COMMISSION ON STEP THERAPY PROTOCOLS Minutes of Virtual Meeting Held May 22, 2025

Call to Order

Kevin Beagan, Deputy Commissioner of the Health Care Access Bureau, presided over the Second Meeting of the Commission on Step Therapy Protocols (Commission) held virtually on May 22, 2025, beginning at 10:00 AM EST. Kevin called the meeting to order and introduced the following agenda items:

Agenda

- 1. Welcome
- 2. Review and Approve Minutes
- 3. Step Therapy Data Collection Tool
- 4. Future Meetings
- 5. Other Matters
- 6. Adjournment

1. Welcome - Attendees

Commission Members	Member Information			
Nancy Ryan	Designee of Executive Director David Seltz of the Health Policy Commission (OPP)			
Kimberly Lenz	Designee of Assistant Secretary for MassHealth Michael Levine			
Caitlin Sullivan	Designee of Executive Director Lauren Peters of the Center for Health Information and Analysis			
Cheryl Bartlett	A representative of the Massachusetts Public Health Association			
Paul Jones	A representative of Blue Cross and Blue Shield of Massachusetts, Inc.			
Sarah Chiaramida	A representative of the Massachusetts Association of Health Plans, Inc.			
Eileen McAnneny (Late Arrival)	A representative of an employer organization			
Darlene Sawicki, CNP	A licensed clinician, other than a physician who has prescribing authority under the scope of her license (MGH)			

Commission Members Not in Attendance	Member Information
Marc Hymovitz	A representative of a patient advocacy organization (ACSCan)
Clinton Pong	A licensed physician in the Commonwealth (PCP, Family Practice)

Guests	Guest Information			
Rebecca Butler	Counsel to the Commissioner, Division of Insurance			
Shannon Lynch	Health Research Analyst, Health Access Bureau, Division of Insurance			
Rita Gallo (Meeting Minutes)	Health Analyst, Bureau of Managed Care, Division of Insurance			

2. Review and Approve Minutes

Motion to Agree to Hold this Meeting Virtually and to Hold All Subsequent Meetings Virtually Unless Designated Otherwise

- Introduced by Cheryl; seconded by Darlene; no discussion requested
- Motion passed unanimously by all Commission members in attendance:

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Voting Member Name	Yes	No	Other
Kevin Beagan	Х		
Nancy Ryan	Х		
Kimberly Lenz	Х		
Caitlin Sullivan	Х		
Cheryl Bartlett	Х		
Paul Jones	Х		
Sarah Chiaramida	Х		
Eileen McAnneny			No Vote; Late Arrival
Darlene Sawicki, CNP	Х		

Kevin solicited additional agenda items, and hearing none, proceeded with the Agenda.

3. Step Therapy Data Collection Tool

Kevin presented the text of M.G.L. c. 1760, Section 12A(g) onscreen, which provides that Massachusetts health insurance carriers are required to submit a step therapy data report annually to the Division of Insurance (Division) in a format prescribed by the Division. Kevin presented the following materials to the Commission for discussion:

- Current version of the data collection tool (Tool) developed by the Division to facilitate the annual report, the review of which will be spearheaded by Shannon, with a walkthrough of certain data elements incorporated based on the Commission's previous discussion;
- Draft Guidelines developed by the Division to assist carriers in completing the Tool; and
- Proposed adoption by the Commission of the Tool in form only, with a separate vote on timing to follow.

Discussion:

- Continuity of Coverage Concerns:
 - Cheryl questioned whether the Tool would capture prescription drug denials resulting from a
 member's transition to a new carrier in which the drug is subject to step therapy protocols, but
 for which no step therapy exception request had been processed by the new carrier; Cheryl
 expressed concern regarding patients' ability to continue to receive prescription medications
 without delay in these scenarios.
 - Kevin indicated that this scenario is likely covered under regulatory requirements for continuation of coverage but that the information may be added to the Tool, if available from carriers.
 - Several Commission members shared information regarding carriers' procedures for pharmacy denial overrides and expedited appeals.
 - Kevin indicated that the Division may request carriers' policies and procedures for handling pharmacy denials of drugs previously approved by a prior carrier as a step therapy exception for discussion at the next Commission meeting.
- <u>Data Collection Methodology</u> Questions raised by Commission members:
 - o How will carriers differentiate between medical and behavioral health data?
 - o Does the "provider specialty" field pertain to prescriber?
 - If the prescriber has several areas of practice (which may straddle medical and behavioral health), how will carriers determine the specialty as it relates to the prescription to which the step therapy exception record pertains? (Paul indicated that this is not always a bright line and was a concern while drafting the bill.)

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- Should the carrier cross-reference internal provider specialty information in preparing the data report or rely upon the self-reported information set forth on the step therapy exception form?
- Kevin proposed that step therapy protocol data be submitted based on provider specialty as reported to carriers on the underlying step therapy exception request forms submitted for review.

Motion to Accept the Division's Proposed Methodology for Collecting Step Therapy Data with

- Introduced by Paul; seconded by Cheryl;
- Following discussion, the motion was withdrawn so that members could discuss individual elements of the data collection too.
- <u>Differentiation of Medical/Surgical and Behavioral Health Data Categories:</u>
 - o Kevin indicated that the draft Guidance currently reflects three categories of data for collection on the Tool: (1) Medical/Surgical, (2) Mental Health, and (3) Substance Use Disorder. As it appears most of the confusion pertains to the classification of Substance Use Disorder drugs, Kevin proposed that Substance Use Disorder data be combined with Mental Health data to form a single category known as Behavioral Health, reducing the number of data classifications to only two. Commission members agreed that this change would reduce confusion and potential misinterpretation.

Motion to Combine Mental Health and Substance Use Disorder Data to Form a Single Category Called "Behavioral Health" in the Collection of Step Therapy Protocol Data

- Introduced by Kim; seconded by Cheryl; no additional discussion
- Motion passed unanimously by all Commission members in attendance:

Voting Member Name	Yes	No	Other
Kevin Beagan	X		
Nancy Ryan	X		
Kimberly Lenz	Х		
Caitlin Sullivan	Х		
Cheryl Bartlett	Х		
Paul Jones	X		
Sarah Chiaramida	Х		
Eileen McAnneny			No Vote; Late Arrival
Darlene Sawicki, CNP	X		

- Collecting data based on whether (1) prescription drug is for medical/surgical conditions or behavioral
 health conditions or (2) the provider is a medical/surgical or behavioral health provider:
 - Commission members questioned whether the drug classification (i.e., the drug name and ICD coding submitted on the step therapy exception request form) would be a clearer determinant than provider specialty in classifying medical/surgical vs. behavioral health data?
 - Commission members agreed that the Division's guidance to carriers should clarify how data should be submitted allow for greater overall consistency and clarity of interpretation.
 - Sarah and Paul agreed to reach out to carriers in their organizations to determine how carriers are classifying step therapy exception requests based on information submitted on the forms.
 - This item, as well as approval of the data collection instrument was tabled to be discussed in the next meeting.

4. Future Meetings

Kevin reintroduced the topic of meeting cadence going forward and proposed that:

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- The Commission's next meeting be held at 10:00 AM EST on June 12, 2025; and
- Quarterly meetings be held at 10:00 AM EST on the second Thursday of the first month of each calendar quarter thereafter for the next 12 months, specifically:
 - o September 11, 2025;
 - o December 11, 2025;
 - o March 12, 2026; and
 - o June 11, 2026.

There were no objections to the cadence proposed above. Kevin indicated that he would issue calendar invites accordingly.

Kevin reiterated that the Division would collect continuity of coverage policies and procedures from carriers for discussion in future meetings. Kevin also indicated that the group would continue to discuss how to define when an exception would be considered medical/surgical as opposed to behavioral health.

5. Other Matters

Kim proposed the following questions, which Kevin agreed would be taken up in the next meeting:

- 1. Percent (%) denied (is that absolute denial or just initial);
- 2. What does a plan do if there is not an "external appeal" vs an internal appeal?
- 3. Are there differences that are defined between internal and external appeals?
- 4. How would a plan report on these exceptions if they are built into criteria but not noted by provider on the "exception" part of the PA form? (flagging that it could lead to under-reporting)

6. Motion to Adjourn Meeting

- Introduced by Cheryl; seconded by Darlene; no discussion requested
- Motion passed unanimously, and Kevin closed the meeting at 10:58 AM EST.

Voting Member Name	Yes	No	Other
Kevin Beagan	X		
Nancy Ryan	X		
Kimberly Lenz	Х		
Caitlin Sullivan	Х		
Cheryl Bartlett	Х		
Paul Jones	X		
Sarah Chiaramida	X		
Eileen McAnneny	X		
Darlene Sawicki, CNP	Х		