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August 14, 2025

Ms. Jolie Matthews

Submitted via electronic mail: jmatthews@naic.org

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

Dear Ms. Matthews,

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

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.

PhRMA shares NAIC's perspective that inappropriate use of prior authorization raises a number of concerns, and we commend NAIC for taking a comprehensive and thoughtful approach to examining the issue and potential regulatory solutions. Recent research regarding utilization management, especially step therapy, may be of interest to the Regulatory Framework Task Force (Task Force). Although occasionally seen as distinct utilization management tools, prior authorization and step therapy may both result in many of the same hurdles and administrative burden discussed in the White Paper. Indeed, as is the case with "embedded step therapy," as described below, they may be indistinguishable to the provider or patient as a practical matter.

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. In the commercial market, Avalere Health found that prior authorization and step therapy for single-source brand medicines increased for all therapeutic areas studied, including conditions such as cancer, depression, rheumatoid arthritis (RA), and diabetes, between 2014 and 2020.[i]

The increase in the use of utilization management practices can result in patients having their prescriptions rejected at the pharmacy counter. A 2025 study performed by IQVIA for patients in the commercial market, found that over 75% of patients were initially denied coverage when trying to fill a new prescription in five therapeutic areas. Initially denied patients who successfully overturned the payer rejection experienced average coverage delays between three to five weeks.[ii] These patients also had to overcome an average of two to four rejections before obtaining approval for their prescribed medicine.[iii]

Onerous and inappropriate utilization management restrictions may interfere with the patient-physician decision-making process and blur the lines between benefits administration and the practice of medicine. Research shows that formulary exclusions and utilization management by PBMs in highly

consolidated markets appear to have spillover effects on patients not covered by the market-leading PBM. An analysis of prescribing patterns for commercially insured patients determined that in areas where a single PBM controls an outsized share of the industry, the leading PBM's preferred product achieves a disproportionately large market share among patients covered by non-market leading PBMs.[iv]

Additionally, recent research has shown that both commercial plans and Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs) have imposed more restrictive utilization management practices. Some of these practices include step therapy requirements that require a beneficiary to step through additional drugs that are not indicated in a drug's Food and Drug Administration (FDA) labeling.[v] Other practices include the use of "embedded step therapy," where a drug is listed as having prior authorization but does not note step therapy and prior authorization criteria that requires a patient to step through at least one drug.[vi] A recent analysis examined similar practices in the commercial market for drugs used to treat psoriatic arthritis, multiple sclerosis, and chronic myelogenous leukemia (CML). The analysis found that step therapy is embedded in prior authorization requirements 59 percent of the time for PsA drugs, 51 percent of the time for CML drugs, and 32 percent of the time for MS drugs.[vii] Additionally, the analysis determined that plans apply step therapy beyond FDA-approved labeling for PsA drugs 63 percent of the time, CML drugs 39 percent of the time, and MS drugs 37 percent of the time.[viii]

The Task Force should consider a closer look at how embedded step therapy and step therapy beyond FDA labeling are utilized within the broader context of prior authorization to augment the very comprehensive work already undertaken in the draft White Paper. Additionally, the Task force may want to consider ways to increase transparency into embedded step therapy practices to allow consumers to choose plans that best fit their needs. For example, state regulators could require insurers to disclose the use of embedded step therapy in consumer-facing materials. We hope this research is helpful to the Task Force and look forward to continuing to engage with NAIC as this important work moves forward. Please do not hesitate to reach out with any questions.

Sincerely,

Charise Richard
Sr. Director, State Policy
PhRMA

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[i] Avalere Health. Utilization Management Trends in the Commercial Market, 2014-2020. November 24, 2021. https://avalere.com/insights/utilization-management-trends-in-the-commercial-market-2014-2020

[ii] *Ibid.*

[iii] *Ibid.*

[iv] Hayden Consulting. PBM Consolidation and its Impact on Geo Prescribing Patterns, November 2023. https://haydencg.com/pbm-consolidation-and-its-impact-on-geo-prescribing-patterns/

[v] 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

[vi] *Ibid.*

[vii] 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

[viii] *Ibid.*