670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

November 19, 2025

Ms. Jolie Matthews

Submitted via electronic mail: jmatthews@naic.org

RE: NAIC Regulatory Framework (B) Taskforce Prior Authorization Framework Final White Paper

Dear Ms. Matthews,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide additional comments on the National Association of Insurance Commissioners' (NAIC) "Prior Authorization White Paper" (White Paper).

As you may know, PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

As discussed in our comment letter on the draft White Paper, PhRMA shares NAIC's perspective that inappropriate use of prior authorization raises many concerns, and we commend NAIC for taking a comprehensive and thoughtful approach to analyzing the issue and potential regulatory solutions in its final White Paper. While occasionally seen as distinct utilization management tools, prior authorization and step therapy may both result in many of the same hurdles and administrative burdens discussed in the final White Paper. Indeed, as is the case with "embedded step therapy," as described below, they may be indistinguishable to the provider or patient.

As previously discussed, the number of medicines subject to utilization management tools such as step therapy and prior authorization has grown over time. Pharmacy Benefit Managers (PBMs) and insurers use step therapy to require patients to fail on one or more alternative drugs before they will cover the medicine originally prescribed by the provider. Prior authorization requires providers to obtain approval from the PBM or insurer in order for a medicine to be covered, which in some cases can lead to delays in care.

As highlighted in our recent comments, we recommend incorporating recent extensive research in the White Paper that shows that commercial plans have imposed restrictive utilization management practices. Some of these practices include step therapy requirements that require a beneficiary to first try drugs that are not Food and Drug Administration-approved (FDA-approved) for a particular use before the beneficiary is able to access the prescribed drug that is FDA-approved for that use.[i] Other practices include the use of "embedded step therapy," where a drug is listed as having prior authorization but does not disclose that the prior authorization requires a patient to complete a step therapy protocol.[ii] A recent analysis examined similar practices in the commercial market for drugs used to treat psoriatic arthritis (PsA), multiple sclerosis, and chronic myelogenous leukemia (CML). The analysis determined that plans apply step therapy beyond FDA-approved labeling for PsA drugs 63 percent of the time and also embed step therapy in prior authorization requirements 59 percent of the time for PsA drugs.[iii]

When examining the broader burdens on patients created by inappropriate utilization management practices, a 2025 IQVIA study found that over 75% of patients in the commercial market were initially denied coverage when trying to fill a new prescription in five therapeutic areas.[iv] The study also found that patients who were initially denied a new prescription, but successfully overturned the payer rejection, experienced average coverage delays between three to five weeks.[v]

We continue to encourage the Task Force to take a closer look at how embedded step therapy and step therapy beyond FDA-approved labeling are utilized within utilization management protocols to bolster the comprehensive work outlined in the final White Paper. Additionally, the Task Force may want to consider ways to increase transparency into embedded step therapy practices to allow consumers to pick the best plan that meets their health needs. For example, state regulators could require insurers to disclose the use of embedded step therapy and step therapy beyond FDA-approved labeling in consumer-facing materials.

We look forward to continuing to engage with NAIC on issues related to utilization management. Please do not hesitate to reach out with any questions.

Sincerely,

Charise Richard
Sr. Director, State Policy
PhRMA

---

[i] Avalere. Part D Prior Authorization Policies May Include Step Therapy. March 2025. https://advisory.avalerehealth.com/insights/part-d-prior-authorization-policies-may-include-step-therapy

[ii] *Ibid*.

[iii] Avalere. Commercial Step Therapy May Include Steps Beyond FDA Label. May 2025. https://advisory.avalerehealth.com/insights/commercial-step-therapy-may-include-steps-beyond-fda-label

[iv] IQVIA. The Impact of Formulary Controls on Commercially Insured Patients in Five Chronic Therapeutic Areas. July 2025. https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-commercially-insured-patients-in-five-chronic-therapeutic-areas

[v] *Ibid*.