

# PHenomenal Hope 2025

*Knowledge, Research & Advocacy in PH*

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## Delphi study to elicit consensus on best practice for prior authorization in pulmonary arterial hypertension

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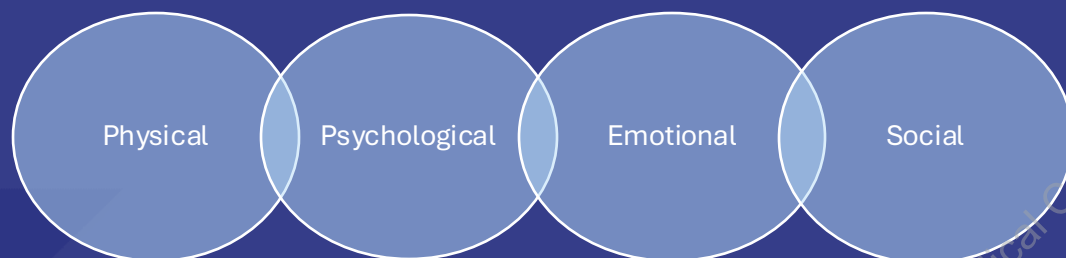
# Team PHeNomenal Hope

Delphi Panel Investigators	
Scientific Advisory Committee	Tonya Zeiger (R.R.T., CPFT) Valentina Alvadzhyan (PharmD, APh, BCPS) Kelly Marcello (FNP-C) Brett Carollo (RN BSN) Akshay Muralidhar (MD)
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Adelphi Values PROVE	Richard Perry (BSc) Medi Stone (BSc) Lucy Nuttall (BSc)

# Background and study overview

# Background

- PAH is a disease with a significant impact on patient functioning:<sup>1</sup>



- In the US, specialty medications, including those for PAH, often require prior authorization (PA) before patients can access therapy.
- The PA process places a substantial burden on healthcare professionals (HCPs) and can have a considerable impact on patients by delaying access to medication.<sup>1-3</sup>

**93%** of physicians think the **PA process has a negative impact** on patients' clinical outcomes.<sup>4</sup>

**24%** of physicians reported that **PA has led to serious adverse events** for patients.<sup>4</sup>

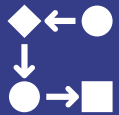
# Study objectives

The aim of this Delphi study is to collate and develop consensus of HCP opinion on the best practices to overcome barriers in the PA process in PAH, strategies for successful PA requests and ways to manage appeal of PA denials to expeditiously obtain therapies for patients.

Key topics that were covered in the Delphi panel, include:



Panelist training, experience and time spent on the PA process



Current standard process for PA and appealing denials



The time burden of submitting and appealing denials and the challenges of obtaining PA



The consequences of the PA process to patients



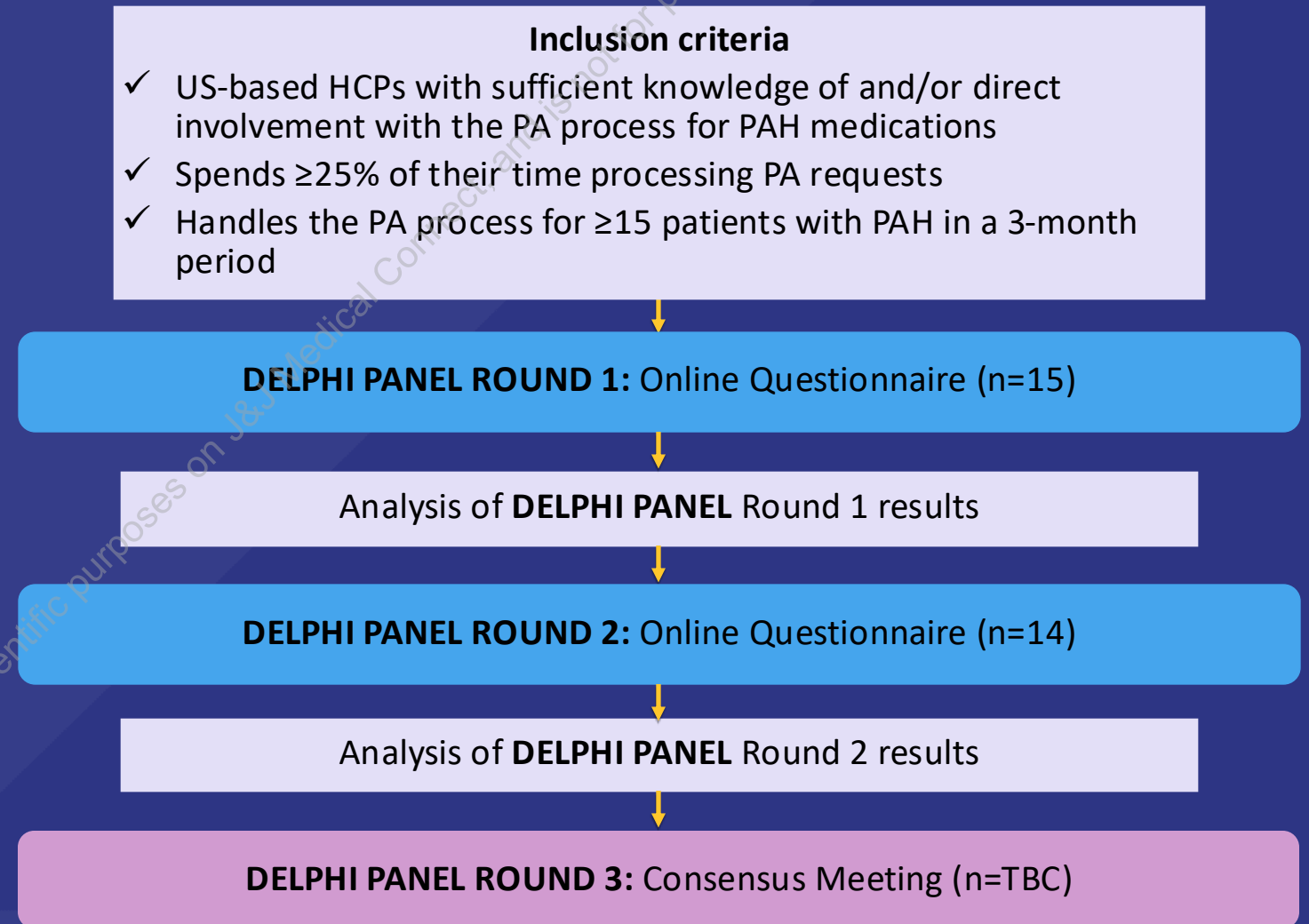
Solutions for standardizing and streamlining the PA process

# Methodology

## Delphi panel and recruitment

The Delphi process is a structured communication technique for *eliciting expert consensus*.<sup>1</sup> This involves two rounds of online questionnaires, and a web-conference consensus meeting.

The study sponsor and investigators, remain “double blinded” from the Delphi panelists’ identities throughout the conduct of the project.



# Methodology

## Panelist characteristics

Criteria	Total number of experts	Criteria	Total number of experts
Role		Proportion of time spent on PA-related tasks per week	
Nurse practitioner	12 <sup>†</sup>	20–49%	12
Pharmacist	3	50–70%	3 <sup>†</sup>
Healthcare area(s) of practice		Number of patients they submit PA requests for in a 3-month period	
Pulmonology	10 <sup>†</sup>	0–14	1
Cardiology	5	15–29	6
		30–49	4
		≥50	4 <sup>†</sup>
Region		Practice type*	
Midwest	4 <sup>†</sup>	Academic medical center (including outpatient clinics)	8 <sup>†</sup>
Northeast	5	Accredited pulmonary hypertension center	7
Southeast	2	Private practice	1
Southwest	2	Community hospital	1
West	2	Specialty pharmacy	2

\*Panelists selected multiple options (n=4). †n-1 for the second-round analysis due to one panelist dropping out.  
PA: prior authorization.



# Methodology

## The questionnaires included:

- Qualitative questions (e.g., free-text response) which were analyzed using thematic analysis.
- Quantitative questions (e.g., Likert rating, ranking, numerical) which were analyzed using measures of central tendency (means, median and mode).

### The first round included:

- Qualitative questions (e.g., free-text response) for panelists to provide insights and context on topics explored

### The second round primarily explored:

- Panelists' agreement with topics/themes from first round free-text responses using Likert rating

## Example of Likert scale question, asked in questionnaire

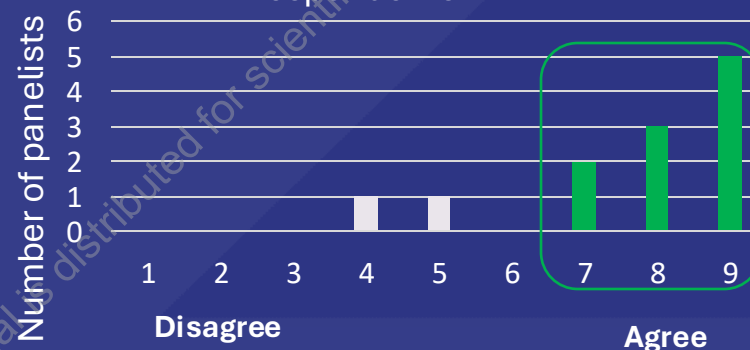
Using the 1 to 9 scale, to what extent do you agree with...

Disagree				Agree				
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



## Likert scale used to rate consensus

Threshold for consensus in agreement is defined as a rating of 7–9 by  $\geq 80\%$  of respondents



## Analysis of example Likert question to inform second-round questionnaire development

	Median	Disagree (rated 1–3)	Agree (rated 7–9)	Consensus?
Factor 1	2.5	10	0	Almost
Factor 2	3	7	1	Not reached
Factor 3	9	0	12	Reached

# Methodology

The questionnaires explored the following topics:

<b>Panelist experience with PA</b>	<ul style="list-style-type: none"> <li>• Information needed for PA submission</li> <li>• Guidance, protocols or documents available to understand the PA process and submission</li> <li>• Resources available to keep up to date</li> </ul>
<b>Current PA process and training for PAH treatment</b>	<ul style="list-style-type: none"> <li>• Which PAH medications are/are not on formulary, depending on insurer</li> <li>• Which PAH medications require PA and if this is clear</li> <li>• PA software and AI awareness, access, use and possible uses</li> <li>• Training/guidance/reference material available regarding PA and PAH medications</li> </ul>
<b>Denials and appeals in PA for PAH treatment</b>	<ul style="list-style-type: none"> <li>• The proportion of PA requests for PAH denied</li> <li>• Reasons for and response to denials</li> <li>• Appeals and documentation required for the appeals process</li> </ul>
<b>Impact of insurance on PA</b>	<ul style="list-style-type: none"> <li>• Delays, cost and coverage of PAH medications</li> </ul>
<b>PA impact on patients</b>	<ul style="list-style-type: none"> <li>• Reduced HCP availability for patients due to time spent submitting PA requests</li> <li>• Patient outcomes affected by PA</li> </ul>
<b>Challenges and solutions for PA for PAH treatment</b>	<ul style="list-style-type: none"> <li>• Ways to streamline the PA process and minimize delays to patient access</li> <li>• Best practices to obtain PA approval for PAH treatment</li> </ul>

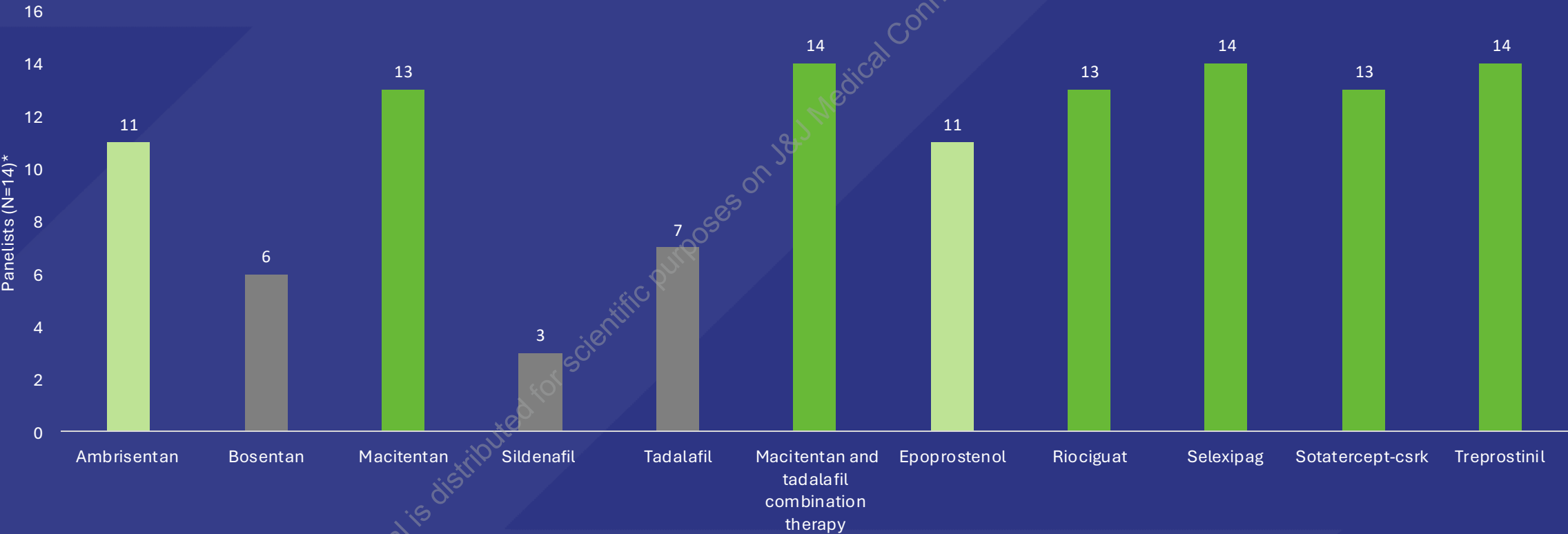
# Results from Delphi panel questionnaires

# PA required for PAH treatments



Consensus\* was reached in agreement on multiple PAH medications typically requiring PA.

PAH medications that typically require PA



12 \*consensus reached if 12, 13 or 14 of 14 HCPs agreed

= consensus in agreement

= almost reached consensus

= consensus not reached

# Overall process for PA



Consensus\* was reached in agreement on the following patient information being required when completing a PA request for PAH treatment.



Patient's diagnosis (n=15)



Patient's clinical symptoms (n=14)



Patient's PH WHO group (n=13)



Patient's functional class (n=12)



Patient's contraindication(s) to preferred formulary medications (n=14)



Diagnostic tests performed (e.g. V/Q scan, RHC) (n=13)



Current therapies prescribed (n=15)



Patient's response to current therapies (n=13)



Previous therapies tried and failed (n=13)



Clinical rationale for choosing the requested therapy (n=13)

PA: prior authorization; PAH: pulmonary arterial hypertension; PH: pulmonary hypertension; RHC: right heart catheterization; WHO: world health organisation.

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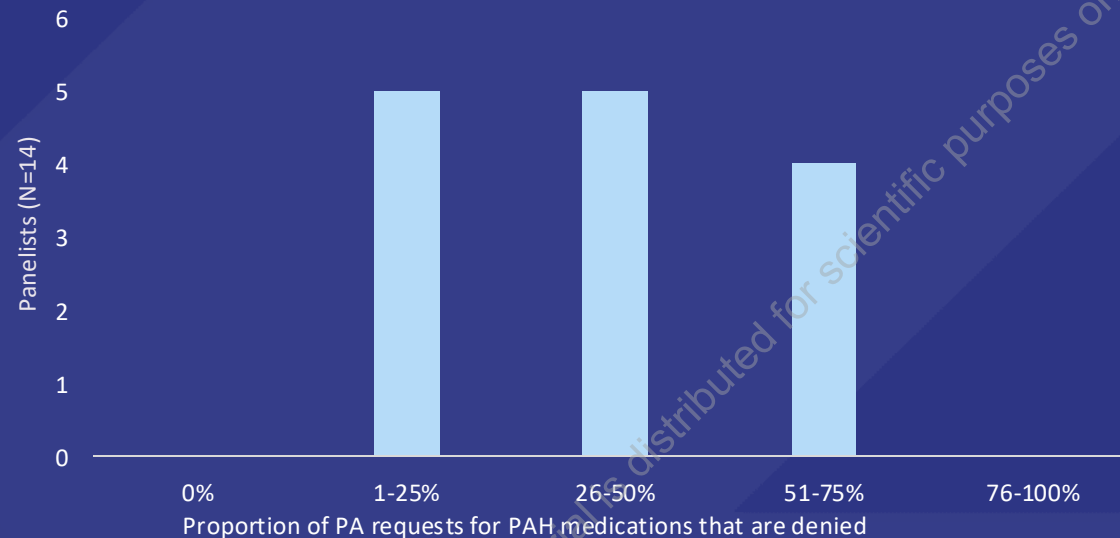
# Denials on the PA process



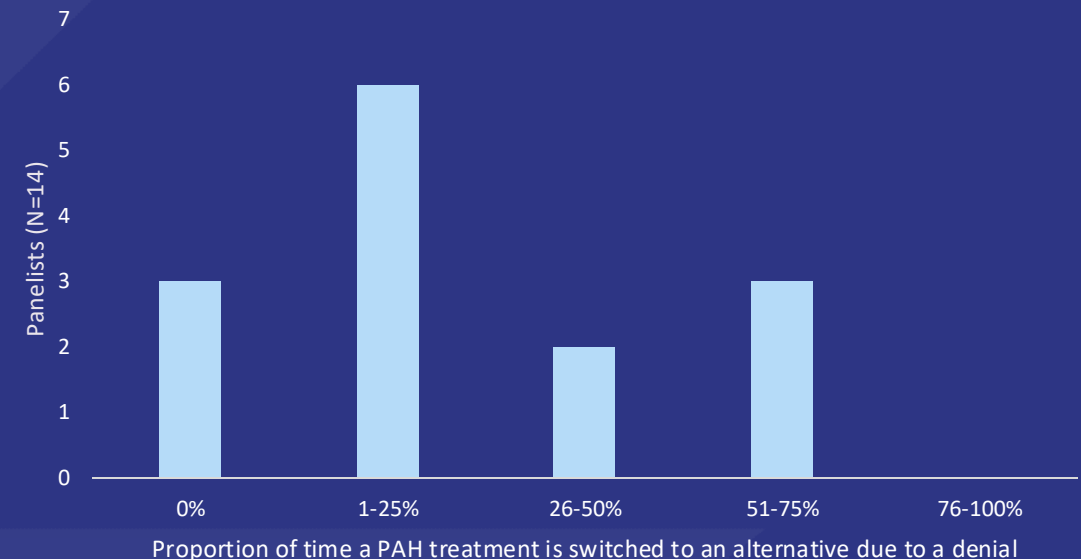
Consensus was reached in agreement that HCPs always appeal PA denials for PAH treatment. The panel noted the proportion of PA requests that are denied and proportion of PA requests that are switched to an alternative treatment due to a denial.

- Consensus was reached in agreement that HCPs always appeal the insurance provider's decision when a PA request is denied and they would still like to prescribe the same medication.

Proportion of PA requests for PAH medication that are denied by insurance providers



Proportion of time a PA request for a PAH treatment is switched to an alternative treatment due to a denial



HCP: healthcare professional; PA: prior authorization; PAH: pulmonary arterial hypertension

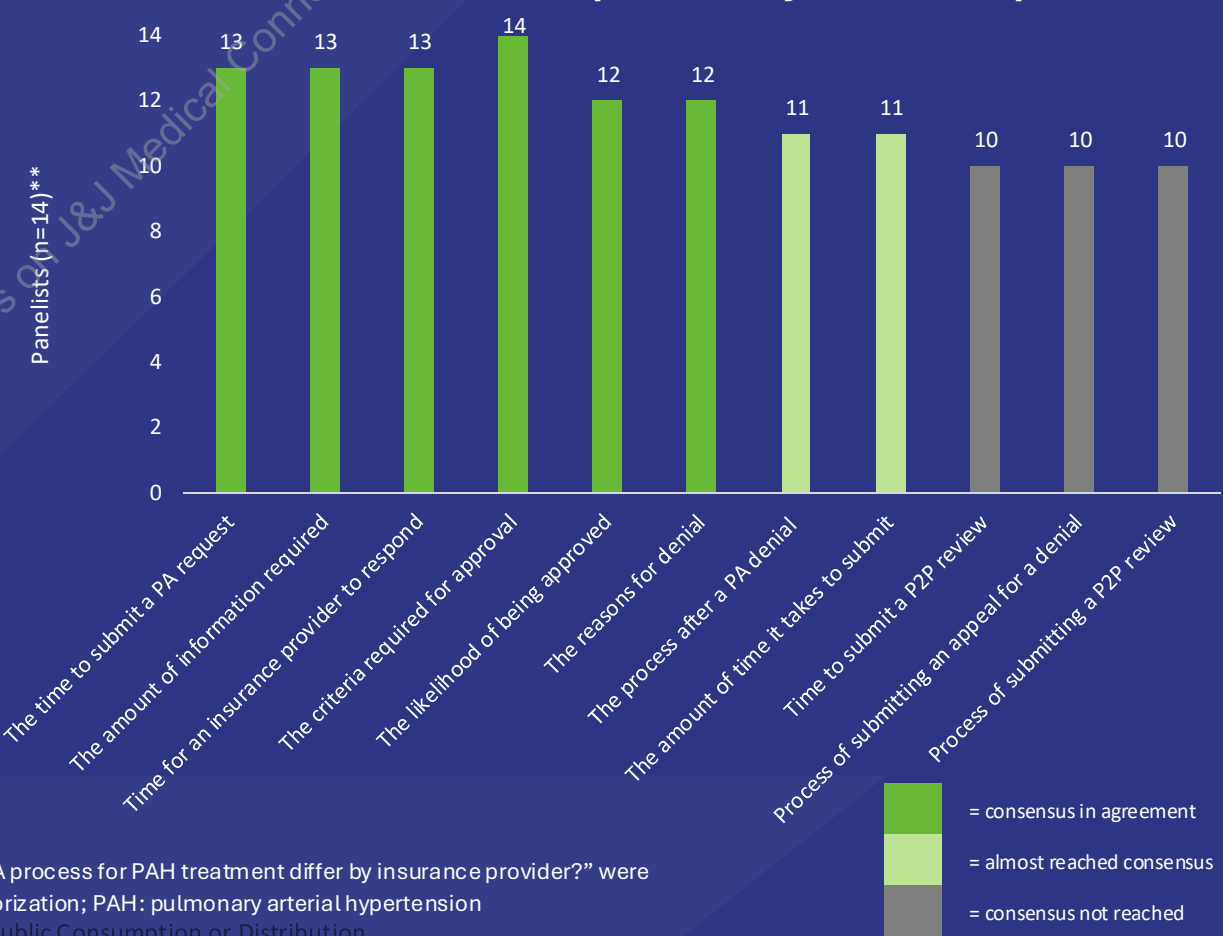
# Impact of insurance on the PA process



**Consensus\*** was reached in agreement on the prior authorization process for PAH treatment differing by insurance provider. The panel noted the number of insurance providers their center work with and the differences in the PA process by insurance provider.

- Consensus was reached in agreement on the PA process for PAH treatment differing by insurance provider.
- Panelists noted their centers’ work with an average of 20 different insurance providers (range 10–50).
- Consensus was almost reached in agreement that insurance providers often direct healthcare providers to prescribe less expensive therapies that are less suitable than the requested medication, during the PA process.

**Differences in the PA process by insurance provider**



15 \*consensus reached if 12, 13, 14 or 15 of 15 HCPs agreed

\*\* Only panelists who answered yes to “Does the PA process for PAH treatment differ by insurance provider?” were asked this question. PA: prior authorization; PAH: pulmonary arterial hypertension

# Prior authorization impact on patients



Consensus was reached in agreement that delays in receiving PAH treatment due to the PA process impacted patient outcomes.

Consensus was reached in agreement that:

- The amount of time required from HCPs to submit PA requests for PAH treatment affects patient care.
- Delays in patients receiving PAH therapies, caused by the PA process, impacts patient outcomes, such as adverse clinical outcomes or a negative impact on patient well-being.

Panelist quotations:



*"I feel it **takes away from our ability.... to spend time with patients.**"*



*"The [PA] process, especially if an appeal is required, **distracts the provider from patient care.**"*



*"**Patients with PAH progress.** A new diagnosis especially for a functional class IV patient is time sensitive. **We often end up having to hospitalize patients due to declining condition due to delays with PAs.**"*



*"[PA] can take **hours** out of one's busy clinical work week. Resources are not always plentiful in PAH for what is required to get the job done."*



*"**When you start a patient on therapy in the hospital, we aren't stopping it** so it can cause a **delay in discharge** which is a **burden to the patient, their finances and the institution** they are hospitalized at."*



# Methods for streamlining the PA process



Consensus was reached on methods for streamlining the prior authorization process, considering the practical implementation.

Consensus was reached in agreement on the following methods of streamlining the PA process:



Standardized PA form across insurances with standardized information to include





Clear communication between the prescriber's office and specialty pharmacy



An online system to track PA process on both the insurer and prescriber sides

Consensus was almost reached in agreement on the following methods of streamlining the PA process:	
Training/guidance for staff on the current information to include on PA submissions	
Insurance providers should be better informed on PAH medications and contraindications	
There should be leniency in PA requirements for accredited pulmonary hypertension centres	
PA submission prior to the specialty pharmacy/HUB conducting benefit investigation to reduce patient delays	

 = consensus in agreement  
 = almost reached consensus

# Steps to minimize delays in the PA process



Consensus was reached on steps that should be taken to minimize delays in patient access to PAH medications, considering their practical implementation.

Consensus was reached in agreement on the following steps that should be taken to minimize delays in patient access to PAH medications:



Use electronic PA tools such as CoverMyMeds



Ensure all documentation is provided in the initial PA request



All Panelists were aware of CoverMyMeds and all but one had access to the software

Panelists noted that:

- *“It does simplify [submission]... I am able to complete and upload documents online”*
- *“Usually makes [submission] quicker and easier...”*
- *“It has reduced the administrative burden and time [to submit PA requests] significantly”*

Consensus was almost reached in agreement on the following steps that should be taken to minimize delays in patient access to PAH medications:	
Frequently follow up with specialty pharmacy on approval status	

= consensus in agreement

= almost reached consensus

# Best practices for obtaining PA approval for PAH treatment



Consensus was reached on best practices for obtaining prior authorization approval for PAH treatment

Consensus was reached in agreement on the following best practices for obtaining PA approval for PAH treatment:



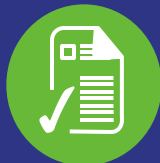
Early submission of PA requests



Submit diagnostic results such as RHC and echo report



Use electronic PA systems



Provide clear, complete documentation with rationale and contraindications



Provide direct responses to any denial reasons

Consensus was almost reached in agreement on the following best practices for obtaining PA approval for PAH treatment:

Use resources such as specialty pharmacy or therapy access teams

Having a dedicated PA team

Provide detailed rationale for medications, in regard to comorbidities

HCP: healthcare professional; PA: prior authorization; PAH: pulmonary arterial hypertension; PH: pulmonary hypertension; RHC: right heart catheterization.

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= consensus in agreement  
= almost reached consensus

# Key takeaways

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# Key takeaways

- **Most PAH medications required PA** e.g., macitentan, macitentan and tadalafil, riociguat, selexipag, sotatercept-csrk and treprostinil
- Healthcare centers work with **multiple insurance providers** and the **PA process for PAH treatment differs** for each insurance provider
- **HCPs always appeal denials** for PA requests when a PA request is denied, and they would still like to prescribe the same medication.
- The **time taken** for HCPs to submit PA requests **affects patient care** and **delays** in approvals **impacts patient outcomes**
- Methods for **streamlining the PA process** include **standardized** PA forms across insurance providers, **clear communication** between the prescriber's office and specialty pharmacy and an **online system** to track PA requests
- Steps that **minimize delays in patient access** to PAH medications include the use of **electronic PA tools** such as CoverMyMeds and ensuring **all information is submitted** at the initial PA request
- **Best practices for PA approval** include **early submission** of PA requests, using **electronic PA systems**, providing **direct responses to any denial reasons**, submitting **diagnostic results** and providing clear, **complete documentation** with rationale and contraindications

# Study importance

Prior to this study, there was limited understanding of the PA process for PAH medications and the variability by insurance provider, as well as the time burden associated with the PA process and how this, and PA delays impacts patient care.

This research will help practices to :



**Understand the standard PA process and training required for those who complete PA requests**



**Suggest methods to streamline the PA process, steps to minimize delays and best practices for obtaining PA approvals**



**Provide recommendations to reduce the time burden on HCPs and decrease delays in patient access to PAH treatments.**

# Thank you

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