MASSACHUSETTS
HEALTH POLICY COMMISSION

Presentation to the Maryland Prescription Drug Affordability Board

May 2021

The Role of the Massachusetts Health Policy Commission

- Independent state agency created through **Chapter 224 of the Acts of 2012**
- Goal to **reduce total health care spending growth** in Massachusetts to meet the **health care cost growth benchmark**
- Governed by an **11-member board** with diverse experience in health care
- **HPC responsibilities** include:
  - Setting statewide health care cost growth benchmark
  - Overseeing development and implementation of performance improvement plans
  - Certifying accountable care organizations and patient-centered medical homes
  - Investing in innovative care models, with a focus on health equity
  - Registering provider organizations
  - Conducting cost and market impact reviews
  - Holding annual cost trend hearings
  - Producing annual cost trends report
  - Supporting innovative care delivery investments

The HPC employs four core strategies to realize its vision of better care, better health, and lower costs for all people of the Commonwealth.

RESEARCH AND REPORT

INVESTIGATE, ANALYZE, AND REPORT TRENDS AND INSIGHTS

CONVENE

BRING TOGETHER STAKEHOLDER COMMUNITY TO INFLUENCE THEIR ACTIONS ON A TOPIC OR PROBLEM

WATCHDOG

MONITOR AND INTERVENE WHEN NECESSARY TO ASSURE MARKET PERFORMANCE

PARTNER

ENGAGE WITH INDIVIDUALS, GROUPS, AND ORGANIZATIONS TO ACHIEVE MUTUAL GOALS

HPC pharmaceutical spending research

Topic	Year	Data Source
Drug spending trends (included in annual Cost Trends Report)	2016 and later	▪ IQVIA ▪ MA All-Payer Claims Database (APCD)
Insulin price growth and patient out-of-pocket spending	2019	▪ APCD
Third-party specialty pharmacy use for clinician-administered drugs	2019	▪ APCD
Provider price variation in oncology drugs	2019	▪ APCD
Pharmacy benefit manager spread pricing	2019	▪ CMS State Drug Utilization Data (SDUD) ▪ National Average Drug Acquisition Cost database (NADAC) ▪ APCD
Prescription drug coupon study	2020	▪ Symphony ▪ APCD

1. https://www.mass.gov/service-details/annual-cost-trends-report
2. https://www.mass.gov/info-details/hpc-datapoints-issue-11-insulin-price-growth-and-patient-out-of-pocket-spending?auHash=RSFnw7rJRkNfPqGQHOIkoLxasA-XPem7zYzobUVrKBE
3. https://www.mass.gov/doc/review-of-third-party-specialty-pharmacy-use-for-clinician-administered-drugs/download
4. https://www.mass.gov/doc/2018-report-on-health-care-cost-trends/download
5. https://www.mass.gov/info-details/hpc-datapoints-issue-12-cracking-open-the-black-box-of-pharmacy-benefit-managers
6. https://www.mass.gov/doc/prescription-drug-coupon-study/download

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The MassHealth Process

Direct Negotiations

MassHealth negotiates directly with a drug manufacturer for a supplemental rebate.

Proposed Value & Public Input

If negotiations fail for high cost drugs, MassHealth may propose a value for the drug and solicit public input on the proposed value for the drug.

Further Negotiations

MassHealth updates its proposed value for the drug as necessary and solicits further negotiations with the manufacturer.

Referral to the HPC

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If negotiations with the manufacturer fail, MassHealth may refer the manufacturer to the HPC for review.

The HPC Process

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The HPC Process

Notice & Requests for Information

HPC notifies the manufacturer that it has been referred by MassHealth for review and requests information, including completion of the Standard Reporting Form.

- HPC determines that a manufacturer's pricing is *potentially unreasonable or excessive*
- Notifies the manufacturer, and requests additional information.

Review

HPC reviews information submitted by the manufacturer.

- HPC solicits information from stakeholders.

Determination

HPC may:

- Identify a proposed value for the drug;
- In consultation with MassHealth, propose a supplemental rebate for the drug;
- Determine that the manufacturer's pricing of the drug is unreasonable or excessive in relation to HPC's proposed value for the drug; or
- Close its review of the drug.

- Within 60 days of receiving completed information from the manufacturer, HPC issues a determination on whether the manufacturer's pricing of the drug is unreasonable or excessive in relation to HPC's proposed value for the drug.

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Factors for Review

- Information on clinical efficacy, effectiveness and outcomes
- Characteristics of the drug, including side effects, interactions and contraindications, potential for misuse or abuse
- Existence of therapeutic equivalents
- Seriousness and prevalence of the condition
- Extent to which Drug addresses unmet need
- Impact on subpopulations
- Impact on reducing need for other care, reducing caregiver burden or enhancing quality of life
- Extent of utilization and expected utilization
- Information on the pricing of the Drug, including prices paid by other countries
- Net price compared to therapeutic benefits
- Analyses by independent third parties, including consideration of methods, models, assumptions and limitations
- Other factors the HPC considers relevant, e.g.
  - Information from the Standard Reporting Form, including the Manufacturer's pricing strategy, research and development expenditures for the drug, etc.

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Process for Drug Pricing Reviews

INPUTS

- Data and documents:
  - **From EOHHS**, including information supporting its target value;
  - **From the Manufacturer**, including:
    - Its own assessment of value;
    - Responses to Standard Reporting Form and other HPC requests; and
    - Other information the Manufacturer believes pertinent to HPC review; and
  - **From patients, clinicians, and other stakeholders**, including information provided in response to standard information requests;
- Publicly available information, including assessments from health technology assessment bodies;
- Support from expert consultants; and
- Feedback from Commissioners.

OUTPUTS

- The HPC will issue a determination of whether **pricing for a Drug is unreasonable or excessive in relation to the HPC's proposed value** of the Drug.
  - Before making a final determination, the HPC must give notice to the Manufacturer that the pricing is *potentially* unreasonable or excessive and solicit additional information.
- Data and documents disclosed by a Manufacturer **must remain confidential**, and the HPC cannot identify specific prices or rebates for drugs.
- The HPC will **disclose third party analyses** it relies upon, and will carefully consider their methodologies and models, as well as assumptions and limitations.

Example Drug Pricing Review Questions

- What clinical benefits are offered by the Drug compared to alternatives (e.g. impacts on clinical outcomes, quality of life, need for other care or caregiver burden, ease of treatment regimen), including differences for subpopulations?
- What are the potential negative impacts from the Drug compared to alternatives (e.g. side effects, interactions or contraindications, potential for misuse), including differences for subpopulations?
- What societal benefits are offered by the Drug? For example, to what extent does the Drug address an unmet need or treat a rare or serious disease for which limited alternatives are available? How does the Drug impact disadvantaged or underserved populations?

Across each domain, the HPC will also assess the quality of the evidence, models or methodologies underlying analyses, and assumptions or limitations

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Example Drug Pricing Review Questions

- How does pricing for the Drug compare to alternative treatments and the costs for care that could be avoided?
- What does formal economic analysis indicate as a value-based pricing range?
- How does pricing compare between different payers (e.g., MassHealth, other Medicaid programs, VA, Medicare, commercial, and international)?
- What would the budget impact be to MassHealth based on pricing at different levels?
- What does the Manufacturer describe as the value of the drug and the rationale for its pricing, including any price increases over time?
- What were the manufacturer's costs to develop, manufacture and distribute the drug and how do those compare to its pricing?

Across each domain, the HPC will also assess the quality of the evidence, models or methodologies underlying analyses, and assumptions or limitations

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Example Drug Pricing Review Questions

- Are there any special considerations relating to the Drug not included elsewhere?
- Are there any special considerations regarding the condition, the affected populations, or treatment with the Drug that are not included elsewhere?

Across each domain, the HPC will also assess the quality of the evidence, models or methodologies underlying analyses, and assumptions or limitations

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Example Analysis

More Likely Reasonable

- Strong evidence that the Drug offers substantial benefits compared to alternative treatments, (e.g. improved clinical outcomes, improved quality of life, reduced need for other care)
- Few, if any, negative impacts (e.g. few side effects compared to alternatives)
- Drug addresses an unmet need and/or addresses the needs of underserved populations
- Pricing is in line with pricing ranges suggested by formal economic analysis and/or pricing is relatively comparable between different payers in the US and internationally

More Likely Unreasonable

- Drug offers minimal improvement compared to alternative treatments, or the evidence for improvement is weak
- Significant potential negative impacts (e.g. significant side effects compared to alternatives)
- Pricing is comparatively high when comparing between payers in the US and internationally and/or when compared to pricing ranges suggested by formal economic analysis
- Manufacturer offers little rationale for price level and/or price increases

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Appendix

Incorporating Input from Clinicians, Patients, and Caregivers

HPC seeks to develop a robust process to incorporate clinician, patient, and caregiver input into the HPC's drug pricing reviews.

Goals for Clinician Input	Goals for Patient and Caregiver Input
• Understand the **nature of the disease** and how the Drug works to treat patients with the condition • Learn from **real world practice**, including how the Drug fits in to the standard of care for treating patients, including why a physician might prescribe the Drug over another treatment option. • Understand the **evidence for the Drug**, including whether outcomes captured in studies are clinically meaningful and whether study design reflects real world clinical practice • Identify if the Drug addresses **treatment gaps or treats patients with unmet need,** including any subpopulations of patients who might experience differential treatment effects	• Learn from patients and caregivers about the **impact of the disease** on health, function and quality of life • Understand the **benefits and disadvantages of the Drug** under review compared to alternative treatment options from a patient and caregiver perspective, including benefits not fully captured in studies, and any unmet need addressed. • Understand if the outcomes in the clinical studies and as captured in economic analyses, including any measurements of quality of life, are **meaningful to patients or have limitations.** • Understand the **diversity of experience** between different patients, including differences based on severity, course of illness, and different socioeconomic and life circumstances.

Key Information Requested through the Standard Reporting Form

Topic	Information Requests
Part I: General Information	General information, such as national drug code(s) (NDC), and FDA-approved indications for use; and information related to each indication in which the Drug is approved, such as estimated eligible population for treatment, method of administration, dosing, treatment duration, and FDA approval pathway(s)
Part II: Clinical Effectiveness, Efficacy and Outcomes	Summary of key clinical trials for the drug; additional evidence of clinical efficacy, effectiveness, and outcomes, such as non-randomized and non-controlled evidence if applicable; and a complete list of all clinical studies related to the Drug
Part III: Pricing	Information on Wholesale Acquisition Costs (WAC), net prices in the U.S., international prices, and information to support drug pricing
Part IV: Utilization	Information on utilization in Massachusetts and the U.S. for the previous 5 years and a description of projected utilization in the next 5 calendar years
Part V: Financial Information	Budget and expenditures for research and development, including funding sources; acquisition cost, if relevant; budget and expenditures for manufacturing, production, and distribution; and marketing budget and expenditures

For more information about the Massachusetts Health Policy Commission:

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