

Background

It has been estimated that one-third to half of all patients in the U.S. are nonadherent to their medications, leading to an avoidable cost of \$290 billion annually.¹ Primary medication nonadherence (PNA) occurs when a medication is prescribed but never obtained by the patient. Reports have shown that over 30% of prescribed medications are never filled or picked up by the patient.²

Primary medication nonadherence has been studied in different therapeutic areas, focusing in traditional pharmacy. Specialty medications have not been included in many research efforts, primarily due to the smaller patient populations often seen with rare and devastating conditions. Valbenazine is an FDA-approved treatment for patients with tardive dyskinesias, characterized by uncontrollable movements of the face and body. Despite the benefits of this therapy, some patients choose never to start this medication.

Objective

The goal of this study is to determine the primary medication nonadherence (PNA) rate for patients with Tardive Dyskinesia who are prescribed valbenazine for the first time.

Methods

- A retrospective database analysis of a single national specialty pharmacy was conducted, identifying all patients initiating valbenazine between March 1 - August 31, 2019.
- To calculate PNA, the PQA method was employed. The PQA has defined PNA as a patient failing to obtain their first medication dispense within 30 days of prescribing.¹
- PNA is calculated by dividing the number of referrals where there is no pharmacy dispensing event within 30 days by the total number of patients who had a first-time referral for valbenazine.¹
- Variables assessed included average age, gender, primary insurer, prescribing physician specialty in addition to the classification of antipsychotic use in the Delayed Ship Cohort. Patient profiles were also reviewed to obtain the reasons for shipment delay/cancellation.
- Descriptive statistics were utilized to determine averages and distribution.

All first time valbenazine referrals from 3/1/2019-8/31/2019 (n= 3,393)

Exclusion Criteria (n=1,927): Reported adverse event; transferred to another pharmacy; transferred to Hub; transferred to assistance product; transferred to commercial product; out of network; duplicate order; cannot fill insurance; anticipated new RX but never received one; valbenazine 80 mg referral

Patients with first time referral for valbenazine 40 mg & valbenazine starterpack 40/80mg (n=1,466)

Of these patients, did they fill valbenazine in ≤ 30 days after the initial referral?



Results

Figure 1: PNA Rates

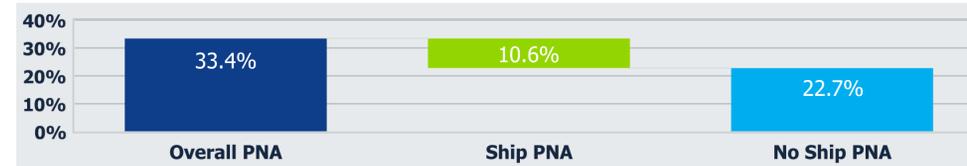


Table 1: Demographics

	No Ship Cohort	Delayed Ship Cohort
Age	Avg: 55 yrs	Avg: 54 yrs
<40 y.o.	16%	16%
40-59 y.o.	43%	47%
≥ 60 y.o.	41%	37%
Gender		
Male	39%	35%
Female	61%	65%
Primary Insurer		
Bridge*	31%	4%
Commercial	15%	10%
Medicaid	19%	14%
Medicare	29%	67%
No Insurance	3%	0%
PAP**	3%	4%
Other	<1%	1%
Prescriber Specialty		
Neurology	20%	13%
Nurse Practitioner	12%	12%
Physician Assistant	5%	4%
Psychiatry	59%	64%
Other	4%	7%

Table 2: Delayed Shipment Reasons

	Healthcare Barrier	Insurance	Patient	Prescriber
Awaiting Foundation Approval	<2%			
Awaiting PAP** Approval	<2%			
Awaiting Patient Contact			35%	
Change in Coverage			4%	
Awaiting Prescriber Contact				6%
Therapy Change				1%
Delay in Prior Authorization/ Appeal Process		21%		
Delay in Prior Authorization Process		30%		
Totals	4%	51%	39%	7%

Table 3: No Shipment-Discharge Reasons

	Healthcare Barrier	Insurance	Patient	Prescriber
No Response from Prescriber				20%
Change in Prescriber- No Transition of Care				1%
Denied; Patient Needs Appointment				1%
Patient on Different Therapy				9%
Discontinued by Prescriber for Unknown Reason				5%
Prescriber Withdrew Prior Authorization				0.3%
High Out of Pocket Cost for Patient		<1%		
Insurance Denied Appeal		2%		
Prior Authorization Denied		<1%		
No Appeal Submitted	5%			
No Prior Authorization Submitted	1.5%			
Pending Free Trial	1.5%			
Patient Deceased			2%	
Patient Declined			15%	
Patient Held Medication			<1%	
Patient Unreachable			35%	
Insurance Info Needed			<1%	
Totals	8%	3%	53%	36%

Discussion

PNA rates have been reported varying from 11.6% to 31.3%.² The overall calculated primary medication nonadherence rate of this study is 33.3% which seems to fall on the higher end of the PNA spectrum. A PNA rate of 22.7% can be attributed most to unreachable patients. It is evident in this study that patient barriers are the most common reason why a patient never receives an initial shipment of valbenazine, calculated at 53%. In contrast, the greatest barrier to a patient having a delay in their initial shipment is payor related. 51% of patient's experienced a delay in the prior authorization process that lead to shipment delays from 30 days of receipt of initial referral and beyond. A PNA rate of 10.6% was calculated in this corresponding cohort.

In addition, approximately 63% of patients in the Delayed Shipment Cohort reported antipsychotic use and 1% of patients reported metoclopramide use. Of those antipsychotics, 85% were classified as atypical, second generation, while 15% were classified as typical, first generation.

Based upon statistical testing, the probability of a patient not receiving a shipment is calculated at 22.7% while the probability that a patient will receive an initial valbenazine shipment is calculated at 77.3%. In addition, statistically significant differences were observed among the Never Shipped Cohort males and females as well as the various age ranges. Patients aged <40, 40-59, and ≥ 60 years old have a probability of 24.2% CI [18.4-30.0], 21.8% CI [18.6-25.0], and 20.9% CI [17.7-24.1], respectively, of not receiving an initial shipment of valbenazine. Among the Never Shipped Cohort males, there is a 23.5% CI [19.9-27.1] chance that this gender will not receive a shipment. In contrast, there is a 20.7% [18.1- 23.3] chance that a female will not receive an initial valbenazine shipment. The z-score significance testing showed a 99.99% confidence that males will ship at a lower rate than females and patients aged <40 years old ship at a lower rate than the other age groups.

Limitations of this study include inability to control for patients who had received samples from their prescriber or had a previous dispense from another pharmacy. In addition, this study included patient reported data regarding antipsychotic use.

Conclusion

Based upon these findings, specialty pharmacies may create solutions to improve outreach communications with patients. Adherence initiatives as well as additional educational tools may target those more vulnerable age and gender groups that are less likely to receive an initial shipment of valbenazine.

From this study, analysis of the current PQA criteria and its applicability to first-time specialty medication dispensing patterns may be further explored.

References

- Adams, Alex J. PharmD, MPH; Stolpe, Samuel F. PharmD. Defining and measuring primary medication nonadherence: development of a quality measure. J Manag Care Spec Pharm. 2016;22(5):516-23. <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2016.22.5.516>. Accessed 2019 December.
- Robyn Tamblin, PhD; Tewodros Eguale, MD, PhD; Allen Huang, MD; Nancy Winslade, PharmD; Pamela Doran, MSc. The incidence and determinants of primary nonadherence with prescribed medication in primary care: A cohort study. Ann Intern Med. 2014;160(7):441-450. doi: 10.7326/M13-1705.

* Bridge; manufacturer provided medication at no cost to patient
**PAP; patient assistance program