

DRUG PRICING REVIEW

STANDARD REPORTING FORM

Health Policy Commission

50 Milk Street, 8th Floor

Boston, MA 02109

**DRUG PRICING REVIEW**

**STANDARD REPORTING FORM**

The attached Standard Reporting Form should be used by a Referred Manufacturer to provide information to the Health Policy Commission (HPC), as required under M.G.L. c. 6D § 8A and 958 CMR 12.00 et seq. Capitalized terms in this form are defined in 958 CMR 12.02. A copy of 958 CMR 12.00 et seq. is available on the [HPC’s website](https://www.mass.gov/service-details/drug-pricing-review) where additional guidance may also be posted (e.g., frequently asked questions).

INFORMATION TO BE PROVIDED TO THE HPC

1. A Referred Manufacturer must provide to the HPC the information requested on the Standard Reporting Form;

1. A Referred Manufacturer must also provide to the HPC its own estimation of the Drug’s value and supporting information, such as existing analyses, in accordance with 958 CMR 12.04. The Referred Manufacturer may cite to material provided to the HPC under (1), (3) or (4) without duplicating any such material. Such estimation should reflect the Drug’s benefits to the Commonwealth and its residents and may include, but shall not be limited to, consideration of the factors described in 958 CMR 12.06;
2. A Referred Manufacturer must provide any additional information requested by the HPC pursuant to 958 CMR 12.04(4); and
3. A Referred Manufacturer may submit any additional data or information to the HPC that it considers to be pertinent to the HPC’s review.

ATTESTATION FORM

All data and information submitted by a Referred Manufacturer shall be accompanied by a signed Attestation Form, as appended to this Standard Reporting Form, certifying that all information reported or provided is true and correct under pains and penalties of perjury.

FORM AND TIMING OF RESPONSES

Referred Manufacturers are encouraged to contact HPC-DrugReview@mass.gov upon receipt of the Standard Reporting Form and any additional requests for information to discuss their submission and timing of response. To the extent that information is not available in the form requested, the HPC shall work with a Referred Manufacturer to determine whether and how substantially similar information may be submitted and accepted as responsive to HPC requests. To the extent that any information requested is already publicly available, a Referred Manufacturer may indicate where such information may be found. To the extent that information provided by a Referred Manufacturer is responsive to more than one request, the Referred Manufacturer may cite to the information provided without duplicating any such information.

Pursuant to 958 CMR 12.04(1), all information shall be submitted to the HPC within thirty (30) calendar days of receipt of the written notice pursuant to 958 CMR 12.03, or request for additional information pursuant to 958 CMR 12.04(4), or such other timeframe as may be agreed upon, in writing, between the Referred Manufacturer and the HPC.

CONFIDENTIALITY

Records disclosed by a Referred Manufacturer under 958 CMR 12.00 et seq. shall not be a public record under M.G.L. c. 4, § 7 or M.G.L. c. 66 and shall remain confidential; provided, however, that the Commission may disclose the narrative submitted by a Referred Manufacturer pursuant to 12.04(3)(g) in Part III (e) and may produce reports summarizing any findings consistent with its responsibilities under M.G.L. c. 6D, § 8A. Such reports shall not identify specific prices charged for or rebate amounts associated with drugs of a Referred Manufacturer and shall not be presented in a manner that is likely to compromise the financial, competitive, or proprietary nature of the information.

INSTRUCTIONS FOR SUBMISSION

Referred Manufacturers should submit information to the HPC via a secure encrypted transmission method, e.g., by sending an encrypted electronic transmission or sending encrypted media. Please contact HPC-DrugReview@mass.gov to determine the most appropriate mode of submission.

**Part I: General Information**

1. Contact Information

Provide the name and contact information of an individual who will be able to answer questions regarding the information submitted in this form.

|  |
| --- |
| **Contact Information** |
| **Name of Manufacturer**  | Click here to enter text. |
| **Contact Name** | Click here to enter text. |
| **Contact Title** | Click here to enter text. |
| **Email Address**  | Click here to enter text. |
| **Telephone Number**  | Click here to enter text. |
| **Street Address**  | Click here to enter text. |
| **City**  | Click here to enter text. |
| **State**  | Click here to enter text. |
| **Zip** | Click here to enter text. |

1. General Drug Information

Provide the following information about the Drug.

|  |
| --- |
| **Drug Information – General** |
| **Non-proprietary Drug Name**  | Click here to enter text. |
| **Brand Name** | Click here to enter text. |
| **National Drug Code(s) (NDC)+** | Click here to enter the NDC(s). |
| **Healthcare Common Procedure Coding System (HCPCS) J code(s) or Q code(s), if applicable** | Click here to enter the HCPCS code(s). |
| **List of the U.S. Food and Drug Administration (FDA)-approved indication(s), when the indication(s) were approved, and any indication(s) for which the Referred Manufacturer is currently seeking approval** | Click here to enter text. |

+ If there are multiple NDCs, provide a description of each, including information on dosage, formulation, and 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 FDA-approved indication listed above, provide the following information. Copy and paste this table, as needed, to provide information about each indication.

|  |
| --- |
| **Drug Information – Indication-Specific**  |
| **Drug indication** | Click here to enter text. |
| **Brief overview (no more than 1 page) of the indication for which the Drug is used, including intended role in therapy and other currently available treatments, including non-drug treatments** | Click here to enter text. |
| **Estimated size of the population for whom treatment with the Drug is indicated in Massachusetts and the U.S., including a brief description of how the estimate was calculated** | Click here to enter text. |
| **Brief overview (no more than 1 page) of the Drug, including the mechanism of action, method of administration, site of care, information on dosing, and average course of treatment** | Click here to enter text. |
| **FDA approval pathway (e.g., New Drug Application (NDA) or Biologic License Application (BLA), including supplement number if applicable) and special designations, if applicable\***  | Click here to enter text. |

**\***Examples of special designations include 505(b)(2), 262(k), 262(k)(4), fast track, Orphan Drug Act designation, accelerated approval, breakthrough therapy, priority review, Qualified Infectious Disease Product (QIDP), Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)

**Part II: Clinical Efficacy, Effectiveness, and Outcomes**

Provide the following information on clinical efficacy, effectiveness, and outcomes of the Drug (categorized by each indication, as applicable), including clinical information submitted to the FDA or successor agency.

1. Summary of Key Clinical Trials

Provide, as an attachment, a summary of the key clinical trials supporting the FDA-approved indications for the Drug, based on the latest evidence available, preferably from randomized controlled trials, including any subgroup analyses.

If summaries are already available in the formats recommended by the International Conference on Harmonization (ICH) or the Academy of Managed Care Pharmacy (AMCP) Format for Formulary Submissions, provide these documents as attachments. To the extent the information is not available in these formats, provide a summary of all key trials including, at a minimum, information regarding the study design and methodology, baseline characteristics of the population studied, inclusion/exclusion criteria, the primary and other outcomes observed, an assessment of the quality of the evidence, analyses performed on any subgroups, and information regarding any adverse reactions. Please limit your summary of each key clinical trial to three (3) pages.

1. Additional Evidence of Clinical Efficacy, Effectiveness, and Outcomes, If Applicable

Provide, as an attachment, a summary of key additional evidence of the clinical efficacy, effectiveness, and outcomes of the Drug. Non-randomized and non-controlled evidence may be included to supplement clinical trial data provided above, such as prospective clinical studies, observational studies, registry studies, post-marketing surveillance data, indirect comparisons, systematic reviews, or meta-analyses. Please limit your response to five (5) pages per indication.

1. Complete List of Clinical Studies

Provide, as an attachment, a complete list of all clinical studies related to the Drug with citations and trial registry identification numbers (e.g., clinicaltrials.gov National Clinical Trial numbers), as applicable, including studies not sponsored by the manufacturer. This list must include all clinical research that is relevant to the manufacturer’s estimation of the value of the Drug, provided separately to the HPC, as described on page (i) of this form. Provide copies of any unpublished reports, such as abstracts, conference posters and presentations.

**Part III: Pricing**

Report all pricing information below by NDC for each NDC reported above in Part I. If the Drug has more than 10 NDCs, please contact the HPC to discuss an alternative approach to providing this information.

1. Wholesale Acquisition Cost
2. Provide the following information about the Drug and its wholesale acquisition cost (WAC). Please add rows and copy and paste the Historical and Current Information table, as necessary, for each NDC.

|  |
| --- |
| **Historic and Current Information: NDC Specific** |
| **NDC** | Click here to enter text. |
|  | **WAC per Unit** | **Effective Date** |
| **Current** | Click here to enter the WAC in US dollars. | Click here to enter the date in mm/dd/yyyy format. |
| **At Market Entry** | Click here to enter the WAC in US dollars. | Click here to enter the date in mm/dd/yyyy format. |
| **Report all changes to the WAC over the previous five (5) calendar years. Add rows if needed.** |
| **Change in WAC per Unit** | **WAC per Unit after Change** | **WAC Effective Date** |
| *$75.00* | *$900.00*  | *1/1/2015* |
| *$5.00* | *$905.00* | *3/1/2015* |
| Click here to enter the change in WAC per Unit in US dollars | Click here to enter the WAC in US dollars. | Click here to enter the date in mm/dd/yyyy format. |
| Click here to enter the change in WAC per Unit in US dollars | Click here to enter the WAC in US dollars. | Click here to enter the date in mm/dd/yyyy format. |
| Click here to enter the change in WAC per Unit in US dollars | Click here to enter the WAC in US dollars. | Click here to enter the date in mm/dd/yyyy format. |
| Click here to enter the change in WAC per Unit in US dollars | Click here to enter the WAC in US dollars. | Click here to enter the date in mm/dd/yyyy format. |
| **Notes** | Click here to enter text. |

1. Report the estimated cost at WAC for a full course of treatment per patient using the Drug for each FDA-approved indication. Use cost per episode or, if the Drug is approved for chronic use, cost per month. If applicable, report separately the expected costs of treatment for patients initiating treatment, incorporating loading doses or dose escalation, and the expected costs of patients on a maintenance dose. If cost per episode or per month varies by the dose used, include ranges. Include a description of all calculation methods and assumptions.

Click here to enter text.

1. U.S. Prices Net of Rebates and Discounts

Report the net unit price of the Drug for each NDC in the U.S. for the categories of payers listed below in US dollars over the previous five (5) calendar years. Reported prices should be dollars received divided by the total number of units provided, net of rebates, discounts (including Medicare coverage gap discounts), chargebacks, incentives, fees, and all other price adjustments applicable to payers. If you provide coupons or co-payment assistance to patients, separately report the price net of all adjustments to payers and net of coupons and co-payment assistance to patients. Include a description of methodology as applicable, including the methodology for calculating average prices. An example is in italics in the table below. Copy and paste the table, as necessary, for each NDC.

| **United States** |
| --- |
| **NDC** | Click here to enter text. |
| **Payer Type** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| ***Example***  | *$80.00* | *$83.00* | *$85.00* | *$88.00* | *$90.00* |
| **Commercial and Medicare - Average Price, weighted by volume+**  | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Department of Veterans Affairs** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Medicaid – Best Price++** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Medicaid - Lowest Price after statutory and supplemental rebates++** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Medicaid - Median Price after statutory and supplemental rebates++** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |

**+** Calculation should reflect the average of prices, weighted by volume, for all entities that provide the Drug to commercial or Medicare beneficiaries with which the Manufacturer has negotiated prices directly, including but not limited to Pharmacy Benefit Managers (PBMs), employers, and health plans.

**++**Medicaid prices need not identify the state(s) in which such prices apply and should indicate which pricing, if any, with Medicaid departments are tied to a value-based agreement.

1. International Coverage and Prices
2. For the countries listed in the table below, indicate if the Drug is authorized for sale or if an application for authorization has been submitted to the regulatory review authority in that country, when the Drug was approved in that country, and the indications for which the Drug is approved. Provide a brief description of any national level coverage recommendations (e.g., all patients with moderate-severe disease who have tried and failed at least one biologic) and include citations or links to details on coverage criteria where available.

| **Country Name** | **Authorization for Sale (Yes/No/Regulatory Submission)** | **Indication(s) for which the Drug is Approved and Date(s) of Approval** | **National Level Coverage Recommendations as Applicable**  |
| --- | --- | --- | --- |
| **Australia** | Enter text. | Enter text. | Enter text. |
| **Canada** | Enter text. | Enter text. | Enter text. |
| **France** | Enter text. | Enter text. | Enter text. |
| **Germany** | Enter text. | Enter text. | Enter text. |
| **Italy** | Enter text. | Enter text. | Enter text. |
| **Japan** | Enter text. | Enter text. | Enter text. |
| **Spain** | Enter text. | Enter text. | Enter text. |
| **Sweden** | Enter text. | Enter text. | Enter text. |
| **Switzerland** | Enter text. | Enter text. | Enter text. |
| **United Kingdom** | Enter text. | Enter text. | Enter text. |

1. Report the unit price for all approved dosage forms of the Drug, in U.S. dollars, in the countries listed in the table below for the previous five (5) calendar years. Prices reported should be the WAC equivalent: average price paid by payers exclusive of rebates, discounts, chargebacks, incentives, fees, and all other price adjustments. The price should be reported as an average for each calendar year. Copy and paste the table below, as necessary, for each approved dosage form and include a brief description of methodology if applicable.

| **Dosage Form** | Enter dosage form. |
| --- | --- |
| **Country Name** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| **Australia** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Canada** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **France** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Germany** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Italy** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Japan** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Spain** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Sweden** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **Switzerland** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |
| **United Kingdom** | Enter price. | Enter price. | Enter price. | Enter price. | Enter price. |

1. For each year that the Drug was available in **three (3)** **or more** of the countries listed in Table III(c)(ii), report the average rebate, discount or other price adjustment, expressed as US dollars per unit, across all the countries in the table. Please report a simple (non-weighted) average, calculated as a sum of the average per unit rebates on the Drug in each country divided by the total number of countries. For any year for which the Drug is not available in at least three (3) of the countries listed in Table III(c)(ii), please skip reporting an average for that year.

Click here to enter text.

1. Information to Support Drug Pricing

Describe briefly (no more than 5 pages) and provide, as an attachment, information to support your pricing of the Drug, including market analyses, economic models, examination of similar drugs, cost-effectiveness analyses, and comparative effectiveness analyses. This includes analyses performed or relied upon by your organization including those performed by an independent third-party. Also 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.

Click here to enter text.

1. Narrative for Public Release

Provide a narrative description, suitable for public release, of factors that contributed to the changes in wholesale acquisition costs and prices net of rebates during the previous five (5) calendar years. **Please note that the response to this section may be released publicly by the HPC.**

Click here to enter text.

**Part IV: Utilization**

Report all utilization information below by each NDC reported above in Part I. If the Drug has more than 10 NDCs, please contact the HPC to discuss an alternative approach to providing this information.

1. Current Utilization

Provide your best estimate of utilization for the Drug in Massachusetts and nationally over the past five (5) calendar years or since the Drug’s approval, if approved fewer than five (5) years ago. Provide your methodology for quantifying utilization. Please list any sources, such as subscription databases, used in your estimation of utilization.

|  |  |
| --- | --- |
| **NDC** | Click here to enter text. |
| **Massachusetts Utilization** |
|  | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| **Commercial Payers** | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **Medicare** | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **Medicaid** | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **All Payer Total** (including payers not listed above) | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **United States Utilization** |
|  | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| **Commercial Payers** | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **Medicare** | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **Medicaid** | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |
| **All Payer Total** (including payers not listed above) | Enter units. | Enter units. | Enter units. | Enter units. | Enter units. |

1. Projected Utilization

Describe projected utilization of the Drug in the next five (5) calendar years, including any anticipated changes in utilization due to demographic changes, changes in disease burden, new indications for which you are seeking approval, or changes in how the Drug is used relative to available treatment alternatives (including generics). Provide, as an attachment, data and analyses sufficient to support your projections, including a description of the methodologies and models used in the analysis. Include any projections of utilization in the next five (5) years that have been presented to shareholders or investors.

 Click here to enter text.

**Part V: Financial Information**

Provide the following financial information using the best information available. Include, as an attachment, a detailed description of your accounting methodology, including direct and allocated costs.

1. Company-Level Research and Development Budget and Expenditures

Provide as an attachment, using the best information available, the following information about your research and development budget and expenditures:

1. Aggregate, company-level prescription drug research and development and other relevant capital expenditures, including facility construction, for the past three (3) years for which final audited data are available;
2. Aggregate, company-level prescription drug research and development budget for the current year;
3. Aggregate, company-level prescription drug research and development expenditures as a proportion of the manufacturer’s total prescription drug expenditures for the past three (3) years for which final audited data are available.
4. Drug Research and Development Budget and Expenditures

Provide as an attachment, using the best information available, the research and development budget for the current year for the Drug and expenditures associated with the full process of bringing the Drug to market, including research, discovery, clinical trials, and the FDA review and approval process. Include expenditures on research and clinical trials after the Drug was approved by the FDA. If the Drug was acquired or is licensed from another company, separately report any information on Research and Development expenditures related to the Drug obtained as part of the acquisition or licensing agreement.

1. Research and Development Funding Sources

Report all outside funding or grants, including any public funding received or tax credits, associated with the process of bringing the Drug to market including research, discovery, clinical trials, and the FDA review and approval process. Include all such funding related to the Drug’s development that was provided to non-profit research institutions as well as to other corporations that were later acquired in connection with this Drug’s marketing. Indicate whether any FDA priority review voucher was received and, if sold, the revenue generated from the voucher’s sale. Add rows, as needed.

|  |
| --- |
| **Funding Sources** |
| **Source** | **Dates of Funding Availability** | **Value** |
| Enter funding source. | Enter date range. | Enter value in $ |
| Enter funding source. | Enter date range. | Enter value in $ |
| Enter funding source. | Enter date range. | Enter value in $ |
| Enter funding source. | Enter date range. | Enter value in $ |
| Enter funding source. | Enter date range. | Enter value in $ |

1. Acquisition Cost

If you acquired the Drug from another manufacturer, report the acquisition cost.

|  |
| --- |
| **Acquisition Cost** |
| **Name of entity from which you acquired the Drug** | Click here to enter text. |
| **Acquisition Date** | Click here to enter the acquisition date in mm/dd/yyyy format. |
| **Estimated Acquisition Cost for the Drug,** including a description of the methodology used to calculate this estimate | Click here to enter the acquisition cost in US dollars. |
| **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 that entity). | Click here to enter text. |

1. Manufacturing, Production, and Distribution Budget and Expenditures

Provide as an attachment, using the best information available, the following information about your manufacturing, production, and distribution budget and expenditures for the Drug:

1. Manufacturing, production, and distribution expenditures for the Drug, including any costs incurred to produce and deliver the Drug to the entity that distributes the Drug through the supply chain each year for the past three (3) years for which final audited data are available;

Manufacturing, production, and distribution budget for the Drug for the current year, including any costs to produce and deliver the Drug to the entity that distributes the Drug through the supply chain.

1. Marketing Budget and Expenditures

Provide as an attachment, using the best information available, your marketing budget and expenditures in the aggregate and for the Drug, including:

1. Aggregate, company-level prescription drug marketing expenditures for the past three (3) years for which final, audited data are available;
2. Aggregate, company-level prescription drug marketing budget for the current year;
3. Aggregate, company-level prescription drug marketing as a proportion of the manufacturer’s total prescription drug expenditures for the last three (3) years for which final audited data are available;
4. Marketing expenditures for the Drug for the past three (3) years for which final audited data are available;
5. Marketing budget for the Drug for the current year.

This section should include any budget items and expenditures related to promoting and selling prescription drug products, including market research, advertising, and publicity. It includes, but is not limited to, television, radio, print media, internet advertising and social media, as well as any marketing or promotional activities that are directed to consumers (e.g., coupons, patient assistance programs, and contributions to patient advocacy groups) or prescribers (e.g., samples, detailing programs, promotional mailings, dinners, gifts, sponsorship of talks or conferences, branded incidentals).

Separately report the following categories of information as a part of the total aggregate prescription drug marketing budget and expenditures and marketing budget and expenditures for the Drug reported above:

**Total Directed to Consumers:** Total budget and expenditures related to marketing and promotion that is directed to consumers

**Total Directed to Prescribers:** Total budget and expenditures related to marketing and promotion that is directed to prescribers.

**COMMONWEALTH OF MASSACHUSETTS**

**HEALTH POLICY COMMISSION**

DRUG PRICING REVIEW

ATTESTATION FORM

I, the undersigned, as a duly authorized representative of , certify under pains and penalties of perjury that:

1. I have read the Health Policy Commission’s regulation 958 CMR 12.00: *Drug Pricing Review* and any instructions provided by the Health Policy Commission, including those contained within the Drug Pricing Review Standard Reporting Form.

2. I have reviewed the submission in response to the Standard Reporting Form and in response to any additional requests of the Health Policy Commission and the information submitted is true, correct, and complete.

Signed on the \_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_\_.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Pursuant to 958 CMR 12.00, all information data and information provided by a Referred Manufacturer to the Health Policy Commission shall be accompanied by this signed Attestation Form.*