

Specialty pharmacist integration into an outpatient neurology clinic improves pimavanserin access

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Abstract

Introduction: Access to pimavanserin, the only Parkinson disease–related psychosis treatment approved by the FDA, is restricted by insurance requirements, a limited distribution network, and high costs. Following initiation, patients require monitoring for safety and effectiveness. The primary objective of this study was to evaluate impact of specialty pharmacist (SP) integration on time to insurance approval. Additionally, we describe a pharmacist-led monitoring program.

Methods: This was a single-center, retrospective study of adults prescribed pimavanserin by the neurology clinic from June 2016 to June 2018. Patients receiving pimavanserin externally or through clinical trials were excluded. Pre- (June 2016 to December 2016) and post-SP integration (January 2017 to June 2018) periods were assessed. Proportional odds logistic regression was performed to test association of approval time with patient characteristics (age, gender, insurance type) postintegration. Interventions were categorized as clinical care, care coordination, management of adverse event, or adherence.

Results: We included 94 patients (32 preintegration, 62 postintegration), 80% male (n=75) and 96% white (n=90) with a mean age of 73 years. Median time to approval was 22 days preintegration and 3 days postintegration. Higher rates of approval (81% vs 95%) and initiation (78% vs 94%) were observed postintegration. Proportional odds logistic regression suggested patients with commercial insurance were likely to have longer time to approval compared with patients with Medicare/Medicaid (odds ratio 7.1; 95% confidence interval: 1.9, 26.7; $P=.004$). Most interventions were clinical (51%, n=47) or care coordination (42%, n=39).

Conclusion: Median time to approval decreased postintegration. The SP performed valuable monitoring and interventions.

Keywords: pimavanserin, specialty pharmacy, medication access, limited distribution

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Introduction

Parkinson disease (PD)–related psychosis (PDP), presenting in up to 60% of patients with PD,¹ is associated with debilitating symptoms, including hallucinations.² Pimavanserin, an atypical antipsychotic, was the first PDP treatment approved by the FDA in April 2016. In a 6-week

trial, pimavanserin demonstrated significant reduction in symptoms of psychosis compared with placebo.³ However, there are several barriers to pimavanserin use: a complex insurance approval process, a manufacturer-implemented limited distribution network (LDN), and high medication cost.^{4,5}

Insurers often require prior authorization (PA) review of high-cost specialty medications to ensure appropriateness of therapy. PA requirements vary but commonly require lengthy forms to be completed on paper, by phone, or online with supporting clinical documentation. This process increases the burden on clinic staff, which may cause delays in care and generate frustration for physicians and patients.⁶ In a 2019 survey,⁷ physicians perceived this process as placing a high burden on staff and indicated that the PA process can lead to treatment abandonment by patients and having a negative impact on overall patient outcomes.

Another barrier to pimavanserin access is distribution through an LDN, which restricts the number of pharmacies permitted to dispense the medication. Motivating factors for a manufacturer-implemented LDN include ensuring safe use and reducing internal costs.⁸⁻¹⁰ However, this model has several implications for patients, providers, and health care institutions. Literature⁸ highlights the potential for LDNs to cause fragmentation of care and increase institutions' costs. Further, LDNs may result in patients having to determine which pharmacy can dispense their specialty medication, contributing to treatment delays.¹¹

Although pimavanserin offers significant benefit, treatment cost is high with an average wholesale price of \$133.64/d, often necessitating financial assistance resources.⁵ Longitudinal monitoring for adverse effects (AEs), response to therapy, and drug-drug interactions (DDIs) is necessary to ensure safety and continued appropriateness of therapy.³ In pimavanserin clinical trials, AEs were reported in up to 11% of patients with common AEs including peripheral edema, confusion, hallucinations, nausea, constipation, and gait disturbances.³ Response to therapy can take up to 2 weeks following treatment initiation; therefore, monitoring patients as they start pimavanserin is beneficial.^{3,4} DDIs can result in serious concerns, such as QT prolongation, and should be monitored throughout the course of therapy.

Health-system specialty pharmacies have demonstrated high rates of medication access and reduced out-of-pocket costs across several disease states after implementing an integrated specialty pharmacist (SP).¹²⁻¹⁴ However, the integrated SP role in PDP has not been studied. Evaluating SP-led care delivery in this population may help inform best practices and improve utilization of

this beneficial therapy. Integrated SPs can reduce unnecessary paperwork and time wasted by advising prescribers on PA requirements and ensuring that step therapy or required clinical documentation is completed before pursuing pimavanserin.

The aim of this study was to measure the impact of SP integration into a neurology clinic on the time to pimavanserin insurance approval. Additionally, we describe a pharmacist-led program for pimavanserin monitoring.

Methods

Study Design

This was a single-center, retrospective cohort study of adult patients prescribed pimavanserin for PDP through the center's neurology clinic. The data collection was divided into 2 periods based on timing of SP integration: preintegration (from June 2016, following FDA approval of pimavanserin, through December 2016; overall, a 6-month period) and postintegration (from January 2017, when the SP was integrated into the clinic, through June 2018; overall, a 17-month period). Patients receiving pimavanserin externally postintegration or through clinical trials were excluded. This study was approved by the Vanderbilt University IRB.

Clinic Workflow

Figure 1 illustrates clinic workflow before and after SP integration. Prior to integration, a clinic nurse worked with the manufacturer hub and payer to navigate the insurance approval pathway (PA, \pm appeal, \pm peer review). The clinic nurse would submit a treatment initiation form and prescription to the hub, which began processing prescriptions for pimavanserin in May 2016. The hub would determine if PA was required and notify the provider. If required, PA forms were completed by a nurse and submitted to the payer for review and approval. If denied, additional clinical documentation as well as an appeal letter were submitted by the nurse or provider. Once approved, the nurse would inform the hub, which would send the prescription to an external specialty pharmacy for fulfillment. This lengthy process became cumbersome and detracted from other clinical responsibilities.

In January 2017, following the center's inclusion in the manufacturer-implemented LDN, an SP was embedded into the clinic to assist with medication access and management tasks for patients prescribed pimavanserin. From this point on, the SP supervised the entire medication access pathway from decision to treat to medication shipment and initiation, reducing complexity

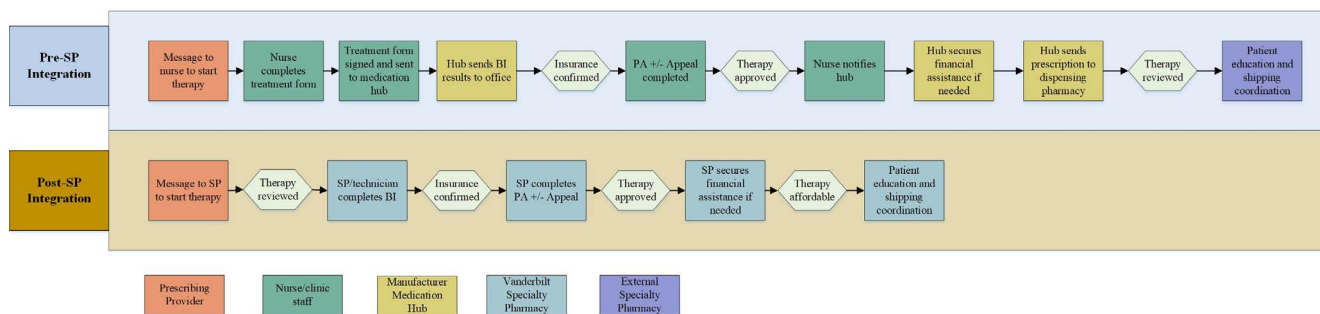


FIGURE 1: Overview of outpatient neurology clinic workflow before and after specialty pharmacist (SP) integration (PA = prior authorization; BI = benefits investigation)

and confusion for both prescribers and patients. Once the provider decided to initiate pimavanserin, the SP received the prescription and reviewed the EHR for appropriateness of therapy. Either the SP or pharmacy technician performed a benefits investigation to determine if PA was required. If required, the SP worked directly with the prescriber to complete any necessary paperwork. If denied, the SP provided additional clinical documentation and an appeal supporting pimavanserin use. Once approved, the SP would ensure the medication was dispensed to the patient in a timely fashion by either the center's specialty pharmacy or an external pharmacy, depending on payer requirements and patient preference. Additionally, the SP provided extensive counseling and served as a liaison between patients and prescribers for medication-related concerns primarily through phone calls and clinical communication via the EHR. Physically embedded in the outpatient neurology clinic, the SP also interacted with patients at scheduled provider office visits when a medication-related concern arose. At each refill, a certified pharmacy technician contacted patients via phone to evaluate patient outcomes and alerted the SP if further action was warranted. The SP performed, at minimum, annual reassessments via phone call to evaluate continued appropriateness of therapy.

Study Objectives

The primary study objective was to measure the duration in days between the provider's decision to treat and insurance approval before and after SP integration. Two time periods were assessed: pre-SP integration (June 2016 to December 2016) and post-SP integration (January 2017 to June 2018). The secondary objective was to describe number and type of SP interventions performed post-integration.

Data Sources

Data for patient characteristics, medication access outcomes, and pharmacist interventions were collected from the EHR and pharmacy database. Interventions were

categorized as clinical care (monitoring, annual reassessments), coordination of care (communication with providers and caregivers), AE management (answering or mitigation of AE-related concerns), and medication adherence. Financial assistance data (foundation grants, manufacturer copay cards or patient assistance, and use of the institution's medication assistance program) were collected from the pharmacy database for patients postintegration. Data was managed using Research Electronic Data Capture hosted at Vanderbilt University.^{15,16}

Statistical Analysis

Descriptive statistics were used to describe patient characteristics. Proportions were calculated for categorical variables; mean, median, SD, and IQR were calculated for continuous variables. Proportional odds logistic regression was performed in the postintegration cohort to test the association of approval time with the following covariates: age, gender, and insurance type.

Results

Of 98 patients reviewed, 4 were excluded (3 patients filling externally, 1 clinical trial patient). Age, gender, race, and insurance type were similar between preintegration ($n = 32$) and postintegration ($n = 62$) groups (Table). Most patients were white (96%, $n = 90$) and male (80%, $n = 75$). Mean age was 73 years (± 9), and 81% ($n = 76$) had Medicare or Medicaid. Figure 2 illustrates time from decision to treat to pimavanserin approval for preintegration and postintegration cohorts.

Preintegration Cohort

Preintegration, 26 (81%) patients received insurance approval. For 25 patients, overall median time to insurance approval was 22 days (IQR 8 to 36). Access time could not be calculated for 1 of these patients due to the date of approval not being documented. Median time

TABLE: Demographic characteristics of study population^a

	Pre-SP Integration n = 32	Post-SP Integration n = 62	All n = 94
Age, y	70.5 ± 7.6	74.7 ± 8.8	73.3 ± 8.6
Male	26 (81)	49 (79)	75 (80)
White	29 (91)	61 (98)	90 (96)
Medicare or Medicaid	25 (78)	51 (82)	76 (81)

SP = specialty pharmacist.

^aAll data is n (%) except for age (which is mean ± SD).

to approval was 32 days for patients with commercial insurance (n = 6) and 17 days for patients with Medicare or Medicaid (n = 19).

PA and appeal outcomes are depicted in Figure 3. For patients receiving initial PA approval (n = 21), median time to approval was 27 days. PA was denied for 4 patients due to either an incomplete form (n = 1) or more clinical information needed (n = 3). For 2 of these patients, approval was secured on first appeal. First appeal was not pursued for 1 of these patients. For the last patient, a second appeal was not pursued after denial of the first appeal.

Preintegration, 78% of patients started pimavanserin. Seven patients did not start treatment due to cost (n = 1), patient preference (n = 3), AEs from sample medication (n = 1), and insurance barriers (n = 2).

Postintegration Cohort

Following SP integration, 59 patients (95%) received approval with overall median time to insurance decreasing to 3 days (IQR 1 to 6). Median time to approval was 8 days for patients with commercial insurance (n = 10) compared with 2 days for patients with Medicare or Medicaid (n = 49). The multiple regression analysis showed the odds of having a longer time to approval for patients with commercial insurance was about 7 times of those with Medicare or Medicaid (odds ratio 7.1; 95% confidence interval: 1.9, 26.7; *P* = .004). A higher percentage of patients started pimavanserin (94% vs 78%) post-SP integration compared with pre-SP integration.

For patients receiving initial PA approval (n = 48), median time to approval was 2.5 days. As depicted by Figure 3, 5 patients received PA denial due to off-label use (n = 2), nonpreferred medication (n = 1), or more clinical information needed (n = 2). Four of these patients received approval on first appeal with median time to approval of 8.5 days. For 1 patient, pimavanserin use was approved on third appeal after a mandated trial of quetiapine was completed, resulting in approval 154 days after decision to

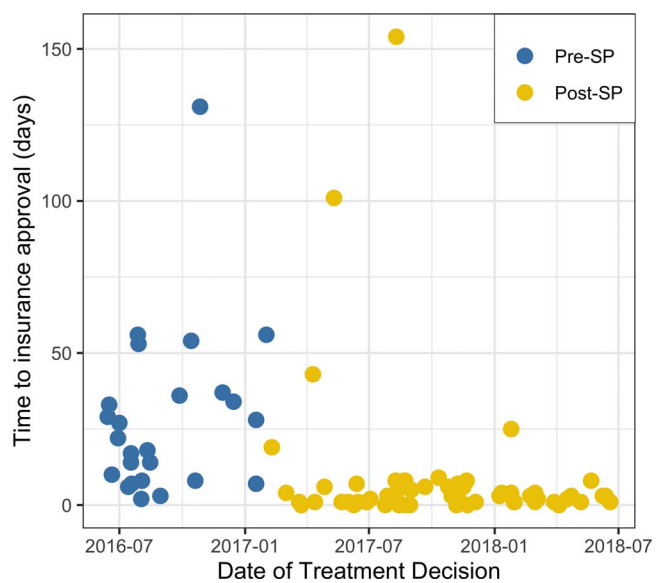


FIGURE 2: The time from prescriber's decision to treat with pimavanserin to insurance approval during the pre- (blue solid circles) and the post- (yellow solid circles) specialty pharmacist (SP) integration; access times for 25 patients in the preintegration cohort and 59 patients in the postintegration cohort are included

treat. Postintegration, 4 patients did not start therapy due to cost (n = 1), AEs from sample medication (n = 1), loss to follow-up (n = 1), and symptom resolution (n = 1).

The SP secured financial assistance for 43 patients: foundation grants (n = 26), manufacturer copay card (n = 13), manufacturer patient assistance program (n = 3), and the institution's medication assistance program (n = 1).

The SP performed 93 interventions: clinical care (n = 47), coordination of care (n = 39), AE management (n = 6), and medication adherence (n = 1). Five patients reported AEs, including poor well-being, confusion, nausea, peripheral edema, combative behavior, and double vision (n = 1 for each). The SP reviewed AE data from clinical trials, offered a resolution when appropriate, and ensured provider follow-up.

Discussion

Our findings demonstrate that SP integration can improve median time to pimavanserin insurance approval and provide beneficial treatment monitoring. Health-system specialty pharmacies have demonstrated benefits in treatment access, initiation, and adherence in other specialty diseases.^{12,13,17-20} Building on previous literature, this study illustrates that SP integration improves time to pimavanserin insurance approval. Advances in specialty therapy, such as pimavanserin, offer promise to patients

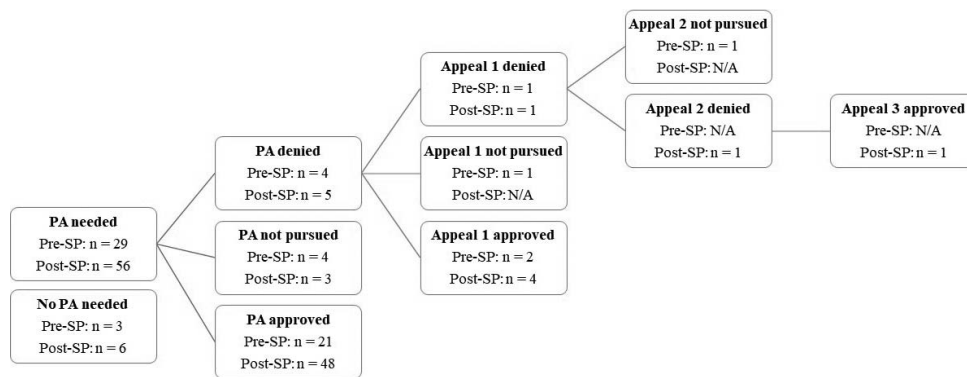


FIGURE 3: Illustration of prior authorization and appeal outcomes for patients in both preintegration and postintegration cohorts (SP = specialty pharmacist; PA = prior authorization; N/A = not applicable)

with chronic, debilitating diseases. To realize therapeutic benefit, patients must be able to afford and initiate therapy. Therefore, having SPs available to streamline the approval process is beneficial. In this study, postintegration patients secured insurance coverage in a median time of 19 days less than preintegration. Symptom improvement can take up to 2 weeks following pimavanserin initiation.^{3,4} PDP symptoms place a significant burden on patients and caregivers; therefore, faster treatment initiation may improve patient and caregiver quality of life.²

Another barrier mitigated by SP integration was navigation of the LDN. Although not evaluated because preintegration data is unavailable, this may have prevented delays in time to medication in hand. Postintegration, more patients initiated pimavanserin. We hypothesize that direct access to an SP with expertise to address access barriers enabled a higher proportion of patients to start therapy.

The multiple regression analysis with the postintegration cohort suggested that patients with commercial insurance were more likely to have a longer time to approval compared with patients with Medicare or Medicaid. We hypothesize that our finding is due to anecdotal experience that commercial insurance plans have more PA requirements and often mandate step therapy before approving pimavanserin. As only 18% (n = 11) of patients had commercial insurance in the postintegration cohort, additional research is needed to further elucidate the impact of insurance type on approval time and determine causality.

Literature^{12,21} regarding the SP role in PD is limited. A study²² conducted in Brazil found that pharmacist involvement in care led to improvement or maintenance of quality of life and improved adherence to antiparkinsonian treatment. A Veterans Affairs study²³ demonstrates that pharmacist-led PD management results in

high-quality, cost-effective care by providing interventions, including dose adjustment and care coordination. Another VA study²⁴ finds that, in 21% of cases evaluated, a pharmacist's recommendations contribute to improvement of medical outcome or resolution of a medical problem. Our study depicts the crucial neurology SP role in the management of psychosis related to PD. Through close follow-up and targeted interventions, the SP ensured safe and effective pimavanserin use.

The SP monitored safety and efficacy prior to every refill as well as during annual medication reassessments. Patients also contacted the SP whenever questions arose during treatment. Safety concerns arose when the patient received another medication that could also cause serious AEs such as QT prolongation, particularly antipsychotics.²⁵ Patients were encouraged to notify the SP of medication changes to ensure necessary DDI screenings were performed, particularly due to concern when multiple medications with potential QT prolongation were prescribed. The SP discussed the importance of proper monitoring (such as an electrocardiogram) with the patient or caregiver and ensured the provider was aware of interaction potential. The SP also discussed treatment expectations prior to initiation of therapy and assessed whether symptoms were well controlled while on therapy.

The SP ensured timely refills were issued to prevent treatment lapses. Medication adherence was addressed when patients reported missed doses. For example, 1 caregiver expressed concern that the patient was missing doses due to falling asleep before taking pimavanserin at night. In this case, the SP counseled the caregiver to change pimavanserin dosing to morning to prevent missed doses. A crucial clinical care intervention performed by the SP was to counsel each patient or caregiver of a formulation change in August 2018. The original pimavanserin 17-mg tablets were discontinued, and patients began receiving pimavanserin 34-mg capsules. Counseling ensured that patients understood the formu-

lation change and that appropriate dosing was now one 34-mg capsule daily instead of two 17-mg tablets daily.

Due to their integrated nature, health-system specialty pharmacies connect patients, physicians, and other health care providers.²⁶ In this study, care coordination interventions resulted from the SP serving as the point of contact and facilitating communication between the patient and other entities: physicians, nurses, and clinic staff. Coordination of care interventions involved discussing treatment concerns with prescribers and formulating management strategies. Often, a clinical care intervention described above resulted in further care coordination. Examples include developing a tapering schedule for a patient transitioning from clozapine to pimavanserin and discussing concerns from a caregiver regarding worsening of PDP and a decline in the ability to perform self-care with the neurology provider, prompting a follow-up appointment with the provider. This type of care coordination can help prevent unnecessary medication discontinuation and ensure optimal therapy outcomes through appropriate dosing and monitoring.

SPs are uniquely positioned to manage therapy for PD's nonmotor components, including psychosis, working alongside physicians and patients to ensure comprehensive disease management.²⁷ Postintegration, 8% (n = 5) of patients reported AEs, ranging from confusion to combative behavior. The SP discussed AE details, addressed questions regarding whether it was medication-related, and discussed types of AEs reported in clinical trials. If appropriate, the SP offered a mitigation strategy; for example, when nausea occurred, the SP recommended taking pimavanserin in the evening. The SP subsequently reached out to the patient to confirm AE resolution and discussed appropriate provider follow-up. The pharmacist-led monitoring detailed above may have helped patients safely continue pimavanserin.

Limitations

Performed at a single academic center, these results may not be generalizable. Because documentation regarding financial assistance was not documented preintegration, change in this outcome was not assessed. Pimavanserin received FDA approval in April 2016; therefore, predetermined criteria for insurance approval may not have been in place at the beginning of the preintegration cohort. However, time to approval in the preintegration cohort did not trend down over the 6 months evaluated (Figure 2). Insurance plan formulary changes may also have impacted approval times. Further research evaluating clinical outcomes related to faster insurance approval is needed. Additionally, future studies should evaluate the

clinical outcomes of pharmacist integration into an outpatient neurology clinic.

Conclusion

Our findings illustrate the positive impact of SP integration on pimavanserin access and support implementation of this model. As more therapies for neurology and movement disorders are developed, the neurology SP role will expand.

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