Dalfampridine Prior Authorization Program: A Cohort Study

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ABSTRACT

BACKGROUND: Dalfampridine (Ampyra) is indicated to improve walking in patients with multiple sclerosis (MS) and was found to be effective in 35%–43% of individuals with MS in clinical trials. Dalfampridine may increase seizure risk, particularly in patients with renal impairment. A U.S. managed care expert consensus panel agreed that patient access to dalfampridine is best managed by a prior authorization (PA) program in accordance with the FDA-approved labeling. To ensure safe and appropriate dalfampridine use, a health plan developed and implemented a 2-phase point-of-sale PA program.

OBJECTIVES: To evaluate dalfampridine PA review decisions, utilization, and pharmacy expenditures following the implementation of a dalfampridine safety and clinical PA program compared with a group of dalfampridine users unexposed to a PA program.

METHODS: The study utilized retrospective administrative pharmacy claims data from a commercial health plan averaging 1.3 million members per month. The plan implemented a 2-phase dalfampridine safety and effectiveness PA program on August 1, 2010. A comparison group that did not implement the dalfampridine PA program was identified from a commercially insured population with approximately 350,000 members per month. Members in both groups were required to be continuously enrolled from August 1, 2010, through January 31, 2011. A member’s earliest paid or rejected claim found from August 1, 2010, through October 31, 2010, was defined as the index claim. Dalfampridine-weighted 30-day supply claims were summed and compared between groups from index date through January 31, 2011. A pharmacy cost avoidance estimate was calculated using the difference in average claims per member from index claim through January 31, 2011, multiplied by dalfampridine wholesale acquisition cost. Overall, dalfampridine utilization was evaluated between the intervention and comparison populations from August 2010 (implementation of PA in intervention group) through December 2011. Linear regression and Poisson models were used to test the trend differences.

RESULTS: The 60 PA-exposed dalfampridine members’ average follow-up was 157 days. Phase 1 approval was obtained by 32 (53.3%) members; 4 (6.7%) members received a denial because of renal impairment; 8 (13.3%) members received a denial due to inability to obtain walking time; 1 (1.7%) member with relapse-remitting MS was denied a PA due to no concomitant disease-modifying agent; and 15 (25.0%) members did not initiate the PA process. Phase 2 approval was obtained by 23 (38.3%) of the 60 members. The 60 PA members had a total of 126 claims and an average utilization of 2.1 (SD 1.8) claims per member. The 20 non-PA dalfampridine members’ average follow-up was 157 days. The comparison group members had a total of 84 claims and an average utilization of 4.2 (SD 2.0) claims per member. The PA program resulted in an average of 2.1 (P < 0.001) fewer claims per member in the PA group. The total dalfampridine cost avoidance estimate was $143,010 or $0.03 per member per month. The overall measure of a monthly claims utilization difference over time was statistically significantly different at P < 0.001, using the linear regression slope trend test. The trend line slope was not statistically significantly different, P = 0.841, between the intervention and comparison populations.

CONCLUSIONS: The study indicates that a dalfampridine PA program potentially improved safety and minimized dalfampridine costs. A PA program is effective in selecting appropriate utilizers for initial therapy. Addition of care management may further optimize use by encouraging adherence and tracking patient response.


What is already known about this subject

• In a 2010 systematic review of published studies assessing various prior authorization (PA) policies, 9 studies met analysis criteria, and all studies reported reductions in pharmacy utilization and expenditures across several disease states.
• In December 2010, a U.S. managed care expert consensus panel convened and recommended that PAs should be utilized by health plans based upon FDA-approved label indications to manage patient access to dalfampridine.
• On July 23, 2012, a MedWatch Alert strengthened the safety warnings for dalfampridine, raising caution when using it in patients with mild renal impairment and increased risk of seizures, a known potential side effect associated with higher blood levels of dalfampridine.

What this study adds

• Our study suggests that a 2-phase dalfampridine PA program appears to be effective in reducing potentially unsafe use because 1 in 15 members who sought dalfampridine PA were denied insurance coverage due to renal impairment.
• The dalfampridine PA program also appears to have an overall significant decrease in dalfampridine utilization as evidenced by the 50% lower utilization within the intervention group.
• In reference to the comparison group, over almost six months, the dalfampridine PA program resulted in a $0.03 per member per month dalfampridine savings in the intervention group.

Prior authorization (PA) programs, utilized by health plans or pharmacy benefit management (PBM) companies, are a means of requiring pre-approval for a drug before allowing coverage based on a member’s pharmacy benefit plan. The purpose of a PA program is to promote safe, appropriate, and cost-effective medication use. According to a 2011 Pharmacy Benefit Management Institute survey of 274 employers, more than three-fourths report utilizing PA programs. In a 2010 systematic review of published studies assessing PA policies, 9 studies met criteria for “good” quality as determined
by consensus among the authors, and quality was based on design, sample size, statistical comparisons, and presence of a control group. All studies found reductions in pharmacy utilization and expenditures.3 The PA policies evaluated in the systematic review4-14 primarily focus on populations with high pharmacy expenditures, for example, Medicaid users of psychotropic medications. In these studies, limited information was provided on the PA review decisions, and none of the PA policies consisted of both safety and medical need criteria.

Dalfampridine (Ampyra) is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS).15 Dalfampridine may increase seizure risk, particularly in patients with renal impairment.15 The U.S. Food and Drug Administration (FDA)-approved labeling states dalfampridine is contraindicated in patients with moderate or severe renal impairment (creatinine clearance less than or equal to 50 milliliter per min [mL/min]) or a history of seizures.15 A July 23, 2012, MedWatch Alert highlighted safety concerns when considering dalfampridine use in individuals with mild renal impairment and increased risk of seizures.16 The FDA required updates to the dalfampridine label regarding renal function measurements before and during therapy with dalfampridine.

Dalfampridine was shown to be effective in 35%-43% of individuals with MS in clinical trials.15 In addition, the FDA approval studies’ “inclusion criteria included the ability to walk 25 feet in 8-45 seconds.”15 Therefore, nonambulatory individuals were excluded from the FDA approval studies. Use of dalfampridine for individuals outside of the labeling studies’ inclusion and exclusion criteria is not currently supported by scientific evidence. Due to these safety and clinical characteristics, a U.S. managed care expert consensus panel has recommended that patient access to dalfampridine should be managed by a PA according to the FDA-approved labeling.37 The objective of our study was to evaluate members’ dalfampridine PA review decisions, utilization, and pharmacy expenditures following the implementation of a dalfampridine safety and clinical PA program compared with a group of dalfampridine utilizers unexposed to a PA program.

## Methods

This study utilized retrospective administrative pharmacy claims data from a commercial Blue Cross and Blue Shield (BCBS) plan in the southeastern region of the United States with a tiered formulary benefit design (e.g., generics $10, brand formulary $25, brand nonformulary $50) frequently with a deductible requirement. Dalfampridine was nonformulary with a PA requirement at the time of the analysis. The plan, with approximately 1.3 million members per month, implemented a 2-phase dalfampridine safety and effectiveness PA program on August 1, 2010. For members with dalfampridine claims history prior to August 1, 2010, a manual PA was entered effective until September 30, 2010, and members were informed that they were required to go through the PA approval process. For all other members, dalfampridine was rejected at the point of sale, and the members’ providers were required to submit information for clinical review. In the first phase of the PA, dalfampridine was approved for 60 days if all of the following criteria were met: (a) the member had a diagnosis of MS; (b) if the member had relapsing remitting MS, and they were receiving concomitant therapy with a disease-modifying agent (DMA); (c) the prescriber was a neurologist or had consulted a neurologist; (d) the member was ambulatory with a baseline-timed 25-foot walk between 8 to 45 seconds; (e) the member did not have a history of seizures; (f) the member did not have moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/min); and (g) the prescribed dosage was 10 milligrams (mg) orally twice daily. For a member to continue receiving dalfampridine after the initial 60 days of therapy approved in Phase 1, the provider had to resubmit documentation confirming all of the Phase 1 criteria. In addition, a member was required to demonstrate, as reported by the provider, at least a 20% improvement in the baseline-timed walking speed (timed 25-foot walk). If all criteria were met in Phase 2, the member received authorization for 1 year of dalfampridine therapy. A comparison group that did not implement the dalfampridine PA program was identified from a commercially insured BCBS population located in the Midwest with approximately 350,000 members per month. Dalfampridine was nonformulary in the comparison population, and nonformulary drugs were covered with a 50% coinsurance.

Members in both groups were required to be continuously enrolled from August 1, 2010, through January 31, 2011. Eligibility files were used to assess continuous enrollment. In both the PA-exposed group and comparison group, pharmacy claims were queried August 1, 2010, through October 31, 2010, for a dalfampridine claim using Medi-Span Generic Product Identifier codes starting with 624060. Each member’s earliest dalfampridine paid or rejected claim was defined as the index claim. Member characteristics were collected for intervention and comparison groups and included gender, date of birth on index claim, presence of dalfampridine found 120 days prior to index claim, presence of DMAs found 120 days prior to index claim, and average member cost share (standard deviation) reported on the index dalfampridine claim. Median member cost share with 25th and 75th percentiles are also reported. For the intervention group, a clinical review team evaluated all PA requests using the PA criteria (reported earlier) and recorded all decisions in a database. The clinical review database was queried to allow a description of approval and denial reasons.

In both the comparison and PA intervention groups, all members’ dalfampridine paid claims from index date through January 31, 2011, were summed, and the average claims per
member was compared between groups using the student’s t-test. Unique counts of members with zero, 1, 2, 3, and >3 claims in the follow-up period between the comparison and intervention were tested using the Fisher’s exact test. Claims were weighted to 30-day supplies; for example, a claim with a 90-day supply was counted as 3 claims. Descriptive statistics were used to describe the dalfampridine reasons for coverage denial and approval. A cost avoidance estimate was calculated using the difference in average claims per member from his or her index claim through January 31, 2011, multiplied by the dalfampridine 30-day supply wholesale acquisition cost (WAC) of $17.60 × 2 tablets × 30 days and the number of dalfampridine members.

The weighted 30-day supply claims per 100,000 members per month from January 2010 to December 2011 is reported. Comparisons of dalfampridine claims per 100,000 members per month between the 2 BCBS populations over the 17 months from August 2010 (implementation of PA in intervention group) through December 2011 were performed with the ANOVA test. A linear regression model was created to test the dalfampridine claims per 100,000 members per month trend slope line difference between the 2 BCBS populations over the 17 months. The month-to-month difference of dalfampridine claims per 100,000 members per month was compared by fitting a Poisson regression model with the log link function, and the log of member counts was used as the offset.

**Results**

Figure 1 shows the intervention and comparison groups analysis flow. Of the 807,801 continuously enrolled members in the intervention group, 60 members (7 per 100,000) had a dalfampridine paid or PA rejected index claim between August 1, 2010, and October 31, 2010. Of these 60 members, 31 (51.7%) had an index paid dalfampridine claim due to prior dalfampridine use with a manually entered PA valid August 1, 2010, through September 30, 2010, and 29 (48.3%) members had a dalfampridine rejected index claim. The clinical review database contained information on 45 (75.0%) of the 60 members. Fifteen members (25.0%) did not seek a PA; 4 (6.7%) members were denied a PA due to safety concerns; 8 (13.3%) members were denied a PA due to not meeting walking time criteria; and 1 (1.7%) member with relapsing remitting MS was denied a PA due to no concomitant DMA. The remaining 32 (53.3%) members received Phase 1 PA approval effective for 2 months. Phase 2 approval, effective for 12 months, was obtained by 23 (71.9%) of the 32 members. Of the 32 members meeting Phase 1 PA approval, 2 (6.3%) members were subsequently denied a Phase 2 PA due to not meeting walking time criteria, and 7 (21.9%) members did not seek a Phase 2 PA.

The comparison group, without a dalfampridine PA program, included 257,414 continuously enrolled members of which 20 (8 per 100,000) had a paid dalfampridine claim between August 1, 2010, and October 31, 2010. As shown in Table 1, the average age of dalfampridine members was 50 years for both groups (standard deviation [SD] 9.9 intervention group; 8.9 comparison group). The prevalence of females was 42 (70.0%) members in the intervention group and 16 (80.0%) members in the comparison group. The percentage of members with a supply of dalfampridine or a DMA in the 120 days prior to their index dalfampridine claims was not different in the intervention and comparison groups (\(P=0.515\) and \(P=0.512\), respectively). Average member cost share on the index dalfampridine claim was higher in the comparison group ($138 vs. $667, \(P<0.001\)). Median (25th, 75th percentiles) member cost share on the index claim were $50 ($35, $70) for the intervention group and $558 ($548, $562) for the comparison group. During the average follow-up of 157 days (range 110 to 181 days), the 60 members seeking dalfampridine insurance coverage in the intervention group had a total of 126 claims for dalfampridine, an average of 2.1 (SD 1.8) claims per member. The 20 members in the comparison group had a total of 84 claims for dalfampridine, an average utilization of 4.2 (SD 2.0) claims per member. As shown in Table 2, the greater than 5-month follow-up indicates that 28.3% of members in the intervention group had 4 or more weighted 30-day supply dalfampridine claims compared with 60.0% of members in the comparison group (\(P=0.016\)). The number of members with no claims during the 5-month follow-up period was 15 (25.0%) in the intervention group compared with 0 members in the comparison group (\(P=0.017\)).

The dalfampridine PA program resulted in an average of 2.1 (\(P<0.0001\)) fewer claims per member in the PA group (average 2.1 claims per member) versus the comparison group (4.2 average claims per member). At a WAC per claim of $1,135, the total dalfampridine cost avoidance estimate over the average follow-up of 5.2 months was $143,010 (2.1 claims × 60 members × $1,135) or $0.03 per member per month (PMPM; $143,000 / [807,801 members × 5.2 months]).

The dalfampridine monthly average claims per day per 100,000 members trend analysis is shown in Figure 2. Within the intervention population, the average monthly claims per 100,000 members decreased from 3.5 in July 2010 to 2.4 in August 2010, following implementation of the dalfampridine PA program on August 1, 2010. The comparison population’s average monthly claims per 100,000 members increased from 4.4 in July 2010 to 6.3 in August 2010. In the month of PA program implementation (August 2010), the dalfampridine utilization was significantly different (\(P<0.001\)) between intervention and comparison groups, and 16 months after implementation (December 2011), the difference remained statistically significantly different (\(P=0.014\)). During the 17 months analyzed, claims utilization was not statistically significantly different for 4 of the 17 months (\(P>0.05\)). However, the
Dalfampridine Prior Authorization Program: A Cohort Study

FIGURE 1: Flow of Members in Intervention and Comparison Groups

**Intervention Group**
- 1,593,930 members with any eligibility and exposed to the dalfampridine PA program
- 807,801 members continuously enrolled August 1, 2010, through January 31, 2011
- 60 members with a paid or rejected dalfampridine claim August 1, 2010, through October 31, 2010
  - 4 members denied PA due to safety concerns
  - 8 members denied PA due to not meeting walking time criteria
  - 1 member denied PA due to no concomitant disease-modifying agent
  - 15 members did not seek a PA
- 32 members received Phase 1 PA approval (2 months)
- 23 members received Phase 2 PA approval (12 months)

**Comparison Group**
- 371,583 members with any eligibility
- 257,414 members continuously enrolled August 1, 2010, through January 31, 2011
- 20 members with a paid dalfampridine claim August 1, 2010, through October 31, 2010
  - 2 members denied PA due to not meeting walking time criteria
  - 7 members did not seek Phase 2 PA
- 257,394 members without a dalfampridine claim
  - 20 members with a paid dalfampridine claim
  - 23 members received Phase 2 PA approval (12 months)

**Flow Details**
- 786,129 members with any eligibility and exposed to the dalfampridine PA program
- 371,583 members with any eligibility
- 786,129 members not continuously enrolled for 6 months
- 114,169 members not continuously enrolled for 6 months
- 257,414 members continuously enrolled August 1, 2010, through January 31, 2011
- 807,801 members continuously enrolled August 1, 2010, through January 31, 2011
- 257,394 members without a dalfampridine claim

**Legend**
- PA = prior authorization.
difference in monthly claims utilization using the linear regression slope trend test, which is a better overall measure of differences over time, was statistically significantly different at \( P < 0.001 \) (Figure 1). The slopes of the trend lines were not statistically significantly different (\( P = 0.841 \)) between the intervention and comparison populations.

**Discussion**

In December 2010, a U.S. managed care expert consensus panel recommended managing patient access to dalfampridine with PAs written according to FDA-approved label indications.\(^{17}\) The panel also recommended that efficacy, safety, and cost be taken into consideration when reviewing dalfampridine for formulary placement.\(^{17}\) Our study suggests that the PA program is potentially improving member safety, since seizure history and renal function were assessed prior to approval. Approximately 7 of 100,000 members sought insurance coverage over 3 months during August 2010 through October 2010. Of these members, 1 in 15 seeking a dalfampridine PA was denied coverage due to renal impairment, and in 1 of 7 did not meet the baseline walking ability required in the FDA approval studies, reducing exposure to dalfampridine and associated adverse event risk. It is unknown how many members failing the baseline walking ability were ambulatory. A payor may elect to require a patient be ambulatory rather than the timed requirement.

Dalfampridine was approved based on the results of 2 controlled trials with 504 MS patients.\(^{15}\) A responder was defined as a patient who demonstrated faster walking times 3 out of 4 visits as measured by a timed 25-foot walk test. A significantly greater number of patients taking dalfampridine were responders compared with placebo (30%-40% vs. 8%-9%). While the results were statistically significant, it is important to consider the clinical significance of dalfampridine treatment and the financial impact on patients and health insurers. In 2009, the average per person per year cost of treating MS was $37,592, of which 56.8% was pharmacy costs.\(^{18}\) Pharmacy costs, in an already high-cost disease, will continue to increase with additional add-on therapies such as dalfampridine. Dalfampridine provides symptomatic management for walking in MS and does not modify disease progression or prevent relapses. In our study, the comparison group had a 50% coinsurance, resulting in a significantly higher cost share per 30-day supply; yet, the average dalfampridine claims per member over 6 months was significantly lower in the PA intervention group, suggesting that a benefit design was not as effective as the PA program in ensuring that individuals at minimal risk for adverse events who met clinical criteria are utilizing dalfampridine. A PA program can help the plan engage in drug safety and appropriate use review for its members. Without PA programs, insurers may experience inappropriate allocation of care resources and costs. The downstream effect could result in avoidable pharmacy and/or medical costs and limit a plan’s ability to promote access to safe and affordable care.

Over an almost 6-month period, the dalfampridine PA program resulted in a $0.03 PMPM dalfampridine savings. The 2-phase dalfampridine PA program appears to be effective in reducing potentially unsafe dalfampridine use and reducing dalfampridine costs. The dalfampridine PA program also appears to have an overall significant decrease in utilization of approximately 2.5 claims per 100,000 members per month over the 17-month time period, or 50% lower than the comparison population.

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### TABLE 1

<table>
<thead>
<tr>
<th>Patients Characteristics, Medication Costs, and Total Health Care Costs</th>
<th>Intervention Group, ( n = 60 )</th>
<th>Comparison Group, ( n = 20 )</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean [standard deviation]</td>
<td>50 [9.9]</td>
<td>50 [8.9]</td>
<td>0.947</td>
</tr>
<tr>
<td>Females, % (n)</td>
<td>70.0 (42)</td>
<td>80.0 (16)</td>
<td>0.386</td>
</tr>
<tr>
<td>Dalfampridine supply in pre-120 days, % (n)</td>
<td>58.3 (35)</td>
<td>50.0 (10)</td>
<td>0.515</td>
</tr>
<tr>
<td>Disease-modifying agent supply pre-120 days, % (n)</td>
<td>56.7 (34)</td>
<td>65.0 (13)</td>
<td>0.512</td>
</tr>
<tr>
<td>Average member cost share on index dalfampridine claim, mean [standard deviation]</td>
<td>$138 [$273]</td>
<td>$667 [$460]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration of follow-up in days, mean [standard deviation]</td>
<td>157 [18.5]</td>
<td>157 [21.9]</td>
<td>0.979</td>
</tr>
</tbody>
</table>

\(^{1}\) Drug supply found within 120 days prior to index dalfampridine claim.

\(^{2}\) Disease-modifying agents included glatiramer, interferon beta, or natalizumab.

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### TABLE 2

<table>
<thead>
<tr>
<th>Dalfampridine Claims from an Individual’s Index Dalfampridine Claim Date(^{4}) through January 31, 2011</th>
<th>Weighted Dalfampridine Claims(^{b})</th>
<th>Intervention Group ( n = 60 )</th>
<th>Comparison Group ( n = 20 )</th>
<th>( P ) Value(^{4})</th>
</tr>
</thead>
<tbody>
<tr>
<td>0(^{d})</td>
<td>25.0% (15)</td>
<td>0</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>15.0% (9)</td>
<td>15.0% (3)</td>
<td>0.017</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>26.7% (16)</td>
<td>10.0% (2)</td>
<td>0.214</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>5.0% (3)</td>
<td>15.0% (3)</td>
<td>0.162</td>
<td></td>
</tr>
<tr>
<td>&gt; 3</td>
<td>28.3% (17)</td>
<td>60.0% (12)</td>
<td>0.016</td>
<td></td>
</tr>
</tbody>
</table>

\(^{4}\) Claim date established during August 1 to October 31, 2010.

\(^{b}\) Weighted claims means were normalized to 30-day supplies, for example, a claim with a 90-day supply was counted as 3 claims.

\(^{4}\) Fischer’s exact test.

\(^{d}\) 0 claims indicates initial claim coverage denied with no subsequent paid claims.
Drugs indicated to treat disability or improve physical function may be difficult to assess for efficacy. Dalfampridine clinical trials utilized a 25-foot walk test as an efficacy endpoint. The PA program in this study used this endpoint to assess responders to therapy. However, a change in the 25-foot walk may not capture all the meaningful improvements in a responding patient. Additionally, physical decline in a progressive disease may make continued improvement in the walk unobtainable, even in responders. Care management, provided via a specialty channel or health plan, may better assess efficacy via consultations with the patient and/or provider on improved mobility, ability to work, and ease of activities of daily living. Use of both a PA and care management may be optimal in selecting appropriate users and ensuring ongoing safety and efficacy during chronic therapy.

Limitations
The current study has limitations worth noting. First, pharmacy claims data do not necessarily capture samples dispensed or cash payment for dalfampridine therapy that could result in the study overestimating the prevalence of individuals not utilizing dalfampridine. Second, the study compared 2 commercially insured populations without randomization. The population characteristics were similar at baseline and duration of follow-up; however, claims analyses are limited in their ability to account for many possible differences among individuals. Third, data are limited to commercial populations in the central and southeastern regions of the United States and therefore may not be generalized to Medicare or Medicaid populations or commercially insured individuals in other geographic areas. Fourth, PA administrative costs, including those incurred by the health plan, PBM, providers, and pharmacists, were not measured. Fifth, the dalfampridine PA criteria included the requirement for a concomitant DMA where clinically indicated, which affected 1 member. The PA criteria used in the current analysis was inconsistent with the dalfampridine approval trials. In the clinical trials, only 63% of patients were using DMAs, and the magnitude of the
Dalfampridine effect was independent of their use. Sixth, all cost avoidance estimates are speculative. We used WAC for cost avoidance estimates because total paid (member plus plan paid) would be unique for each plan based on proprietary pharmacy network discounts and potential pharmaceutical manufacturer rebates. A plan should use its own data to calculate its savings. Seventh, the intervention and comparison groups had very different average dalfampridine index claim member cost shares. Despite this difference, which would disadvantage any cost-avoidance estimate by potentially deterring the comparison group from filling dalfampridine claims, our study found a difference in utilization of dalfampridine. Lastly, coupons or other drug manufacturer incentives could have reduced dalfampridine costs and increased utilization. We are unable to control for market forces, such as coupons; however, we believe these market forces to be equally influential in the two groups.

Conclusions

Despite the limitations just mentioned, our study findings support the use of a dalfampridine PA program to help ensure safe prescribing as evidenced by the renal impairment risk avoidance and investigational use in those members failing to meet baseline walking ability. The dalfampridine PA program was associated with an overall significant dalfampridine utilization decrease of 2.5 fewer claims per 100,000 members per month over the 17-month period. Our analysis also suggests that over the more than 5-month analysis period, a dalfampridine cost savings of $0.03 PMPM was realized as a result of the dalfampridine PA program. Future research assessing a PA program should incorporate an evaluation of actual medical outcomes and avoided costs, which include total costs of care and administration costs of running a PA program.

DISCLOSURES

This study was performed without external funding, and the authors report no financial or other potential conflicts of interest related to the subject of this article. At the time of the study and writing of the article, Gleason, Starner, and Phillips were employed by Prime Therapeutics LLC, a pharmacy benefit manager company, and Fenrick and Delgado-Riley were employed by Florida Blue, a health insurer. Concept and design were contributed primarily by Gleason and Phillips, with input from Starner, Fenrick, and Delgado-Riley. Gleason, Fenrick, and Delgado-Riley had primary responsibility for data collection, with assistance from Phillips and Walters; data interpretation was the work of Gleason and Phillips, with input from Starner and Qui. The manuscript was primarily written by Starner and Gleason, with assistance from Delgado-Riley; its revision was primarily the work of Starner and Gleason, with assistance from all the authors.

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REFERENCES


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