

**CONFIDENTIAL**  
**POLICY UNDER DEVELOPMENT/ATTORNEY CLIENT-PRIVILEGED/ATTORNEY WORK PRODUCT**

**COMMONWEALTH OF MASSACHUSETTS**  
**HEALTH POLICY COMMISSION**

**DRUG PRICING REVIEW**  
**STANDARD REPORTING FORM**

The Health Policy Commission (HPC) requests the following information pursuant to 958 CMR 12.00 et seq. Your organization may append additional data or information to this Standard Reporting Form that it considers to be pertinent to the HPC's review. The HPC may request additional information that it deems necessary, beyond that provided in response to this Standard Reporting Form, pursuant to 958 CMR 12.04(4). All information must be accompanied by a signed Attestation Form.

Please note that 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.

**Definitions**

<b>Drug</b>	A pharmaceutical product manufactured by the Referred Manufacturer which resulted in referral to the HPC pursuant to M.G.L. c. 118E, § 12A(g); in the event that the Referred Manufacturer has been referred to the HPC based on more than one such product, the term refers to all such products, and information on each product should be provided separately.
<b>Payer</b>	Any private or public payer for health care services, and, collectively, individuals who pay directly for health care services.

All other capitalized terms in this form have the same definition as provided in 958 CMR 12.02.

**Part I: General Information**

Please provide the name and contact information of an individual that would be able to answer questions regarding the information submitted in this form, including the following elements:

<b>Contact Information</b>	
<b>Name of Manufacturer</b>	Click here to enter text.
<b>Contact Name</b>	Click here to enter text.
<b>Email Address</b>	Click here to enter text.
<b>Telephone Number</b>	Click here to enter text.
<b>Street Address</b>	Click here to enter text.
<b>City</b>	Click here to enter text.
<b>State</b>	Click here to enter text.
<b>Zip</b>	Click here to enter text.

Please provide the following information about the Drug:

<b>Drug Information</b>
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<b>Drug Name</b>	Click here to enter text.
<b>Brand Name</b>	Click here to enter text.
<b>National Drug Code (NDC)</b>	Click here to enter the 10-digit NDC.
<b>Healthcare Common Procedure Coding System (HCPCS) J code, if applicable</b>	Click here to enter the code, beginning with J
<b>Overview of disease(s) or condition(s) for which the Drug is used</b>	Click here to enter text.
<b>Mechanism of action</b>	Click here to enter text.
<b>Method of administration and dosage</b>	Click here to enter text.
<b>Average course(s) of treatment</b>	Click here to enter text.
<b>FDA approval pathway (e.g. New Drug Application (NDA) or Biologic License Application (BLA)) and special designations, if applicable (e.g. fast track approval, rare disease and orphan drug, priority review)</b>	Click here to enter text.

## Part II: Clinical Effectiveness

Please briefly describe, and provide as attachments, details of the key trials that provide evidence of the clinical benefits of the Drug. These should be based on the best evidence available, preferably from randomized controlled trials (RCTs). Non-randomized and non-controlled evidence may be needed to supplement RCT data. Please include a detailed summary of clinical evidence submitted to the U.S. Food and Drug Administration (FDA), or any successor agency. Please indicate clinical evidence that has also been submitted to regulatory bodies in other countries (e.g. the United Kingdom's National Institute for Health and Care Excellence). For each trial, please include, at a minimum, information regarding the study design and methodology, the population studied, the primary and other outcomes observed, an assessment of the quality of the evidence, analysis for any subgroups and information regarding any adverse reactions.

Click here to enter text.

## Part III: Pricing

### (a) Wholesale Acquisition Cost

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Please provide the following information about the Drug and its wholesale acquisition cost (WAC).

<b>Historic Information</b>	
<b>Wholesale Acquisition Cost (WAC) at Introduction to Market</b>	Click here to enter the WAC in US dollars.
<b>WAC Effective Date</b>	Click here to enter the date in mm/dd/yyyy format.
<b>Notes</b>	Click here to enter notes about the WAC, including but not limited to, the dose or unit of the drug that the WAC represents

<b>Current Information</b>	
<b>Current WAC</b>	Click here to enter the WAC in US dollars.
<b>WAC Effective Date</b>	Click here to enter the date in mm/dd/yyyy format.
<b>Total undiscounted cost for average course(s) of treatment</b>	Click here to enter the total undiscounted cost in US dollars.
<b>Notes</b>	Click here to enter notes about the WAC, including but not limited to, the dose or unit of the drug that the WAC represents

Please report all WAC increases over the previous 5 calendar years. Please add columns as necessary. An example is in italics in the table below.

<b>Wholesale Acquisition Cost Changes over the Previous 5 Calendar Years</b>				
<b>WAC Effective Date</b>	<i>1/1/2015</i>			
<b>WAC Increase Amount</b>	<i>\$75.00</i>			
<b>WAC After Increase</b>	<i>\$900.00</i>			
<b>Notes</b>				

**(b) Massachusetts and National Prices**

Please report the average unit price of the drug in Massachusetts and nationally by payer type and pharmacy benefit manager in US dollars, net of rebates, for the previous 5 calendar years. An example is in italics in the table below.

<b>Massachusetts</b>					
<b>Payer Name</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<i>Example Payer</i>	<i>\$80.00</i>	<i>\$83.00</i>	<i>\$85.00</i>	<i>\$88.00</i>	<i>\$90.00</i>
Average Commercial Payer	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Average Medicaid	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Average Medicare	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Average Pharmacy Benefit Managers	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Others – Explain here	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.

<b>United States</b>					
<b>Payer Name</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
<i>Example Payer</i>	<i>\$80.00</i>	<i>\$83.00</i>	<i>\$85.00</i>	<i>\$88.00</i>	<i>\$90.00</i>
Average Commercial Payer	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Average Medicaid	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.

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<b>United States</b>					
<b>Payer Name</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Average Medicare	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Average Pharmacy Benefit Managers	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Others – Explain here	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.

**(c) International Prices**

Please report the average price of the drug in the 5 countries outside of the United States with the highest volume purchased for the previous 5 calendar years.

<b>Country Name</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>
Country 1	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Country 2	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Country 3	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Country 4	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.
Country 5	Enter price.	Enter price.	Enter price.	Enter price.	Enter price.

**(d) Information to Support Drug Pricing**

Please describe briefly in the space below and provide as an attachment a detailed summary of information to support your pricing of the Drug, including market analyses, examination of similar drugs, and other analyses performed or commissioned by your organization.

[Click here to enter text.](#)

**(e) Narrative for Public Release**

Please provide either in the space below or as an attachment a written, narrative description, suitable for public release, of factors that contributed to the changes in wholesale acquisition cost and prices net of rebates during the previous five (5) calendar years.

[Click here to enter text.](#)

**Part IV: Utilization**

**(a) Current and Projected Utilization**

Please detail utilization for the Drug in Massachusetts and nationally in the previous 5 calendar years and expected utilization in the next 5 calendar years. Please describe the units being measured (doses, patients).

<b>Massachusetts Utilization</b>										
	<b>Observed</b>					<b>Projected</b>				
	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
<b>Commercial Payers</b>	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units

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<b>Medicare</b>	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units
<b>Medicaid</b>	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units
<b>All Payer Total</b> (including payers not listed above)	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units

<b>United States Utilization</b>										
	<b>Observed</b>					<b>Projected</b>				
	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
<b>Commercial Payers</b>	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units
<b>Medicare</b>	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units
<b>Medicaid</b>	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units
<b>All Payer Total</b> (including payers not listed above)	Units	Units	Units	Units	Units	Units	Units	Units	Units	Units

**(b) Projected Utilization Supporting Information**

Please provide details to support your projected utilization of the Drug in the next 5 years either in the space below or as an attachment, including a description of the methodologies and models used in the analysis.

[Click here to enter text.](#)

**Part V: Financial Information**

Please provide the following financial information:

**(a) Research and Development Expenditures**

Please report all research and development expenditures for the Drug and your aggregate, company-level research and development and other relevant capital expenditures, including facility construction, for the most recent year for which final audited data are available. Expenditures should include salary and benefits, direct expenses, including all fixed assets, outsourcing, payments to predecessor entities, and any other costs associated with the process of bringing the Drug to market including research, discovery, clinical trials, and the FDA review and approval process. Please breakout your expenditures into each of the categories listed below, reported separately for the Drug and for all aggregate, company level expenditures:

**Salary and Benefits:** Includes compensation associated with individuals involved in Research and Development, including all forms of monetary and non-financial compensation going to employees and arising from their employment

**Direct Expenses:** Includes fixed assets such as buildings, computer and other equipment, shipping/delivery expenses, software, furniture and fixtures, intangible assets (e.g., patented technology, licensing agreements, equipment lease agreements, trade secrets)

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**Outsourcing:** Includes costs for external contractors, hired for the purpose of Research and Development

**Payments to Predecessor Entities:** Includes the portion of any payments to predecessor entities for conducting Research and Development activities

**Other (please describe):** Includes the portion of any payments to predecessor entities for conducting Research and Development activities and payments for priority review vouchers

**Research and Development Total:** Total budget and expenditures related to Research and Development

**(b) Research and Development Funding Sources**

Please 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.

Funding Sources	
Source	Value
Enter funding source.	Enter value in \$
Enter funding source.	Enter value in \$
Enter funding source.	Enter value in \$
Enter funding source.	Enter value in \$
Enter funding source.	Enter value in \$

**(c) Acquisition Cost**

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

<b>Name of entity from which you acquired the Drug</b>	Click here to enter text.
<b>Acquisition Date</b>	Click here to enter the acquisition date in mm/dd/yyyy format.
<b>Acquisition Cost</b>	Click here to enter the acquisition cost in US dollars.
<b>Acquisition Details</b> (e.g., whether the Drug was acquired through the merger with or acquisition of another entity and/or if any other Drugs were acquired by your organization from that entity).	Click here to enter text.

**(d) Manufacturing, Production, and Distribution Budget and Expenditures**

Please report your budget and all expenses associated with manufacturing, producing, and distributing the Drug, including any costs incurred to produce and deliver the drug to the entity that distributes the drug through the supply chain. Information should be provided for the most recent fiscal year for which data are available. Please breakout your expenditures into each of the categories listed below:

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**Salary and Benefits:** Includes compensation associated with individuals involved in manufacturing, production, and distribution, including all forms of monetary and non-financial compensation going to employees and arising from their employment

**Direct Expenses:** Includes fixed assets such as buildings, computer and other equipment, shipping/delivery expenses, software, furniture and fixtures, intangible assets (e.g., patented technology, licensing agreements, equipment lease agreements, trade secrets)

**Outsourcing:** Includes budget and costs for external contractors, hired for the purpose of manufacturing, production, or distribution

**Raw Materials (Cost per Unit):** Includes raw ingredients (therapeutic and non-therapeutic) used to produce the Drug

**Supplies:** Includes supplies that are not included in the raw materials (cost per unit), such as packaging materials, bottles, vials, etc.

**Other (please describe):** Includes any other budget items or costs related to manufacturing, producing, or distributing the product not reported above

**Manufacturing, Production and Distribution Total:** Total budget and expenditures related to Manufacturing, Production and Distribution

**(e) Marketing**

Please report your marketing, including advertising and lobbying, budget and expenditures for the Drug, and your aggregate, company-level budget and all expenses associated with marketing. This section should include any budget items and expenditures related to promoting and selling the drug product, including market research, advertising, and lobbying. It includes, but is not limited to, television, radio, print media, internet advertising and social media, as well as any marketing or advertising activity costs that are directed to consumers (e.g. coupons and contributions to patient advocacy groups), prescribers (e.g. samples), and policymakers. Information should be provided for the most recent fiscal year for which data are available. Please breakout your expenditures into each of the categories listed below, reported separately for the Drug and for all aggregate, company level expenditures:

**Salary and Benefits:** Includes compensation associated with individuals involved in marketing, advertising and lobbying activities, including all forms of monetary and non-financial compensation going to employees and arising from their employment

**Direct Expenses:** Includes fixed assets such as buildings, computer and other equipment, shipping/delivery expenses, software, furniture and fixtures, intangible assets (e.g., patented technology, licensing agreements, equipment lease agreements, trade secrets)

**Outsourcing:** Includes costs for external contractors, hired for the purpose of marketing, advertising, and lobbying

**Other (please describe):** Includes any other budget items or costs related to marketing, advertising, and lobbying not reported above

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

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

**Total Lobbying in Massachusetts:** Total budget and expenditures related to lobbying in Massachusetts

**Total Lobbying Nationally:** Total budget and expenditures related to lobbying at the national level

**Marketing, Advertising, and Lobbying Total:** Total budget and expenditures related to marketing, advertising and lobbying, including activities directed to consumers, prescribers, and policymakers