

Savings on High-Cost Drugs Such as Atypical Long-Acting Injectable Antipsychotics: Switching to Billing Under the Pharmacy Benefit in Outpatient Settings

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ABSTRACT

Objective: Access to health care can be improved by controlling and optimizing expenditures, specifically the high-cost drugs such as atypical long-acting injectable (LAI) antipsychotics. This type of LAI is usually covered under the medical benefit and/or pharmacy benefit. We sought to compare financial outcomes of the medical benefit billing option with the pharmacy benefit billing option for atypical LAIs in an adult outpatient psychiatric clinic and to determine insurance companies' reasons for nonpayment when the medical benefit billing model was utilized.

Methods: A retrospective chart review with patients 18 years of age and older who were receiving atypical LAI antipsychotics in the outpatient psychiatric department during two time periods—January 7 through February 6, 2016 and August 15 through September 14, 2016—to evaluate medical (N = 31) and pharmacy (N = 23) benefit study periods, respectively.

Results: The estimated loss when using the medical benefit billing option was \$14,520 per month. Switching to billing under the pharmacy benefit resulted in a monthly gain of \$2,100. The net savings from the switch were estimated at \$16,620 per month. No patient lost access to treatment or was switched to another medication solely because of the change in billing option. The reasons for nonpayment (N = 10) provided by medical insurance companies were prior authorization/step therapy required (40%), insurance terminated (30%), and coverage through Medicaid Rx only (30%).

Conclusion: This study revealed a significant financial loss related to atypical LAI antipsychotics when the medical benefit model was utilized. By switching to billing under the pharmacy benefit, potential savings for high-cost drugs such as LAIs can be realized.

Keywords: cost-saving, high cost, long-acting injectables, LAIs, billing, reimbursement, outpatient

INTRODUCTION

The United States spends more on health care than any other country.¹ Estimated total healthcare spending for 2019 is projected to reach \$4.1 trillion, including \$225 billion for mental health.² However, the gap between mental healthcare needs and available resources is large and growing.³ More than half of adult patients with mental illnesses received no treatment in the past year, and one out of five patients who did receive

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treatment continue to report unmet treatment needs.⁴ Quality of care for mental disorders remains suboptimal and requires the implementation of evidence-based practices.⁵ For many patients, having insufficient finances to cover treatment costs remains a major barrier to accessing quality care.^{4,6} Also, it is essential that mental health institutions can effectively manage scarce financial resources to provide the best patient care.

More than \$58 billion of the expected spending that is attributed to prescription drugs will account for 26% of all mental healthcare costs.² A significant amount of resources will be spent on newer atypical antipsychotic agents, including their long-acting injectable (LAI) formulations. Optimizing medication management and implementing cost-saving practices would allow mental health clinics to better allocate limited resources and improve quality of care by focusing on patient-centered outcomes. High-cost medications also remain a major focus for payers and mental health organizations for controlling and optimizing expenditures.

Payers, in collaboration with pharmacy benefit managers (PBMs, third-party administrators of prescription-drug programs for commercial and government health plans), have been developing and implementing programs that provide clinical services to patients with mental health requirements and allow for the control of medication costs. Examples of such cost-controlling tools include prior authorization (PA), preferred products or step therapy, patient cost-share, and medication-utilization management. In addition, there are two billing options for specialty drugs such as LAI antipsychotics: they can be covered under the medical benefit and/or the pharmacy benefit.

Coverage under the medical benefit implies that a healthcare institution is submitting claims to a health-insurance company to receive payment for medication administered and services provided. The institution must first buy the medication, administer it to the patient, and then bill the payer, expecting to be reimbursed later. However, the claim might not be processed properly or the insurance company might deny it, leaving the organization with a financial loss. The need to buy and stock medications, the complicated payment systems, and delays in reimbursement can all make the medical-benefit billing option less attractive than the pharmacy-benefit billing option.

Previous presentation: A portion of the results included in this article was presented at the American Society of Health-System Pharmacists Midyear Meeting in Las Vegas, Nevada, December 4–8, 2016.

Disclosure: The authors report no financial or commercial interest in regard to this article.

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Pharmacy-benefit billing avoids these financial issues by shifting billing to a retail pharmacy. In this case, a healthcare provider sends a prescription to a pharmacy (regular retail, specialty, or mail-order, depending on insurance company requirements) and the pharmacy deals with medication acquisition, claim submission, and payment processing. The medication is delivered or mailed to a provider's office or dispensed to the patient for in-office administration. Even though the pharmacy benefit option has fewer billing issues for practitioners, it still has limitations. To avoid unnecessary rescheduling and reduce potential noncompliance with treatment among patients who are mentally ill, a provider has to ensure that all related issues are resolved and that medication is available for administration prior to the patient's visit. In the case of a change in the patient's treatment, a missed appointment, or discharge from the clinic, the practitioner has to return the medication to the pharmacy and refund the payer within a specified period of time, which requires additional stock management efforts.

Our institution, an adult outpatient psychiatric department (AOPD) that is part of a large, nonprofit, metropolitan, community teaching hospital in New York, previously employed the medical-benefit billing option. The inpatient pharmacy department acquired risperidone LAI (Risperdal® Consta®, Janssen), paliperidone palmitate extended-release injectable suspension (Invega Sustenna®, Janssen), aripiprazole extended-release injectable suspension (Abilify Maintena®, Otsuka America Pharmaceutical), and aripiprazole lauroxil extended-release injectable suspension (Aristada®, Alkermes), all atypical LAI antipsychotics, and they were kept as AOPD floor stock in amounts approved by the pharmacy and therapeutics (P&T) committee. Before initiating treatment with a patient, a practitioner was responsible for verifying eligibility and obtaining

PA if needed. When the patient was due to receive the next dose of LAI, the practitioner would obtain the medication from the floor stock, administer it to the patient, then document the charges in the electronic health record (EHR) system. A patient account specialist used this information to prepare and send insurance claims and patient bills, and to process payments.

At our AOPD, the medical benefit method did not provide adequate reimbursement for the expensive LAIs; therefore, the decision was made to acquire these medications using the pharmacy benefit option before they were administered to patients. A new procedure was developed to optimize the acquisition process, and this was implemented in July 2016. We conducted this study to evaluate the financial impact of the intervention.

METHODS

A retrospective chart review of patients aged 18 years or older who received atypical LAI antipsychotics in the AOPD was conducted during two time periods—January 7 to February 6, 2016, and August 15 to September 14, 2016—to evaluate the medical-benefit and pharmacy-benefit options, respectively. Pregnant women were excluded from the review. As all the medications were given monthly (with the exception of biweekly risperidone), a one-month timeframe was considered appropriate to include all eligible patients and avoid duplicate encounters. If a patient received two injections of risperidone LAI during the study period, both injections were included in the analysis. Hospital billing and payment records were assessed for relevant information. Regarding the medical benefit, the records were assessed at four months, then updated at Month 6 after the end of the study period to allow sufficient time for insurance companies to process claims and payments. Corresponding

Table 1 Medical Benefit Reimbursement Information

Visit Date	LAI Given	Charges Entered	Insurance	Acquisition Cost, \$	Insurance Paid, \$
1/7/16	Abilify Maintena 400 mg	Yes	Medicaid	1,155.80	0
1/7/16	Risperdal Consta 50 mg*	Yes	Medicaid	789.12	0
1/7/16	Invega Sustenna 117 mg	Yes	Fidelis/Medicaid	569.33	0
1/11/16	Invega Sustenna 156 mg	Yes	Healthfirst/Medicaid	732.13	0
1/19/16	Risperdal Consta 25 mg	Yes	Medicaid	393.94	0
1/19/16	Risperdal Consta 37.5 mg	Yes	Fidelis/Medicaid	583.96	737.16
1/19/16	Risperdal Consta 37.5 mg	Yes	Healthfirst/Medicaid	583.96	13.82
1/19/16	Risperdal Consta 37.5 mg	Yes	Blue Cross Blue Shield	583.96	11.4
1/20/16	Risperdal Consta 37.5 mg	No	Healthfirst/Medicaid	583.96	0
1/21/16	Invega Sustenna 156 mg	Yes	Medicaid HMO	732.13	0
1/25/16	Invega Sustenna 117 mg	Yes	Fidelis/Medicaid	569.33	656.61
1/26/16	Risperdal Consta 25 mg	Yes	Blue Cross Blue Shield	393.94	692
1/28/16	Invega Sustenna 156 mg	Yes	Wellcare/Medicaid	732.13	0
1/29/16	Abilify Maintena 400 mg	Yes	Healthfirst/Medicaid	1,155.80	67.63
2/3/16	Abilify Maintena 400 mg	Yes	Healthfirst/Medicaid	1,155.80	1,509.99
				10,715.29	3,688.61

* Data for Risperdal Consta include two doses as the drug was given every two weeks.

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insurance companies were contacted to identify reasons for claim rejections. The institutional review board approved the study and granted a waiver of consent.

Obtaining accurate and complete billing and insurance payment records from an institution's financial database is usually a time-consuming process; thus, we randomly selected only half of the eligible medical benefit patients for the records request to include all the major payer types (Table 1). To avoid selection bias, all of the identified patients who were billed under the medical benefit model during January 7 through February 6, 2016, were stratified by insurance type—private or public. Half of the patients were randomly selected (defined as every other person) from the computer-populated list, and we submitted a request for their billing and payment records to the financial office. The average financial gain/loss per patient, which was calculated based on the patients selected at random, was applied to the whole medical-benefit patient sample.

Collecting acquisition and reimbursement data from a retail pharmacy database was not difficult, and all eligible patients billed under the pharmacy benefit were included for analysis. Data from institutional, insurance, and retail-pharmacy electronic records included patient demographics, primary psychiatric diagnosis, name and dose of the atypical LAI antipsychotic agent prescribed, date of medication administration, name of patient's insurance, acquisition cost of and total amount paid for the medication, and reason for payment rejection (if applicable).

The primary objective was to compare the medical- and pharmacy-benefit billing options in regard to the financial outcomes for atypical LAIs, defined as the difference between the total amounts paid and the costs of acquisition. The secondary objective was to evaluate reasons for nonpayment by insurance companies with the previously utilized medical-benefit billing model.

RESULTS

Of the 1,770 adult medical benefit patients who were screened, 31 eligible patients who received atypical LAIs were identified. All of the patients had medical insurance coverage, and approximately 87% of participants had different Medicaid plans. The most commonly used atypical LAI antipsychotic was paliperidone palmitate ($n = 16$), followed by risperidone ($n = 9$), and aripiprazole ($n = 6$). For the 15 randomly selected patients, the total acquisition cost of the LAIs that were administered was \$10,715, and the total amount received during the six months following the medical benefit study period was \$3,689. In one instance, the insurance company was not billed for the medication because the charge had not been entered in the EHR system. The total underpayment for the 15 patients was \$7,026, and the estimated loss for all 31 patients was \$14,520 per month (Figure 1). Detailed information about medical benefit reimbursement is presented in Table 1.

During the transition from the medical-benefit billing option to the pharmacy-benefit billing option, three patients were discharged from the clinic and one new patient was started on aripiprazole lauroxil, resulting in 29 potentially eligible patients. Of those 29 patients, four had to use mail-order specialty pharmacies and were not included in the analysis. The LAIs of two patients were not covered by their plans; therefore, one patient was switched to an oral formulation and

Figure 1 Medical Benefit Billing Option

Patient selection

- 1,770 adult outpatients were screened
- 31 eligible patients were identified
- No patients met exclusion criteria

Patient sample

- 31 patients were included
- 15 of 31 patients were randomly selected by accessing institution financial records

Data collected from hospital records for 15 randomly selected patients

- Acquisition cost: \$10,715
- Total amount paid: \$3,689
- Loss: \$7,026 for 15 selected patients

Estimated financial outcome for entire sample of 31 patients

- Loss for 15 patients was extrapolated to whole patient sample
- Total estimated loss: \$14,520/month

the other patient was enrolled in a manufacturer's patient-assistance program. Twenty-three eligible pharmacy benefit patients were included in the analysis. All of the patients consented to have their atypical LAI prescriptions filled at the institutional retail pharmacy in the hospital. It is important to note that no patient lost access to treatment or was switched to another medication because of the change in billing option alone.

Among the 23 pharmacy benefit patients, 78% were covered by various Medicaid plans. The most commonly prescribed medication was paliperidone palmitate ($n = 11$), followed by risperidone ($n = 6$), aripiprazole ($n = 5$), and aripiprazole lauroxil ($n = 1$). The acquisition cost and total amount paid were \$39,031 and \$41,131, respectively, which resulted in a \$2,100 financial gain for this period (Figure 2). Table 2 displays detailed information about pharmacy benefit reimbursement.

The net financial outcome from the intervention was estimated at \$16,620 per month for the two medical and pharmacy benefit samples. With respect to the secondary endpoint, we investigated 11 instances of inadequate reimbursement for LAIs under the medical benefit. In 10 cases, payments had been denied by health insurance companies for the following reasons: PA/step therapy required (40%); insurance terminated (30%); and coverage available through Medicaid Rx only (30%). In one case, the provider had not entered the charge in the patient's EHR.

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Figure 2 Pharmacy Benefit Billing Option

Patient sample

- 29 eligible patients were identified
- 6 patients were excluded (4 mail order prescriptions and 2 LAIs were not covered)
- 23 patients were included in analysis

Data collected from retail pharmacy records

- Acquisition cost: \$39,031
- Total amount paid: \$41,131

Financial outcome

- Gain of \$2,100 for 23 patients per month

DISCUSSION

In the AOPD, cost-savings on atypical LAI antipsychotics are possible when billing takes place under the pharmacy benefit option rather than the medical benefit option. The dollar amount may vary from one institution to another depending on their specific policies, but the potential for financial loss or nonpayment is a major underlying concern for any organization billing under the medical benefit model.

In response to the fast-growing mental health expenditure in the U.S., healthcare payers are increasingly applying utilization controls.⁷ In 10 of 15 (73%) medical benefit cases that we evaluated, insurance companies either did not pay at all for LAIs or paid an amount that was not sufficient to offset acquisition costs. The major reason for claim rejection was PA or a step-therapy approach (40%), which requires the prescriber to receive authorization from the insurance company prior to giving the initial dose, or to adjusting the dose, or if the approved period has expired (usually 12 months).

The PA process became disruptive and burdensome for prescribers.⁸ The greater complexity of forms and the diversity of information that is required for PA have extended the time

Table 2 Pharmacy Benefit Reimbursement Information

Visit Date	LAI Given	Insurance	Acquisition Cost, \$	Insurance Paid, \$
8/15/16	Invega Sustenna 117 mg	Medicaid CSC	1,046.35	1,094.20
8/15/16	Abilify Maintena 400 mg	Healthfirst/Medicaid	1,716.05	1,816.17
8/16/16	Risperdal Consta 25 mg*	Blue Cross Blue Shield	1,517.32	1,553.36
8/16/16	Abilify Maintena 400 mg	Blue Cross Blue Shield	1,716.05	1,756.61
8/17/16	Risperdal Consta 50 mg	Healthfirst/Medicaid	3,034.84	3,212.04
8/18/16	Invega Sustenna 117 mg	Healthfirst/Medicaid	1,046.35	1,107.58
8/18/16	Abilify Maintena 400 mg	Healthfirst/Medicaid	1,716.05	1,816.17
8/19/16	Invega Sustenna 156 mg	Fidelis/Medicaid	1,395.19	1,476.69
8/19/16	Invega Sustenna 117 mg	Medicare A&B/Medicaid	1,046.35	1,094.2
8/19/16	Risperdal Consta 50 mg	Medicare A&B/Medicaid	3,034.84	3,236.92
8/22/16	Abilify Maintena 400 mg	Healthfirst/Medicaid	1,716.05	1,816.17
8/22/16	Risperdal Consta 37.5 mg	Healthfirst/Medicaid	2,276.12	2,409.24
8/22/16	Invega Sustenna 156 mg	United HealthCare PPO	1,395.19	1,458.62
8/24/16	Invega Sustenna 156 mg	Healthfirst/Medicaid	1,395.19	1,476.68
8/25/16	Risperdal Consta 37.5 mg	Fidelis	2,276.12	2,409.24
8/30/16	Risperdal Consta 50 mg	Medicare A&B/Medicaid	3,034.64	3,179.48
8/30/16	Invega Sustenna 117 mg	United HealthCare/Medicaid	1,046.35	1,104.58
8/30/16	Invega Sustenna 156 mg	Wellcare/Medicaid	1,395.19	1,484.52
9/2/16	Invega Sustenna 117 mg	United HealthCare	1,046.35	1,107.58
9/6/16	Invega Sustenna 117 mg	Healthfirst/Medicaid	1,046.35	1,094.2
9/6/16	Abilify Maintena 400 mg	Aetna	1,716.05	1,766.17
9/9/16	Invega Sustenna 156 mg	MetroPlus	1,342.82	1,476.68
9/13/16	Aristada 882 mg	Medicare A&B/Medicaid	2,075.35	2,184.06
			39,031.16	41,131.15

* Two doses are shown for Risperdal Consta as the drug was given every two weeks.

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required to complete the form from a period of 10 to 15 minutes to as much as an hour.⁹ It is difficult, if not impossible, for a practitioner to follow all of the insurance companies' different requirements and the frequent changes in preferred drug lists, coding systems, dispensing limits, mandatory use of generic drugs, and so on. For example, one insurance company required three different PAs for initiating treatment with paliperidone palmitate, which the prescriber was unaware of: two PAs for loading doses of 234 mg and 156 mg and a third PA for the maintenance dose of 117 mg. Another payer's representative requested a special current procedural terminology (CPT) code from the practitioner that the practitioner could not provide. As a result of these difficulties, the PAs were not obtained on time and the requests for payment were denied.

The idea of billing the insurance company after medication has been administered assumes that all the requirements have to be fulfilled before administration. One option for verifying current patient LAI status is to call the medication coverage provider and inquire about reimbursement, but this is time-consuming. In addition, the outdated system that payers use to calculate doctors' fees means that clinics and doctors are paid only enough to justify a 15-minute appointment,¹⁰ and it is challenging for practitioners to squeeze even a five-minute phone call into this timeframe without compromising patient care.

Another reason for payment being rejected was the termination of insurance (30%). This can easily be resolved by training staff to verify a patient's insurance eligibility at each office visit when a LAI is due to be administered. Commercial and public health insurance programs offer multiple online tools for verifying current health coverage status (for example, ePACES, a Web-based application developed on behalf of the New York State Department of Health). Implementing institutional policy and assigning certain individuals the responsibility of verifying patient eligibility can minimize such financial losses; however, a decision has to be made on the day of the patient's visit if his or her insurance is not active. It is possible to apply for a manufacturer's patient-assistance program, which can provide medication at no cost, otherwise an alternative treatment plan should be considered.

Finally, 30% of payments were rejected under the medical benefit because LAIs were only covered by a prescription medication plan. An elaborate payment system in which one payer pays for medical services and another pays for actual medication costs creates a loophole through which payments can be rejected simply because of billing an inappropriate payer. It is often difficult to find information about patient medication coverage, and it might differ from the patient's medical plan.¹¹ Currently, there appears to be no single reliable tool available for healthcare providers to promptly identify which payer is responsible for a patient's medication coverage.

In general, employing the pharmacy benefit method in an outpatient clinic can help institutions avoid nonpayment situations. Retail pharmacies are able to process prescription drug claims several days prior to a patient's visit. In the case of rejection, PBMs give the pharmacy the specific reason for rejection ahead of time. This allows the prescriber to resolve the reimbursement issue or consider an alternative treatment plan prior to the patient's clinic visit.

Although billing under the pharmacy benefit can help to avoid or minimize financial losses, it is not always ideal. It requires additional efforts in maintaining the records of all patients on atypical LAIs, including the medication name, dosages, and dates of administration. The records can help identify which patients are due for medication administration within the next three to five days (the period of time that payers typically allow for an early refill) and notify patients' pharmacies to process the claims ahead of time. All of the covered LAIs can be kept in the pharmacies and dispensed to patients prior to their office visit or delivered to the outpatient clinic (which is preferred). Any medications that were not administered must be returned to the dispensing pharmacy and the claims reversed within 30 days.

Detailed recommendations for optimizing expenditures for high-cost medications in outpatient settings are provided in Figure 3. This algorithm can be applied to any high-cost medication in outpatient settings that is covered under the pharmacy benefit, and the process can be accomplished by individual prescribers or by a designee. A clinical pharmacist or a pharmacy resident has the knowledge and clinical expertise to assume this role while assisting the healthcare practitioner in treatment assessment and medication management, monitoring for potential adverse reactions and interactions, educating patients and families, and identifying and resolving reimbursement problems.¹²

The limitations of our study include its retrospective chart review design and small sample size. In addition, fluctuating acquisition costs and reimbursement rates can affect the net financial outcome. However, it is important to note that atypical LAIs are increasingly being used because of their therapeutic possibilities; therefore, our estimated drug-cost savings of \$16,620 per month could be greater. Since we conducted our study, the number of patients in the AOPD who are currently receiving atypical LAIs has almost tripled, and this has enabled the clinic to consider new patient-oriented services.

CONCLUSION

Our study revealed a significant financial loss that is related to atypical LAI antipsychotic agents when billing takes place under the medical benefit option. This loss was estimated at \$14,520 per month for 31 patients. The reasons for nonpayment by health insurance companies included a requirement for PA/step therapy (40%), termination of patient insurance (30%), and drug coverage being provided through Medicaid Rx only (30%). By switching to billing under the pharmacy benefit option, potential savings can be made for LAIs and some other high-cost medications. In our study, the net savings gained by switching billing models were estimated at \$16,620 per month; these were ultimately applied toward improving access to and the quality of mental health care for patients. We hope that similar savings can be achieved with other high-cost drugs.

ACKNOWLEDGEMENTS

Thanks to Gerard Quinn, PharmD, BCPS, BCPP, and Cathleen Mathew, PharmD, for their efforts in conducting this research.

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Figure 3 Recommendations for Optimizing Expenditures for High-Cost Medications in Outpatient Settings

Review current policies and procedures

- Obtain during initial visit, document in EHR, and verify before each visit information on medical and prescription medication coverage
- Inquire and obtain prior authorization before treatment initiation
- Ensure that all claims are submitted to appropriate payers
- Extend prior authorization after initial period has expired

Evaluate reimbursement rate under the medical benefit

- Allow sufficient time for payers to process claims and payments (up to 6 months)
- Verify 340B eligibility and appropriate acquisition cost for every patient
- Obtain specific and detailed payment information

If reimbursement is suboptimal, investigate reasons

- Not all charges included in EHR or claims not submitted to payers
- Prior authorization not received
- Insurance terminated
- Billed to medical plan, but covered only by prescription medication plan
- Other

Consider prerequisites for pharmacy-benefit billing option

- Person responsible for process
- 340b contract pharmacy
- Safe, locked place to keep patient medications (refrigerator may be required)
- Medication delivery and return process
- HIPPA-compliant patient signature log required for retail pharmacy
- Alternative options if patient has no coverage for high-cost medication

Implement transition

- Develop new policies and procedures
- Assign individuals responsibility
- Ask patients for permission to fill medication at contract pharmacy
- Process prescriptions at patient-selected/payer-required pharmacies
- Resolve emerging issues or consider alternative options prior to patient visit

Re-evaluate process under pharmacy benefit

- Reassess patients whose therapy was modified because of switch
- Review delays with mail-order deliveries
- Ensure timely return of signed dispensing logs and unused medications
- Ask for feedback from patients and practitioners to improve process
- Re-evaluate financial outcomes

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