was set at a lower level for the base analysis in the earlier sections of the budget impact analysis.

[Response]

g) Limitations of the Budget Impact Assessment

- Describe limitations to the current budget impact assessment (500-word limit).

[Response]

References:

[Reference]

Indication 2: [Indication]

Market Competition and Context

- Provide a narrative on market competition and context with a description of how the market share is defined (500-word limit).

[Response]

Uptake and Market Share Table

- Provide percentages of market share in the provided table.

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Eligible WA Population	X	X	X	X	X	X
Reviewed Drug	X%	X%	X%	X%	X%	X%
[Therapeutic Alternative 1]	X%	X%	X%	X%	X%	X%
[Therapeutic Alternative 2]	X%	X%	X%	X%	X%	X%

Past Revenue

- Provide revenue information on the current year and the past five years.

	Year -5	Year -4	Year -3	Year -2	Year -1	Current Year
Reviewed Drug						
[Therapeutic Alternative 1]						

[Therapeutic Alternative 2]

Projected Revenue

- Provide revenue projection for the next five years.

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Reviewed Drug						

Budget Impact Analysis

- Include in-text numbering citations and a list of full reference information, using an AMA format.
- Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.

a) Reviewed Drug

- Complete the template table, including details of the treatment regimen and method of administration.
- Specify the sources of information and data used to complete the table, for example the prescribing information or trial data.

Optimization of population	Provide details of any optimization of the population (compared to the indicated population in the state of Washington), or state if no optimization is proposed.	
	Descriptions	Source
Acquisition cost (USD)*		
Method of administration		
Dosage		
Average length of a course of treatment		
Average interval between courses of treatments		
Anticipated number of repeat courses of treatments		
Dose adjustments		
* When the reviewed drug is recommended in combination with other treatments in the Prescribing Information, the price of each intervention should be presented.		

b) Health Condition and Position of the Drug in the Treatment Pathway

- Present the clinical pathway of care that shows the context of the proposed use of the drug within the pathway. This information should be summarized in a diagram.
- Describe established clinical practice for the population eligible for treatment with the reviewed drug.
- State the line of treatment the reviewed drug will be used in, for example, 'second-line treatment' or 'second-line and third-line treatment.'
- Explain how the new technology may change this existing pathway including any impacts on subsequent treatments.

- State the comparator technologies being considered.
- Where benefits/savings are achieved, show these per each relevant year.
- Provide details of other clinical guidelines which are considered current and targeting the US population.
- Describe any issues relating to current clinical practice, including any variations or uncertainty about established practice.

[Response]

c) Eligible Population

- Briefly describe the incidence and prevalence of the condition and life expectancy for people with the condition.
- State how many people are eligible for treatment with the drug in the state of Washington and for any subgroups considered. Include data for the next 10 years.
- Provide details of any assumptions used and include all steps taken to calculate the eligible population.

[Response]

d) Resources Necessary for Use of the Reviewed Drug and Therapeutic Alternatives

- Describe disease-related expenditure.
- Describe inclusive treatment costs (e.g. drug acquisition, diagnostic, administration, monitoring, side effect treatment). Identify use of resource to the Washington payers associated with the reviewed drug.
- State whether any concomitant therapies are required by the Prescribing Information or were administered in the key clinical trials (for example, for managing adverse reactions) with the drug.
- State if and to what extent the reviewed drug affects patient monitoring, compared with established clinical practice in the US.
- Provide a table that clearly sets out all relevant costs for the drug.
- This table should include the costs of administration, monitoring, managing adverse events, and any other costs that should be taken into account when assessing the budget impact of the drug.
- Provide information (source data, calculations, basis for assumptions) on the unit costs used.
- Provide a table that clearly sets out the relevant costs for the therapeutic alternatives or current standard of care. This should include all costs and the information described for the reviewed drug.

[Response]

e) Summary Table of Annual Budget Impact

- Provide a summary table. The suggested table format can be modified to fit the analyzed elements for the 10-year time horizon.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Eligible WA Population for Treatment with Reviewed Drug										

WA Population Expected to Receive Reviewed Drug										
Budget of Treatment Without Reviewed Drug										
Budget of Treatment with Reviewed Drug										
Net Budget Impact										

f) Uncertainty Analysis

- Describe uncertainty (uncertainty analysis) (1000-word limit).
- If conducting one-way sensitivity analysis, include a tornado diagram.
- Include different scenarios if applicable.
- Include a sensitivity analysis with 100% adherence to the drug regimen, if the adherence level was set at a lower level for the base analysis in the earlier sections of the budget impact analysis.

[Response]

g) Limitations of the Budget Impact Assessment

- Describe limitations to the current budget impact assessment (500-word limit).

[Response]

References:

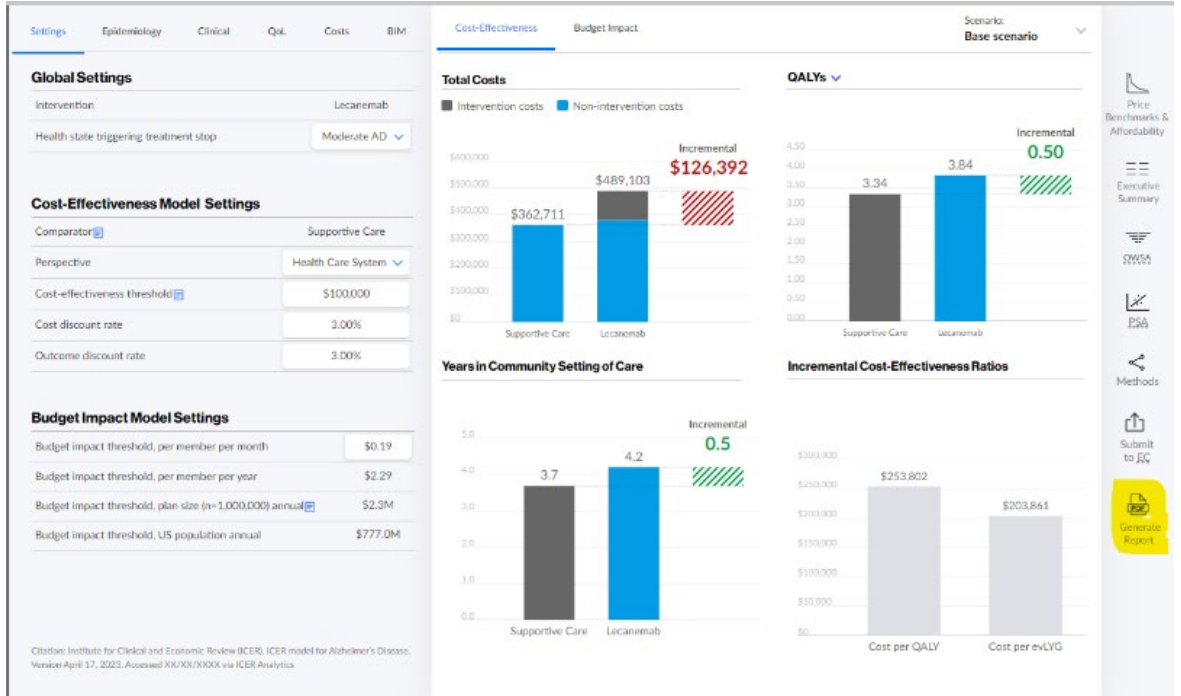
[Reference]

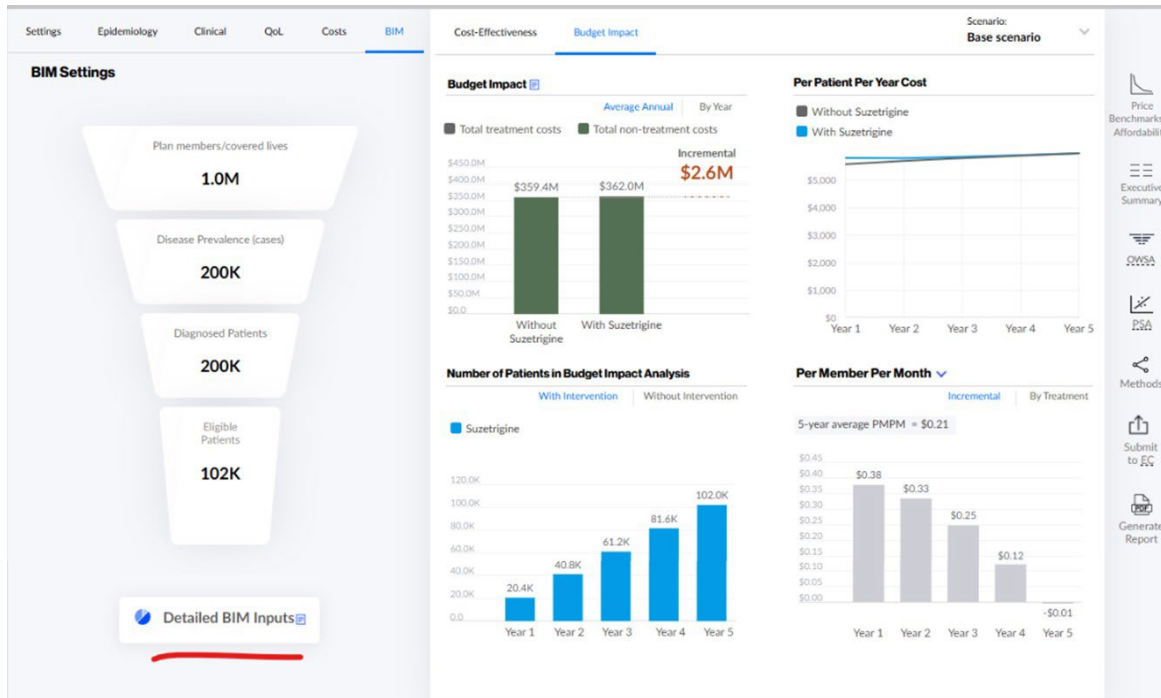
5. Interactive Model for the Budget Impact Analysis

- Submission of a budget-impact analysis model is strongly recommended by using the ICER Analytics Interactive Modeler, if there is any relevant model published already. In this case, please submit any parameter specifications that need to be adjusted from the base scenario with supporting documents and justifications for the adjustments.
- Please create a table under this section to compare between ICER original values and updated values with a list of citations. Include in-text numbering citations and a list of full reference information, using an AMA format. Submit a copy of the full-text manuscripts and reports (i.e. references) to the portal.
- Additionally, use the “Generate Report” option to download your model from the ICER Analytics as a PDF file.
- As the “Generate Report” option does not include the “Detailed BIM Inputs,” please include the screenshot of this part (where to find this is indicated on the image below).

Parameters Changed	ICER Value	Manufacturer Alternative Value	Source/Citation

References:
[\[References\]](#)





- Alternatively, a copy of the in-house model file for the budget impact analysis in an Excel format can be submitted. A detailed description or a manual explaining the model, the parameters, and assumptions are requested, so that the HCA staff can verify and make adjustments if needed for the Board's requests.

6. Additional Information for Drug Pricing (if applicable)

- As separately submitted files, provide existing information produced for and reviewed by your organization's senior leadership (e.g., current or previous officers, directors, trustees, partners, senior managers, etc.) sufficient to describe the pricing strategy for the drug, such as memos, PowerPoint presentations, or other communication.
- Information relied upon by your organization, including those performed by an independent third-party should be included.

XI: Off-Label Usage of the Drug (if applicable)

- List off-label indications. Information for each off-label indication is requested.
- Include estimates on the drug utilization information for the off-label indications in the state.
- Describe how estimates are made for the information on the table (500-word max).

1. Summary Table for Off-Label Usage

Off-Label Indication	Efficacy Information	Safety Concerns	Estimated Number of Washingtonians Using Drug For Off-Label Indication	Relative Frequency of Use for Off-Label Indication vs. Labeled Indication

[Response]