Pulmonary Hypertension Association
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Comments on the National Association of Insurance Commissioners' Prior Authorization White Paper

on behalf of the

Pulmonary Hypertension Association

August 29, 2025

Thank you for the opportunity to comment on the NAIC Prior Authorization While Paper. Many of the perspectives shared in the current white paper reflect those of the pulmonary hypertension community and PHA applauds NAIC for your thoughtful, multi-stakeholder approach to this topic. In the comments below we have highlighted some places where the experiences of health care providers and patients impacted by PH align closely with the white paper, as well as places where there is some variation.

About Pulmonary Hypertension and the Pulmonary Hypertension Association

Pulmonary hypertension (PH) describes high blood pressure in the lungs, which can occur without a known cause, or in conjunction with underlying heart, lung or rheumatologic disease, blood clots in the lungs, or sleep disordered breathing. The disease can impact anyone of any age. Without prompt, appropriate treatment, PH can be rapidly progressive and fatal.

One form of PH, pulmonary arterial hypertension (PAH), is a rare disease that constricts the arteries in the lungs that carry oxygenated blood back to the body, causing shortness of breath and overworking the heart muscle. **PAH is a lifelong condition with available treatments but no cure.**

PAH is a complex, progressive and frequently fatal condition, with an average life expectancy of around seven years. It is frequently misdiagnosed and 75% of individuals have already developed significant, debilitating symptoms at the time of diagnosis[1]. Delayed access to the most appropriate, highest impact treatment, whether from misdiagnosis or benefits management requirements, can lead to loss of function that is not always recovered even after appropriate therapy is started. In the worst-case scenario, delayed access to appropriate therapy can lead to death[2].

PAH requires careful management by a specialist care team. Available therapy options address four distinct disease pathways and are frequently used in combination for maximum clinical effectiveness. Delivery mechanism varies by

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therapy and is sometimes quite complex. Treatment for advanced PAH often includes an around-the-clock infusion directly into the patient's heart administered via a pump the patient carries with them at all times. Oral, inhaled, injected and short-term infusion treatment options are also prescribed.

Due to the complex nature of the disease, appropriate therapy varies by patient, even among individuals with similar clinical presentation. In addition, some PAH patients have dramatic responses to even small changes in treatment, such as the small differences between brand and generic therapy.

When ideal therapy is delayed or disrupted, patients may experience a rapid health decline leading to emergency room visits, loss in functional ability and possibly a permanent transition to more aggressive, costly treatment. While PHA recognizes the importance of treating only patients who have been correctly diagnosed, we believe that therapy choices should be driven by expert clinical judgement and the patient-clinician relationship.

The **Pulmonary Hypertension Association** (PHA) is the country's leading PH organization. PHA's mission is to extend and improve the lives of those affected by PH. PHA is a unique, multi-stakeholder organization serving health care professionals as well as patients and their loved ones. PHA houses a clinical program accreditation indicative, a national observational patient registry and a robust continuing medical education program. In addition, the organization provides peer support groups, online and in-person education and advocacy opportunities to people living with PH and their loved ones.

<u>PHA's Prior Authorization Initiative</u>
In 2023, the Pulmonary Hypertension Association launched a multi-stakeholder initiative to understand the impact of prior authorization requirements on patient care and, if possible, reduce the burden of prior authorization on people with PH and their expert health care providers. To date the initiative has included:

- A survey of PH accredited care centers about health care providers' experiences with prior authorization. ("Survey")

- A Zoom-based, single-blinded focus group with representatives from a range of national and regional payers and PBM's. ("Focus Group")

- An in-person, day-long meeting between PHA, PH-treating health care professionals and invited payer and PBM representatives. Drug and device manufacturers active in the PH space were invited to observe the discussion but played a very limited role. ("Summit")

Learnings from these activities will be noted throughout the remainder of the comments. While they have not been formally published, summary documents from each event are available on request.

Provider Perspective

In a 2023 survey of PH Accredited Care Centers, PHA received responses from 79 health care providers representing 66 medical practices in 33 states. Respondents were a mix of RNs, advanced practice providers and physicians. 35% of respondents acted as the PH program coordinator for their institution.

Nearly half (48%) of centers indicated that staff spent more than 20 hours/week managing prior authorization and re-authorization of PH therapy. 16% reported staff spending 41-60 hours/week, notably more than the 13 hour per week average observed in the NAIC white paper.

72% of respondents saw 90% or more of their authorization requests eventually approved. A majority (58%) of respondents received that approval on first submission, however, a significant minority (38%) had to make an appeal 25-50% of the time.

Throughout PHA's prior authorization initiative, expert health care professionals have described challenges and barriers to successful treatment authorization.

- Technology is often antiquated, failing to align with electronic medical record systems.
- Authorization requirements and paperwork vary by payer.
- Authorization requirements often lag behind current clinical guidelines, sometimes by many years.
- Authorization forms for PH therapy often request test results or other information that are not relevant to diagnosing the disease, making it challenging, or even impossible to complete the form.

When these challenges result in the need for an appeal, new barriers arise:

- Initial denials may not include clear guidance about the reason for the denial.
- The health care professional reviewing the case may lack expertise in pulmonary hypertension.
- Payers who provided an initial denial in a matter of days may take weeks, or even months, to respond to appeals.
- Peer-to-peer discussions between the treating physician and the appeal reviewer are difficult to schedule and cause further treatment delays.

Providers communicated that even after an authorization was approved, it had to be renewed every six to twelve months, sometimes disrupting therapy that the patient in question had been doing well on for years. **In pulmonary hypertension, and other high-risk, life-long conditions, a six- or even twelve-month renewal period is too short, adding unnecessary burden to both patients and health care professionals.**

Impact on Patient Care

A majority of health care professional survey respondents (63%) indicated that authorization requirements always or often delayed their patients' access to needed care.

The most common impacts of this delayed care were unnecessary extensions of hospital stays (80%), worsening of PH symptoms caused by running out of or delaying the start of a drug (84%), and the mental distress patients and their families and caregivers experience (91%).

Insurer Feedback

PHA engaged payers in direct conversation about streamlining the prior authorization and re-authorization process for PH therapy during both the focus group and summit. One of the most significant takeaways from those conversations was that every payer representative believed that authorization-related delays and disruptions were happening **at other companies but not their own.**

There was, and continues to be, a lack of interest in engaging in voluntary change because each payer believes they are not the problem. Therefore, legislative and regulatory change will likely play a critical role in addressing authorization-related barriers to effective care.

Solutions and Examples

PHA strongly supports a gold carding approach to reducing authorization barriers and maximizing effective care. Careful consideration should be given to the required approval rate, given that many authorization requests are initially denied based on minor administrative errors rather than mid-alignment with treatment guidelines. A 90% required approval rate to be eligible for gold should focus on eventual approval, not approval on first submission.

Payers told PHA that the administrative burden of implementing a gold carding program for a rare disease outweighed the value to the payer. PAH was deemed too small a patient population to be considered for gold carding.

PHA developed a list of à la carte elements that we believe could help streamline the authorization process and improve patient care. While they have value individually, these elements are best integrated into a comprehensive gold carding program.

Program Features

	Program Feature	Description
1	**Establishment of Collaborative Care Team**	Payer designates individuals that will facilitate the implementation and administration of the program
2	**Use of urgent request process for review**	Utilize or augment existing urgent PA process to facilitate rapid review and escalate resolution
3	**Outreach to accredited care centers to obtain missing information required for clinical review**	Use of telephonic or other established method of communication for payer to contact accredited care centers to obtain additional information for PA review
4	**Conducting peer to peer prior to denying any request**	Proactive outreach from payer to accredited care center to discuss request before denial
5	**Indefinite or extended authorization approvals**	For PA authorization, indefinite approval is preferred; payers should approve requests for a minimum of 12 months to decrease administrative burden
6	**Outreach to accredited care centers for reauthorization**	Payer contacts health care professional approximately 1 month in advance of authorization expiring to request reauthorization
7	**Treatment regimen approvals (alignment of reauthorization dates)**	For payers limiting authorizations (i.e., not indefinite), approve all PH-specific therapies as a regimen and align dates for reauthorization (without requiring individual PA requests for each product)
8	**Application of abbreviated criteria for subsequent PH therapies**	If other PH therapies have been approved, remove duplicative criteria that will not change (i.e., diagnosis, use of prior therapies)

Takeaways

NAIC's whitepaper on prior authorization parallels the PH community experience in many ways. However, some additional nuance in the whitepaper regarding small population disease, and high-risk, life-long conditions will help make model legislation more effective.

- In pulmonary hypertension, and other high-risk, life-long conditions, a six- or even twelve-month renewal period is too short, adding unnecessary burden to both patients and health care professionals.

- Payers perceive the administrative burden of implementing a gold carding program for a rare disease as outweighing the value to the payer. Rare diseases may need to be "bundled" or gold carding for rare diseases may need to be incentivized in other ways.

- Streamlining paperwork requirements is important, but care should be taken so that "universal" forms do not require test results or other information that is not relevant to the diagnosis being considered.

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[1] Badesch DB, et al. Pulmonary arterial hypertension: baseline characteristics from the REVEAL Registry. Chest. 2010;137(2):376-87.

[2] Hassoun, P, et al. Pulmonary arterial hypertension. N Engl J Med. 2021;385:2361-2376