

Commission on
Step Therapy Protocols

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Acknowledgements

The enclosed report is being furnished to the secretary of health and human services and the joint committee on health care financing in accordance with Chapter 254 of the Acts of 2022.

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This report represents the report of the Commission on Step Therapy Protocols ("Commission"), enacted as a Commission within the Division of Insurance ("Division") (M.G.L. c. 176O, § 12B). This biennial report presents information regarding step therapy protocols established by health insurance carriers, including commercial insurance companies licensed under M.G.L. c. 175, Blue Cross and Blue Shield of Massachusetts authorized to do business under M.G.L. c. 176A and M.G.L. c. 176B, and Health Maintenance Organizations licensed under M.G.L. c. 176G (collectively "Carriers"). As is noted within M.G.L. c. 176O, § 12B(c), "[n]ot later than October 1 of each even-numbered year, the commission shall submit a report that includes findings from the commission's review and recommendations, including any draft legislation necessary to implement the recommendations, to the secretary of health and human services and the joint committee on health care financing."

Managed Care Regulation

M.G.L. c. 176O ("Health Insurance Consumer Protections") established standards that apply to insured managed care plans issued or renewed in Massachusetts by Carriers. The Division promulgated 211 CMR 52.00 ("Managed Care Consumer Protections and Accreditation of Carriers") to establish standards, including the requirement that Carriers offering insured managed care plans be accredited biennially by the Division for compliance with Massachusetts managed care standards.

Among the accreditation standards, Carriers are permitted to employ utilization review to consider requests for care. Within 211 CMR 52.03, "utilization review" is defined as "a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures or settings. Such techniques may include, but are not limited to, ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review."

The following is noted in M.G.L. c. 176O, § 12(a):

> "Utilization review conducted by a carrier or a utilization review organization shall be conducted under a written plan, under the supervision of a physician and staffed by appropriately trained and qualified personnel and shall include a documented process to: (i) review and evaluate its effectiveness; (ii) ensure the consistent application of utilization review criteria; and (iii) ensure the timeliness of utilization review determinations.
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> A carrier or utilization review organization shall adopt utilization review criteria and conduct all utilization review activities under said criteria. The criteria shall be, to the maximum extent feasible, scientifically derived and evidence-based, and developed with the input of participating physicians, consistent with the development of medical necessity criteria under section 16. Utilization review criteria shall be applied consistently by a carrier or a utilization review organization and made easily accessible and up-to-date on a carrier or utilization review organization's website and upon request to the general public; provided, however, that a carrier shall not be required to disclose licensed, proprietary criteria purchased by a carrier or utilization review organization on its website, but shall disclose such licensed, proprietary criteria relevant to particular treatments and services to insureds, prospective insureds and health care providers upon request. If a carrier or utilization review organization intends either to implement a new preauthorization requirement or restriction or amend an existing requirement or restriction, the carrier or utilization review organization shall ensure that the new or amended requirement or restriction shall not be implemented unless the carrier's or utilization review organization's website has been updated to reflect the new or amended requirement or restriction.
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> Adverse determinations rendered by a program of utilization review or other denials of requests for health services, shall be made by a person licensed in the appropriate specialty related to such health service and, if applicable, by a provider in the same licensure category as the ordering provider."

Within 211 CMR 52.08, the Division has promulgated standards that apply to utilization review, including requirements associated with any adverse determination notifications when a Carrier does not agree with a request for services or supplies, and a description of the rights that a consumer has to appeal an adverse determination through processes that are internal, i.e., within the Carrier – or external, i.e., through the Office of Patient Protection.

An Act Relative to Step Therapy and Patient Safety

Chapter 254 of the Acts of 2022 ("Chapter 254"), "An Act Relative to Step Therapy and Patient Safety," creates the standards applying to step therapy protocols, amending the Massachusetts laws to add M.G.L. c. 176O, § 12A, pertaining to insured managed care plans; and M.G.L. c. 118E, § 51A, pertaining to the MassHealth Program. As is noted within M.G.L. c. 176O, § 12A(a), a "step therapy protocol" is a "utilization management policy or program that establishes the specific sequence in which a prescription drug for a specified medical condition is covered by a carrier."

The following is noted in M.G.L. c. 176O, § 12A(b):

> "(1) Clinical review criteria used to establish a step therapy protocol shall not require an insured to utilize a medication that is not likely to be clinically effective for the prescribed purpose, based on peer-reviewed clinical evidence, in order to obtain coverage for a prescribed medication. Any requirement imposed by a carrier or utilization review organization to utilize a medication other than that prescribed shall permit the insured to seek an exception to the step therapy protocol pursuant to subsection (c).
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> (2) When establishing clinical review criteria to be used for a step therapy protocol, a carrier or a utilization review organization shall take into account the needs of atypical patient populations and diagnoses.
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> (3) This section shall not require a carrier or a utilization review organization to establish a new entity to develop clinical review criteria used for step therapy protocols."

The following is further noted in M.G.L. c. 176O, § 12A(c):

> "(1) If coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier directly or through a utilization review organization through the use of a step therapy protocol, the insured and prescribing health care provider shall have access to a clear, readily accessible and convenient process to request an exception to such step therapy protocol. An insured or their prescribing health care provider may request an exception to such protocol, and such request for an exception shall be granted if:
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> (i) the prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction in or physical or mental harm to the insured;
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> (ii) the prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen;
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> (iii) (A) the insured or prescribing health care provider has provided documentation to the carrier or utilization review organization establishing that the insured has previously tried the prescription drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of action; and
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> (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or
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> (iv) the insured or prescribing health care provider has provided documentation to a carrier or utilization review organization establishing that the insured: (A) is stable on a

prescription drug prescribed by their health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the insured;

(2) All carriers shall have a continuity of coverage policy in place to ensure that the insured does not experience any delay in accessing the drug prescribed by their health care provider, including a drug administered by infusion, while the exception request is being reviewed; provided, however, that the continuity of coverage policy shall include, but not be limited to, a 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the insured has already been prescribed and on which the insured is stable; and provided further, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to drugs covered by the plan.

(3) Upon granting an exception to the step therapy protocol, a carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the insured's health care provider. A denial of an exception shall be eligible for appeal by an insured.

(4) Nothing in this section shall prevent: (i) a pharmacist from effecting substitutions of prescription drugs consistent with section 12D of chapter 112; or (ii) a health care provider from prescribing a prescription drug that is determined to be medically appropriate."

The following is further noted in M.G.L. c. 176O, § 12A(d), (e) and (f):

"(d) A carrier or a utilization review organization shall grant or deny a request for an exception to the step therapy protocol or a request to appeal a denial of an exception not more than 3 business days following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If additional delay would result in significant risk to the insured's health or well-being, a carrier or a utilization review organization shall respond not more than 24 hours following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If a response by a carrier or a utilization review organization is not received within the time required under this paragraph, an exception to the step therapy protocol shall be deemed granted.

(e) This section shall apply to carriers that provide coverage of a prescription drug pursuant to a policy that meets the definition of a step therapy protocol, regardless of whether the policy is described as a step therapy protocol.

(f) The division shall promulgate regulations necessary to implement this section."

The Division issued Bulletin 2024-03 - https://www.mass.gov/doc/bulletin-2024-03-step-therapy-protocols-pursuant-to-chapter-254-of-the-acts-of-2022-chapter-254-issued-january-16-2024/download - to notify all Carriers of the requirements of Chapter 254. Subsequent to the issuance of the noted Bulletin, Carriers submitted implementation plans to the Division that identified the steps that they took to fully implement the provisions within their utilization plans.

Commission on Step Therapy Protocols

Formation of Commission

Chapter 254 of the Acts of 2022 created a Step Therapy Protocols Commission within the Division of Insurance. The following is noted in M.G.L. c. 176O, § 12B(a):

"a. There shall be a commission on step therapy protocols within the division. The commission shall consist of:

the commissioner of insurance or a designee, who shall serve as chair;
the executive director of the health policy commission or a designee;
the assistant secretary for MassHealth or a designee;
the executive director of the center for health information and analysis or a designee;
and 7 members appointed by the governor,
1 of whom shall represent the Massachusetts Public Health Association,
1 of whom shall represent Blue Cross and Blue Shield of Massachusetts, Inc.,
1 of whom shall represent the Massachusetts Association of Health Plans, Inc.,
1 of whom shall represent a patient advocacy organization,
1 of whom shall represent an employer organization,
1 of whom shall be currently practicing as a licensed physician in the commonwealth, and
1 of whom shall be currently practicing as a licensed clinician, other than a physician, who has prescribing authority under the scope of their licensure.

The commission shall meet as needed to satisfy the reporting requirements of this section."

The following members of the Commission were officially appointed in February 2025:

Commission Members	**Member Information**
Kevin Beagan	Designee of Insurance Commissioner (DOI), Chair
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.
Marc Hymovitz	A representative of a patient advocacy organization (ACSCan)
Clinton Pong	A licensed physician in the Commonwealth (PCP, Family Practice)
Eileen McAnneny	A representative of an employer organization
Darlene Sawicki, CNP	A representative of MGH as a non-physician licensed Massachusetts prescriber

The members had their organizational meeting on April 17, 2025, and elected to hold quarterly meetings. Subsequent to the organizational meeting, the Commission met on the following dates:

May 22, 2025,

June 12, 2025,

December 11, 2025,

March 12, 2026,

June 11, 2026, and

September 10, 2026.

As of the submission of this report, two members – Cheryl Bartlett and Paul Jones – have notified the Commission that they will no longer be able to serve the Commission. The Commission is seeking nominees from the Massachusetts Public Health Association and Blue Cross and Blue Shield of Massachusetts to be considered for appointment by Governor Healey.

The minutes of the meetings through June 11, 2026, are included in an Appendix to this report.

Charge of the Commission

The following is noted within M.G.L. c, 176O, § 12B(b):

"b. The commission shall study and assess the implementation of step therapy process reforms established in section 51A of chapter 118E and section 12A. The commission shall:

> (i) analyze the impact of step therapy protocols on total medical expenses, health care quality outcomes, premium cost and out-of-pocket costs to the consumer and the health care cost benchmark; and
> (ii) assess the efficacy of the step therapy exception process in ensuring that consumers diagnosed with medical conditions that rely on stability or have achieved a positive clinical response on a medication are able to maintain that course of treatment including, but not limited to, a form of multiple sclerosis. The commission shall also examine any available empirical data on the impact of step therapy protocols on health disparities related to outcomes, access, and medication adherence.

c. Not later than October 1 of each even-numbered year, the commission shall submit a report that includes findings from the commission's review and recommendations, including any draft legislation necessary to implement the recommendations, to the secretary of health and human services and the joint committee on health care financing.

Step Therapy Reports

The following is noted within M.G.L. c, 176O, § 12A(g):

"(g) Annually, each carrier shall report to the division, in a format prescribed by the division:

(i) the number of step therapy exception requests received by exception;
(ii) the type of health care providers or the medical specialties of the health care providers submitting step therapy exception requests;
(iii) the number of step therapy exception requests by exception that were denied and the reasons for the denials;
(iv) the number of step therapy exception requests by exception that were approved;
(v) the medical conditions for which patients are granted exceptions due to the likelihood that switching from the prescription drug will likely cause an adverse reaction in or physical or mental harm to the insured;
(vi) the number of step therapy exception requests by exception that were initially denied and then appealed; and
(vii) the number of step therapy exception requests by exception that were initially denied and then subsequently reversed by internal appeals or external reviews."

The Division worked with Carriers to collect and report information according to standard templates that were developed with input from members of the Commission. The Division gave the following instructions within Bulletin 2023-03:

> "The Division is mandated to develop and implement prior authorization forms for health services and considered developing modifications to previously standardized prior authorization forms for use in reviewing requests for medication. In order to enable a clear, readily accessible, and convenient process to request an exception to Carriers' step therapy protocols pursuant to M.G.L. c. 176O, §25(c), the Mass Collaborative, composed of representatives from insurance Carriers, provider groups, and associations, considered amendments to the following forms based on the specific provisions of M.G.L. c. 176O, §12A(c):
>
> **Massachusetts Standard Form for Medication Prior Authorization Requests (issued with Bulletin 2016-08)**
> **Massachusetts Standard Form for Hepatitis C Medication Prior Authorization Requests (issued with Bulletin 2017-04)**
> **Massachusetts Standard Form for Chemotherapy and Supportive Care Prior Authorization Requests (issued with Bulletin 2022-07)**

The Division presented the draft amendments to the noted forms during an information session, held on August 23, 2023. The Division considered comments raised at and after the information session and now approves those forms, as included in the Appendix to this Bulletin, as the standard prior authorization forms to replace those issued along with Bulletins 2016-08, 2017-04, and 2022-07. Bulletins 2016-08, 2017-04, and 2022-07 are thus rescinded as of today's date. With respect to the applicable health services, Carriers may no longer require the use of any other paper form other than the standard forms included in the Appendix to this Bulletin, which Carriers shall make available for use by all contracted providers.

As is the case whenever the Division approves prior authorization forms, the Division expects that Carriers shall take all necessary steps to amend their utilization review systems to accept any standard prior authorization form that may be submitted by providers by mail, as an attachment to electronic mail, or by facsimile machine. The applicable standard prior authorization form will serve as sufficient information upon which the insured health plan should make its decisions about the medical necessity and appropriateness of the requested service or procedure, including step therapy decisions. The standard prior authorization forms are designed to create a clear, readily accessible, and convenient process for members and providers to request an exception to the step therapy protocol and submit information for the exceptions process.

Carriers wishing to modify the format from the standard form are required to submit screenshots of all such forms for the Division's review before their use in the market. Data collected electronically by Carriers for prior authorizations should be identical to the data collected on these paper forms.

The Division is aware that Carriers and providers may be at differing degrees of readiness for implementing standard prior authorization forms. Although many provider organizations may be ready to implement the new forms, other providers may not yet be prepared. The Division sends this guidance to remind Carriers of their obligations. As the paper forms become

available, the Division strongly encourages Carriers to consider taking steps to work with provider organizations to educate contracted and other providers about the use of uniform prior authorization forms for approved medications. Carriers are encouraged to work with contracted providers to use the standard and electronic forms within 90 days after the issuance of this Bulletin."

Within the updated prior authorization forms, a section was specifically added that requested the following information:

F. Exceptions to Step Therapy ***Please complete the applicable section(s).***
Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No If yes, briefly describe details of contraindication, adverse reaction, or harm:
Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regiment? ☐ Yes ☐ No If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No If yes, please provide details for the previous trial(s): **Drug Name:** **Dates/duration of use:** Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response Briefly describe details of adverse reaction or inadequate response: **Drug Name:** **Dates/duration of use:** Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response Briefly describe details of adverse reaction or inadequate response:
Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member? ☐ Yes ☐ No If yes, briefly provide details on the member's stability and the likely adverse reaction or physical or mental harm:

When submitting reports, Carriers were asked to separate step therapy requests based upon whether the request was for medical/surgical or behavioral health/substance use treatment services.

There was a debate about whether reporting in this manner should be based on provider specialty or by drug type. Several commission members expressed a preference for Carriers reporting by provider specialties, as it is consistent with current reporting methodologies to other agencies and would not require additional programming to implement. The final template was approved at the June 12, 2025 meeting. Carriers were asked to submit data from calendar year 2024 (Calendar Year 2024 Report) by no later than October 1, 2025, and all subsequent years, beginning with calendar year 2025, by May 1 of the following year.

Calendar Year 2024 Report

The Division received reports from 14 companies and detailed information is included in supplementary information accompanying the commission report.

Medical/surgical

The Carriers reported a total of 61,266 medical/surgical step therapy exception requests. Of these, 39,972 (65.2%) were authorized. Of the remaining 21,301 (34.8%) that were not authorized, 1,241 were sent to an internal appeal and 713 were authorized on appeal (57.5% of those sent to internal appeal). Of the 417 (33.6%) that were still denied on internal appeal, carriers reported that only 1 was sent for an external review[1] and this 1 exception request was authorized following the external review.

Of the 61,266 submitted step therapy exception requests,

- 11,117 (18.1%) were because the provider indicated that the step therapy drug was contraindicated or there was an adverse reaction,
- 13,363 (21.8%) were because the provider indicated that the step therapy drug was ineffective,
- 21,133 (34.5%) were because the provider indicated that the step therapy drug was previously tried and found to be ineffective and
- 15,653 (25.5%) were because the provider indicated that switching to the step therapy drug would cause an adverse reaction.

Behavioral health/substance use

The Carriers reported a total of 3,706 behavioral health/substance use step therapy exception requests. Of these, 2,761 (74.5%) were authorized. Of the remaining 939 (25.3%) that were not authorized, 30 were sent to an internal appeal and 24 were authorized on appeal (80% of those sent to internal appeal). Of the 6 (20.0%) that were still denied on internal appeal, carriers reported that only 1 was sent for an external review and this 1 exception request was authorized following the external review.

Of the 3,706 submitted step therapy exception requests,

- 752 (20.3%) were because the provider indicated that the step therapy drug was contraindicated or there was an adverse reaction,
- 863 (23.3%) were because the provider indicated that the step therapy drug was ineffective,
- 1,248 (33.7%) were because the provider indicated that the step therapy drug was previously tried and

[1] External appeals are with an independent review organization and are coordinated by the Office of Patient Protection.

found to be ineffective, and
- 843 (22.7%) were because the provider indicated that switching to the step therapy drug would cause an adverse reaction.

Calendar Year 2025 Report

The Division received reports from 14 companies and detailed information is included in supplementary information accompanying the commission report. Similar to the 2024 report, the calendar year 2025 figures reflect Carrier-reported data and are subject to the significant methodological and reporting limitations described below; they should not be interpreted as comparable measures of step therapy utilization across carriers or years, nor should they be used as the basis for any legislative or policy recommendations.

Medical/surgical

The Carriers reported a total of 104,979 medical/surgical step therapy exception requests. Of these, 67,187 (64.0%) were authorized. Of the remaining 37,792 (36.0%) that were not authorized, 4,265 were sent to an internal appeal and 1,826 were authorized on appeal (42.8% of requests sent to internal appeal). Of the 2,439 (57.2%) that were still denied on internal appeal, carriers reported that only 28 were sent for an external review and, of these 28, 16 exception requests were authorized following the external review.

Of the 104,979 submitted step therapy exception requests,
- 16,306 (15.5%) were because the provider indicated that the step therapy drug was contraindicated or there was an adverse reaction,
- 19,606 (18.7%) were because the provider indicated that the step therapy drug was ineffective,
- 44,853 (42.7%) were because the provider indicated that the step therapy drug was previously tried and found to be ineffective, and
- 24,214 (23.7%) were because the provider indicated that switching to the step therapy drug would cause an adverse reaction.

Behavioral health/substance use

The Carriers reported a total of 6,169 behavioral health/substance use step therapy exception requests. Of these, 4,375 (70.9%) were authorized. Of the remaining 1,794 (29.1%) that were not authorized, 104 were sent to an internal appeal and 67 were authorized on appeal (64.4% of those sent to internal appeal). Of the 37 (35.6%) that were still denied on internal appeal, carriers reported that none were sent for an external review coordi through the Office of Patient Protection in the Health Policy Commission.

Of the 6,169 submitted step therapy exception requests,
- 1,315 (21.3%) were because the provider indicated that the step therapy drug was contraindicated or there was an adverse reaction,
- 1,509 (24.5%) were because the provider indicated that the step therapy drug was ineffective,
- 1,848 (30.0%) were because the provider indicated that the step therapy drug was previously tried and found to be ineffective, and
- 1,497 (24.3%) were because the provider indicated that switching to the step therapy drug would cause an adverse reaction.

Review/Limitations of the 2024/2025 Experience

The total number of medical/surgical step therapy exception requests increased 71.3% from CY2024 to CY2025 (61,266 in CY2024 to104,979 in CY2025). The total number of behavioral health/substance use step therapy exception requests increased 66.5% from calendar year 2024 to CY2025 (3,706 in CY2024 to 6,169 in CY2025).

Although the reported numbers may show a significant increase in reported step therapy exception requests from

calendar year 2024 to calendar year 2025, the calendar year 2024 statistics should not be compared to the calendar year 2025 statistics, given implementation timelines. Because the Division issued Bulletin 2024-03 in January 2024 and Carriers submitted implementation plans to implement the exception requests in 2024, it is assumed that the calendar year 2024 figures underreport the true calendar year 2024 figures.

It is also important to report that there are significant differences in the information submitted across individual Carriers. Of the companies reporting medical/surgical exception requests for calendar year 2024, there were 2 large Carriers reporting 0 requests and another 2 reporting requests under 40. When looking at what was reported for calendar year 2025, there was 1 large Carrier reporting 0 requests and another 3 reporting requests under 40. It is clear that there is inconsistency in how data is collected and reported.

The reported data shows substantial variation in step therapy exception requests across Carriers and between calendar years 2024 and 2025. These differences should be interpreted with significant caution. Based on feedback from Carriers, the variation appears to reflect differences in reporting methodologies, system capabilities, provider submission practices, and interpretation of the Division's reporting requirements, rather than necessarily reflecting meaningful differences in how Carriers administer step therapy.

Most significantly, Carriers did not apply a uniform definition of a "step therapy exception request." Some Carriers reported only requests in which a provider specifically sought an exception from step therapy requirements. Others reported a broader universe of prior authorization requests involving drugs subject to step therapy, even where an exception was not specifically requested or step therapy was only one component of the applicable coverage criteria. As a result, the data reported by different Carriers may not represent comparable populations of requests.

Additional variation resulted from differences in electronic prior authorization and PBM systems. In some systems, the statutory step therapy exception questions are embedded within broader prior authorization workflows. Providers may therefore select one or more exception categories even when an exception is not necessary to approve the request. In other cases, a request may be denied for reasons unrelated to step therapy—such as failure to satisfy indication, prescriber, or other coverage criteria—but may nevertheless appear in step therapy reporting because the step therapy form or workflow was used.

Provider completion of the forms also affected the data. Carriers reported instances in which providers selected multiple exception reasons for a single request or completed all available fields in an electronic workflow regardless of applicability. This may result in overcounting or inconsistent categorization of exception reasons.

Finally, differences in PBM and Carrier system capabilities affect the ability to separately identify drugs subject to step therapy, distinguish an actual exception request from a broader prior authorization request, and determine the basis for approval or denial. Ambiguities in the existing reporting instructions, including the distinction between a step therapy request and an exception request and how denials unrelated to step therapy should be classified, further contributed to inconsistent reporting.

Accordingly, the 2024 and 2025 data should not be interpreted as providing a reliable measure of the prevalence of step therapy exceptions, differences in Carrier practices, or changes in actual step therapy activity over time. In particular, the reported 71.3% increase in medical/surgical requests and 66.5% increase in behavioral health/substance use requests should not be characterized as increases in actual exception requests. They represent increases in reported requests under reporting methodologies that were not sufficiently standardized to support a valid year-over-year comparison.

The significant variation among Carriers, including large Carriers reporting no or very few exception requests while others reported substantially higher volumes, further demonstrates the need for standardized definitions and reporting criteria before meaningful comparisons can be made. The Division and industry representatives should

therefore continue working to clarify the reporting instructions and redesign the reporting template so that future reports capture a consistently defined universe of step therapy exception requests. The industry representatives indicated that they would go back to the Carriers for additional suggestions about revising the reporting criteria and redesigning the exception request form with the goal of collecting more accurate data for the report to the legislature. For the purpose of calendar year 2026 reporting, the decision was to continue with the same template but to redesign the template that would be used for calendar year 2027 reporting.

Continuity of Coverage Plans

The Commission collected and examined Carriers' Continuity of Coverage plans to determine how Carriers explain Continuity of Coverage for those undergoing Step Therapy review. The purpose of the Continuity of Coverage plans is to ensure that members do not experience a lapse in coverage when transitioning between health plans.

The Commission members examined all the submitted materials and found that the processes outlined by the Carriers did reflect the process outlined in the law, but certain Carriers did a much better job at explaining the Step Therapy process and continuity of coverage than others. The Commission suggested that the Division work with Carriers to develop a set of information to include in future editions of the plans.

Other Regulations Impacting Step Therapy

The Division explained newly enacted licensing requirements for Pharmacy Benefit Managers (PBMs), and the Division established an interim 1-year licensing term for PBMs, effective January 1, 2026, under the new PBM law until the accompanying PBM regulation, which outlines the more robust licensing requirements for a full 3-year term, was adopted. The Division has initiated a more robust review 3-year licensing process as of July 2026 for the period between 2027 and 2029. The Center for Health Information and Analysis ("CHIA") provided an update on its oversight of pharmacy benefit managers (PBMs), which includes collecting information on formulary design and associated utilization management requirements, PBM business practices, rebates received from prescription drug manufacturers, the extent to which these rebates are passed through to patients and carriers, and fees charged for services provided to carriers and plan sponsors.

The Division also discussed the work it is doing to modify existing managed care regulations to limit or eliminate certain unnecessary and burdensome prior authorization (prospective review) requirements. The resulting regulation may aid in streamlining requests for certain services, supplies, and prescriptions. The final regulation has now been promulgated, and the Division plans for clarifying guidance to oversee a less complex process to review some requests for care.

Next Steps

Annually, the Commission performs a review of Carriers' step therapy protocols based on information collected by the Division. The Commission acknowledges that it needs to do more in the upcoming period to address its statutory charges and intends to expand its review by delving further into these processes within the next-most reporting period.

There was agreement among the Commission members that the immediate focus is to get the exception reports right (i.e., Carrier details and summary reports with added information from Carriers), provide guidance to Carriers about improving Continuity of Coverage plans and to look for new sources of information to evaluate the processes used by Carriers. As part of this process, the Commission aims to compare Carriers' utilization review policies and procedures and differences among Carriers to develop more standardized processes, where appropriate, going forward.

The Commission intends to continue holding regular meetings, examine all complaints made about step therapy processes and obtain additional public input to understand areas of further investigations.

In the course of reviewing Carrier-submitted reports, it was evident that Carriers' information was reported inconsistently. The Commission recommends that the Division work with Commission experts to further clarify reporting requirements and specifications to provide critical evaluation of each of the Carrier's processes.

At this time, the Commission does not have any legislative recommendations but may offer such recommendations for future consideration based upon its continued review and evaluation of Carriers' reported data and procedures.

Appendix A – Minutes of Commission Meetings.