The Burden of Prior Authorization for Pulmonary Hypertension Medications: A Practical Guide for Managing the Process

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Medications for pulmonary hypertension (PH) are expensive and often require prior authorization from insurance payers. The task of submitting prior authorization requests and appealing denials can burden PH practices with a heavy workload and delay or interrupt medical treatment. However, it is possible to reduce this burden, improve success rates, and reduce waiting times by implementing a standard office workflow for managing the prior authorization process. Such a system involves several key components: assessment of existing staff and level of expertise; dedicated office staff to oversee the process from start to finish; streamlined gathering, storage, and transmittal of patient documents; direct communication with pharmacies and Risk Evaluation Mitigation Strategy programs; and careful documentation of PH diagnosis and treatment plans for a given patient, aimed at reducing the necessity for appeals. This article reviews prior authorization strategies and systems used at PH clinics, and case studies in other therapeutic areas that demonstrate how such systems can reduce staff time and waiting time for initiation of medications while improving the rate of success. The article also describes the special challenges of requesting prior authorization for PH medications prescribed to pediatric patients.

Pulmonary hypertension (PH) is a chronic, progressive, and often fatal disease affecting both adults and children. It encompasses a spectrum of different conditions, which are segmented, according to clinical characteristics, into 5 distinct groups (ie, World Health Organization [WHO] Groups 1-5).[1] Treatment of patients with PH is initially guided by WHO Group and disease severity. However, in practice, the treatment of patients with PH is also influenced by many other factors, including cost, tolerability, and adherence.

Since 1995, the US Food and Drug Administration (FDA) has approved 14 medications for adult patients with Group 1 PH (pulmonary arterial hypertension [PAH]). One medication is approved for Group 4 PH (chronic thromboembolic pulmonary hypertension [CTEPH]) that is either deemed surgically inoperable or persists after pulmonary artery thromboendarterectomy (PTE). For pediatric patients over the age of 3 years, only 1 medication (bosentan) has received FDA approval, and this medication was not approved for use in pediatric patients until September 2017. A second PH medication (oral sildenafil) was approved for use in children by the European Medicines Agency but carries a warning against pediatric use in its FDA labeling.[2] Because of the limited FDA indications for adult and pediatric patients, many PH programs have set precedents to use PH-specific therapy off label for patients with PH in other WHO classification groups.

All PH therapies require long-term treatment and are costly. In 2010, the estimated cost of individual PH medications ranged from $18,000 to $244,000 per patient, per year. Pharmacy costs are only expected to increase as recent clinical guidelines increasingly advocate combination therapy for PH, with more intensive treatment of early-stage disease.[1,3-6]

Insurance plans and payers are attempting to contain the cost of PH treatment by controlling access to these medications through the process of prior authorization, in which clinicians who prescribe medications for PH are required to obtain authorization from the insurer before any portion of the medication cost is paid. Most commonly, the provider must document the patient's specific diagnosis and medical need so that the insurers can assess their alignment with FDA indications. Based on this request, the insurer then determines whether the medication is covered under the plan and whether this benefit includes any specific limits, such as quantity, out-of-pocket levels, and copayments. Cost control has been a major rationale for prior authorization of medications. Prior authorization can also provide a layer of quality control to ensure that treatments are used in the most medically appropriate manner in patients who are most likely to experience benefit. Further, prior authorization can provide a safety check to ensure that medications with potentially serious side

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effects are avoided in especially high-risk patients.[7]

Regardless of the reasons behind it, prior authorization forces PH patients and their providers to navigate an additional barrier when seeking access to critical medications—a barrier that is perceived to be time-consuming, nontransparent, and often subject to changing rules. A 2016 survey by the American Medical Association found that prior authorization places a heavy burden on medical practices.[8] Among the 1000 primary care and specialist physicians surveyed, an average of 16.4 staff hours per week were devoted to prior authorization requests. Twenty-six percent of respondents reported that the process of requesting prior authorization often led to treatment delays of at least 3 days. Eighty percent reported having to submit periodic, repeat requests for prior authorization so that patients could continue using the same medication for a chronic condition.

Consistent with these unfavorable perceptions, some studies have documented the negative impacts of prior authorization in a range of clinical arenas, such as pain management[9,10] and mental health.[11,12] These negative outcomes include more emergency department visits,[9] increased rates of drug discontinuation,[11,12] and increased medical costs.[10] Similarly, a systematic literature review and meta-analysis found that formulary restrictions, including prior authorization, have a negative effect on adherence to medication regimens across a broad range of disease states.[13]

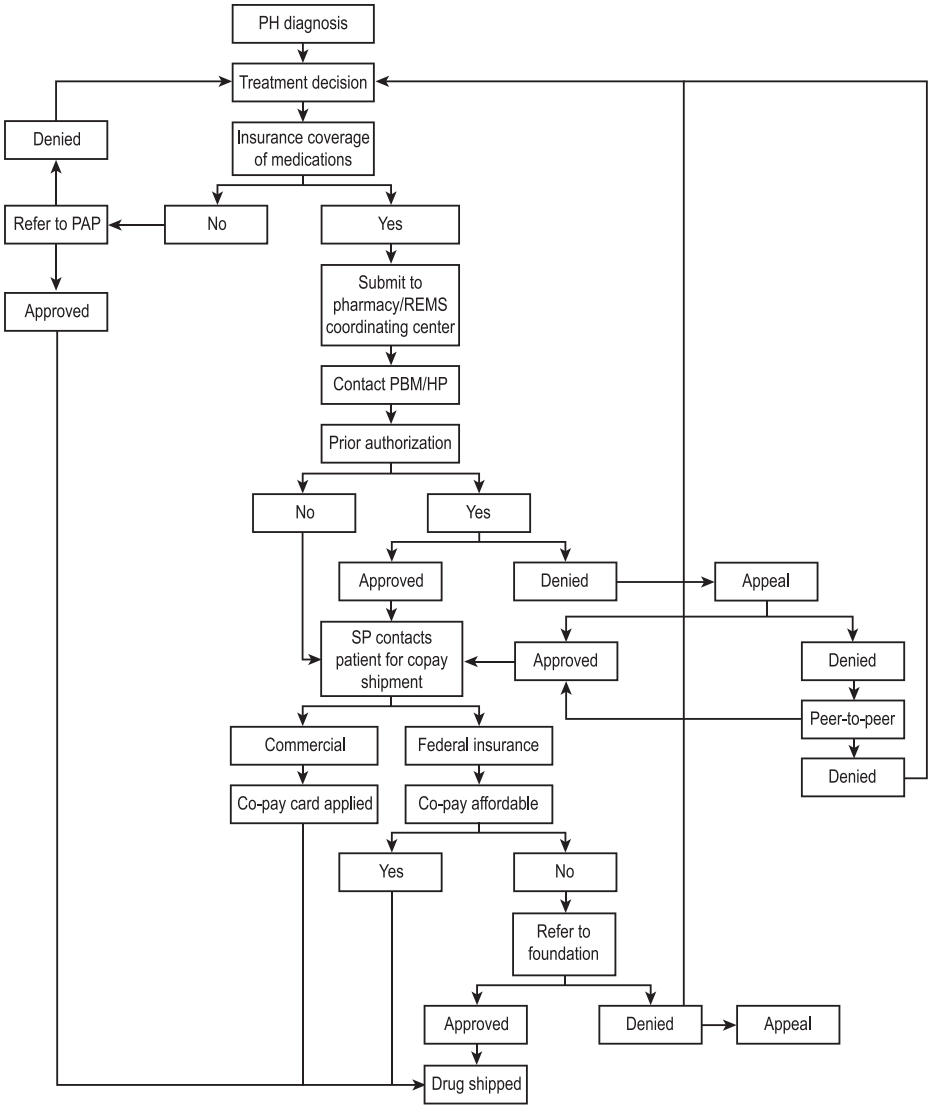

Figure 1: Obtaining access to PAH medications. A flow diagram depicting steps to follow to best support patients in securing PH medications. Adapted from Stewart T, Burks M, Nolley SH, et al. Collaborative care: a defining characteristic for a pulmonary hypertension center. *Pulm Ther*. 2017;3(1):93-111. Abbreviations: HP: health plan; MD: medical doctor; PAP: patient assistance program; PBM: pharmacy benefit manager; REMS: Risk Evaluation Mitigation Strategy; SP: specialty pharmacy.

PRIOR AUTHORIZATION FOR PH MEDICATIONS

In the outpatient setting, access to PH medications is rarely immediate and often requires insurance preauthorization. Figure 1 provides an overall schema for evaluating patients' drug coverage, submitting prior authorization requests and appeals, and managing issues of copay affordability.[14] Depending, in part, on the route of administration, PH medications may be covered under an insurance plan's medical benefit or under the pharmacy benefit. Orally administered medications are generally covered through the plan's pharmacy insurance, which may be separate from the medical insurance. In contrast, many prostacyclin analogs are requested through a plan's medical benefit, since inhaled or infused administration requires a medical device and additional supplies.[14]

The request for prior authorization is communicated to the insurer via fax, telephone call, or an electronic prior authorization. Medical need is evaluated through a series of medical questions designed to determine if the patient's medical condition matches with the insurance plan's predetermined criteria for approval. Table 1 summarizes information about a specific patient's PH that is commonly requested to determine if a medication meets the insurer's criteria for coverage. This includes documentation of a specific diagnosis of PH and provides the patient's WHO Group and functional class. The insurer may also request results from the most recent office visit or right heart catheterization. The insurer will also typically request information about current and prior medications that the patient has taken for PH, including the drug class (eg, endothelin receptor antagonist, prostacyclin analog) for each agent, start and

Table 1. Typical Questions Asked by Insurers During the Prior Authorization Review Process to Assess Medical Necessity

PH Diagnosis
• What is the diagnosis (WHO classification Group and subgroup)? • What is the patient's functional class? • What were the results of the most recent right heart catheterization (most commonly mean pulmonary artery pressure, pulmonary capillary wedge pressure, pulmonary vascular resistance)?
Previous PH Medications
• What other medications have been tried? When? Outcome? • Is the medication being requested a new start or a continuation? - If a continuation, what has the patient's response been? - Has the patient had a trial of an equivalent generic alternative?
Other Relevant Information
• Has the patient had a vasodilator trial, and what was the outcome? • What medications are contraindicated for this patient and why? • What other medications is this patient taking? • What were the results of the patient's most recent liver function tests? • Is the patient of childbearing age? Has the patient had a pregnancy test?

discontinuation dates for each medication, and the reasons for any changes or discontinuations of drug therapy (eg, adverse event or lack of efficacy). It is also important to be prepared to provide information regarding why relevant lower-tier medications were skipped (eg, contraindications, anticipated drug interactions, and patient factors such as low functional capacity or insufficient social support).

CASE STUDIES: PRIOR AUTHORIZATION OFFICE SYSTEMS

Fortunately, recent case studies have shown that medical practices can institute office systems that facilitate prior authorization. Implementing these systems reduced the expenditure of staff time, increased the rate of success, and decreased medication wait times.[15,16] These studies included diverse patient populations with chronic conditions such as hepatitis C, asthma, diabetes, erectile dysfunction, and psychiatric illnesses, in which high-cost specialty medications have become available in recent years.

Case Study 1: Hepatitis C Clinic

Dunn and colleagues have described a program instituted at the University of Maryland Medical Center to facilitate prior authorization for medications to treat patients with hepatitis C virus (HCV) infection.[16] The authors began by examining the clinic's existing workflow for prior authorization to identify areas for improvement. As a result of this review, starting in late 2014, a pharmacy technician specialist (PTS) was assigned to work inside the HCV clinic, alongside a registered nurse. By positioning a PTS within the clinic, the specialty pharmacy was able to access patient clinical data directly for the first time; prior to this, patient data had been communicated to the specialty pharmacy via fax. The nurse scheduled clinic visits and laboratory tests to obtain patient data necessary for authorization—such as HCV genotype, viral load, biopsy results, and liver fibrosis score—as well as follow-up tests, required 4 weeks after initiation of treatment, to demonstrate clinical benefit. The PTS reported these data directly to the insurer's pharmacy benefits manager.[16]

With 180 patients treated (68 before the intervention and 112 after), average wait times for prior authorization were reduced by 7.8 days, from 23.4 days to 15.6 days (P=.02). Data were not available to compare the success rates of prior authorization requests. However, based on the reduced wait times, the program was expanded, with a second PTS assigned to serve 2 additional clinics.[16]

Case Study 2: Primary Care Clinic

In 2014, in an effort to streamline prior authorization of medications to treat a range of chronic conditions, including asthma, diabetes, erectile dysfunction, pain, heartburn, and psychiatric illnesses, a centralized prior authorization process was implemented through the pharmacy at the UC Davis Health System central primary care clinic.[15] The goal of this program was to select patients more carefully, up front, for any medications that required prior authorization.

New prescriptions and refills automatically generated a prior authorization request, which was transmitted into a specific section of the patient's electronic medical record. Pharmacy technicians had full access to these electronic medical records, allowing them to evaluate each request based on the patient's insurance type, indication for treatment, other medications that had been previously tried, and potential opportunities for trying alternate medications that did not require prior authorization. Once the pharmacy technician determined there was no reason to substitute an alternative medication, the prior authorization request was forwarded to the insurer.

This system produced several positive results. The average processing and waiting time for prior authorization was reduced from 7.02 days to 0.53 days (P<.001). The approval rate improved from 68% to 93% (P<.002). The average time between the prior authorization request and filling of the prescription was reduced from 5.52 days to 2.49 days (P<.02). The average amount of staff time that was expended, per request, was reduced from 64 minutes to 15 minutes (P<.001); this led to a reduction in direct staff costs, per request, from $37.50 to $11.50 ($P$<.001).

Systems for Prior Authorization

These case studies illustrate several strategies instituted to improve the efficiency of the prior authorization process. Many PH centers in the United States have developed standard workflows for streamlining prior authorizations, minimizing staff time, and maximizing the likelihood of approval. These practices are outlined in Table 2. Both the case studies and our own experiences have identified areas that can improve the prior authorization process. These include determining and setting the standard format for prior authorization submission based on office staffing and resources by choosing to initiate the process by phone, fax, or email; identifying the parts of the prior authorization process that can be done by nonlicensed

Table 2. Tips on Securing Approvals

Educate Patients
• Set realistic expectations and keep patient updated. Patients should understand: - Expense of PH medications across the spectrum of options - Difference between PA and refill authorization - to renew PA regularly, every 3 to 12 months, and how long the process can take
Avoid Pitfalls
• Be cautious about initiating therapy ahead of PA approval • Document amount of patient's copay • Confirm patient's ability to afford copays (or lack thereof) • Access copay assistance if needed
Assign PA Coordinator and Delegate Roles
• Assign staff member as the PA coordinator to track and oversee PAs, start to finish • Consider breaking up the process, based on which part is best handled by which staff member (PA team) • Use stickers with contact information for PA coordinator and PA team • Task specialty pharmacy and HUB programs to: - Proactively track when PA renewals are due - Query patients on insurance changes, especially at times when insurance is likely to change (eg, January, July, and approaching age 65 years)
Streamline Office Procedures
• Develop standard office and post–right heart catheterization note templates for clearly documenting the need to initiate therapy, change therapy, and continue therapy. They should include: - Accurate and clear diagnosis (including WHO Group and subgroup) - Functional class - Current symptoms - Drug classes of prior and current medications - Clear start and discontinuation dates of medications - Response to current therapy (describe response using PH-relevant endpoints like oxygen blood saturation, WHO functional class, dyspnea scale) - Reasons for therapy changes and discontinuations (eg, efficacy, adverse events) - Reasons for forgoing lower-tier medications that were not tried (eg, contraindications, comorbidities, anticipated drug interactions, patient's lack of functional capacity or social support to adhere) Maintain easy-to-access system for retrieving clinical documentation used to obtain prior PAs and past prior approval letters • Maintain central repository where important documents can be accessed for each insurer/payer: - PA forms - Procedures and contact information - Clinical criteria for approving PH medications Consider using systems for electronic form identification, completion, and submission - CoverMyMeds ZappRx

Abbreviation: PA, prior authorization.

program staff to best use provider time and expertise; consistent documentation of often-required PH clinical information for prior authorization over time; and the use of electronic platforms to store, upload, and submit prior authorization documents.

Some centers have designated staff within the practice who act as prior authorization coordinators, overseeing the process from start to finish. This coordinator role may be shared by clinical and nonclinical staff, as the clinical staff (often a nurse) generally have a full clinical caseload. The addition of a nonclinical coordinator to the prior authorization team can help offload some of the work of the clinical coordinators, such as acting as a facilitator between the insurance company, specialty pharmacy, and PH center; providing patient demographics and additional paperwork that may be needed by the insurance company; and tracking the progress of the prior authorization request. Relieving the clinical coordinators of the administrative aspects of prior authorization requests allows the completion of prior authorization requests in a timelier manner. A specialty pharmacist who tracks important events proactively, such as the dates on which prior authorization renewals are due or the times at which insurance changes are likely to occur (eg, open enrollment times or when a patient approaches 65 years of age), can also be assigned. Some programs use forms as part of their workflow, creating stickers that include the provider/program contact information. This saves time compared to entering the information repeatedly by hand.

It may be helpful to maintain a central repository where staff can access important information for the most common insurers in their geographic area, including standard prior authorization forms, procedures, contact information, and clinical criteria necessary for requesting approval of specific medications.

In response to the burden that the PA process creates, 2 online platforms have been developed. CoverMyMeds® and ZappRx® are both designed to streamline the PA process. Depending on PH program staffing resources, use of these platforms may minimize the duplication effort by combining the processes of obtaining required forms, prescribing a specialty medication, tracking the order, and documenting medical need for prior authorization. They also allow for different parts of the prior authorization process to be efficiently handled by the most appropriate staff and providers. These systems can also store and retrieve, for later use, the documentation of medical need that was initially submitted for each patient. For some insurers, immediate review and decision responses back into the platform can occur within minutes. In some cases, tools with these functions may already exist within the specific electronic medical record system used in the practice.

Requests for prior authorization are sometimes denied, even when best practices are followed. These situations can create stress for patients and families. Fortunately, however, denials can be

Table 3. Tips on Overturning Denials

Initiate a Peer-to-Peer Review:
• Document name and contact information • Secure a clear verbal commitment to saying "yes"
Maintain a Library of Resources:
• Template appeal letters • Review articles • Published clinical trials • Current clinical practice guidelines for treating PH, from relevant medical organizations (eg, ACCP, ATS) • Especially helpful when requesting coverage for off-label use
Have patients with employer-provided coverage contact their human resources department for help
Don't give up!

Abbreviations: ACCP, American College of Chest Physicians; ATS, American Thoracic Society.

appealed through multiple levels, and many are overturned during the process. Insurers generally provide a clear pathway for appealing an initial denial. In addition to submitting a formal appeals package to the insurer, the physician may also request a direct conversation with the insurer's medical reviewer, known as a peer-to-peer review.

The goal of a first-level appeal is to bolster the case for medical necessity. Appeals packages should cite (and include copies of) clinical practice guidelines from relevant organizations that recommend the medication for the appropriate patient group. A number of organizations publish such guidelines, including the American Thoracic Society and the American College of Chest Physicians.[1,5,17] Appeals packages should also cite and include clinical studies demonstrating the efficacy and safety of the medication in the relevant PH patient group. Table 3 outlines some additional approaches to overturning denials, which have been helpful in our practice.

Finally, it is important to consider the concerns of the patients, their caregivers, and their families. It is important to educate patients on the cost of PH medications and the prior authorization process both for initiation and continuation of PH medications, as well as to inform the patient about copayment amounts, confirm that copays are feasible for them, and help the patient to access financial assistance when necessary.

Special Considerations in Pediatric PH

Prior authorization for pediatric patients with PH presents a special challenge. It is complicated by a paucity of clinical data in pediatric patients and a dearth of approved medications and readily available pediatric formulations.

Pediatric PH is clinically distinct from adult PH.[18] Pediatric PH can be multifactorial, encompassing multiple groups of the adult PH classification scheme, and it can also be categorized by topics not represented in the adult classification scheme. As a result, it is challenging to classify pediatric PH for third-party payers since their approvals are based exclusively on the adult schema. Further, up until 2015, there were no formal pediatric-specific recommendations for the diagnosis, treatment, and management of pediatric PH, making it very difficult to demonstrate medical need for PH therapies. Fortunately, the landscape is changing. In 2015, guidelines were published by the American Heart Association and the American Thoracic Society, in conjunction with an expert panel, outlining recommendations for the diagnosis, evaluation, and treatment of pediatric PH.[19] The guidelines are a significant advancement for pediatric PH; however, the consensus statements are based on very little available evidence. Few prospective trials have studied PH medications in the pediatric population, and few data are available to define optimal dosing.[18]

Of the 14 medications that are FDA-approved for PH, only 1 (bosentan) is currently approved by the FDA for use in children. This approval is restricted to children older than 3 years of age.[20] Many patients are under 3 years of age; thus, a large population is left that requires the off-label use of PH therapies. Further complicating matters, approval of the medication is often only the first step. Once medication approval is obtained, it may then be necessary to obtain approval for a pediatric-appropriate formulation, such as a compounded medication for an infant or child who cannot swallow a pill, either due to developmental stage or an inability to safely swallow. An insurance company may eventually approve the medication but not the compounding ingredients. This can result in extended time and effort spent demonstrating the need for a liquid formulation for an infant or young child or sometimes having to switch to a different medication.

All of these factors make it difficult to document medical need and to submit prior authorization requests for PH medications in children and may result in health care professionals feeling overwhelmed and unprepared to do so. Being prepared to address the questions outlined previously and implementing the processes described in Table 2 may help to facilitate the process.

CONCLUSION

Prior authorization for medications can place a substantial burden on PH programs and patients. However, it appears from recent reports in other disease states that this burden may be greatly reduced, and success rates improved, through a set of best practices that can be implemented. Developing an efficient system for processing prior authorizations for PH-specific medication is crucial for patient care, as it ensures that patients receive prompt and continued access to PH medications that will benefit them the most.

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References

1. Galiè N, Humbert M, Vachiery JL, et al. 2015 ESC/ERS Guidelines for the diagnosis

and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS): Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). *Eur Heart J*. 2016;37(1):67-119.
2. Revatio [package insert]. New York, NY: Pfizer; 2014.
3. Hill NS, Cawley MJ, Heggen-Peay CL. New therapeutic paradigms and guidelines in the management of pulmonary arterial hypertension. *J Manag Care Spec Pharm*. 2016;22(3 Suppl a):S3-S21.
4. Maron BA, Galiè N. Diagnosis, treatment, and clinical management of pulmonary arterial hypertension in the contemporary era: a review. *JAMA Cardiol*. 2016;1(9):1056-1065.
5. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. *Chest*. 2014;146(2):449-475.
6. Sitbon O, Gaine S. Beyond a single pathway: combination therapy in pulmonary arterial hypertension. *Eur Respir Rev*. 2016;25(142):408-417.
7. Starner CI, Fenrick B, Coleman J, Wickersham P, Gleason PP. Rosiglitazone prior authorization safety policy: a cohort study. *J Manag Care Pharm*. 2012;18(3):225-233.
8. American Medical Association. 2017 AMA prior authorization physician survey. https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf. Accessed September 2, 2018.
9. Hartung DM, Touchette DR, Ketchum KL, Haxby DG, Goldberg BW. Effects of a prior-authorization policy for celecoxib on medical service and prescription drug use in a managed care Medicaid population. *Clin Ther*. 2004;26(9):1518-1532.
10. Margolis JM, Johnston SS, Chu BC, et al. Effects of a Medicaid prior authorization policy for pregabalin. *Am J Manag Care*. 2009;15(10):e95-e102.
11. Soumerai SB, Zhang F, Ross-Degnan D, et al. Use of atypical antipsychotic drugs for schizophrenia in Maine Medicaid following a policy change. *Health Aff (Millwood)*. 2008;27(3):w185-w195.
12. Zhang Y, Adams AS, Ross-Degnan D, Zhang F, Soumerai SB. Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder. *Psychiatr Serv*. 2009;60(4):520-527.
13. Happe LE, Clark D, Holliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *J Manag Care Spec Pharm*. 2014;20(7):677-684.
14. Stewart T, Burks M, Nolley SH, et al. Collaborative care: a defining characteristic for a pulmonary hypertension center. *Pulm Ther*. 2017;3(1):93-111.
15. Cutler T, She Y, Barca J, et al. Impact of pharmacy intervention on prior authorization success and efficiency at a university medical center. *J Manag Care Spec Pharm*. 2016;22(10):1167-1171.
16. Dunn EE, Vranek K, Hynicka LM, Gripshover J, Potosky D, Mattingly TJ II. Evaluating a collaborative approach to improve prior authorization efficiency in the treatment of hepatitis C virus. *Qual Manag in Health Care*. 2017;26(3):136-139.
17. Pepke-Zaba J, Ghofrani HA, Hoeper MM. Medical management of chronic thromboembolic pulmonary hypertension. *Eur Respir Rev*. 2017;26(143):160107.
18. Hansmann G, Apitz C. Treatment of children with pulmonary hypertension. Expert consensus statement on the diagnosis and treatment of paediatric pulmonary hypertension. The European Paediatric Pulmonary Vascular Disease Network, endorsed by ISHLT and DGPK. *Heart*. 2016;102(Suppl 2):ii67-ii85.
19. Abman SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. *Circulation*. 2015;132(21):2037-2099.
20. Tracleer [package insert]. South San Francisco, CA: Actelion Pharmaceuticals; 2017.