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The Impact of Discontinuing Coverage of Second Generation Antihistamines in A Managed Care Organization

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THE IMPACT OF DISCONTINUING COVERAGE OF SECOND GENERATION ANTIHISTAMINES IN A MANAGED CARE ORGANIZATION

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The Impact of Discontinuing Coverage of Second Generation Antihistamines in a Managed Care Organization

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ABSTRACT

Background: Second generation antihistamines (SGAs) are approved to treat seasonal and/or perennial allergic rhinitis (AR) and chronic idiopathic urticaria (CIU). It is estimated that 82% of Americans with AR use antihistamines, with the majority using SGAs due to their low side effect profile. As policy, over-the-counter (OTC) SGAs were not covered in this health plan population (cetirizine and loratadine products were available OTC prior to the study period, while fexofenadine products became available OTC during the study period). On January 1, 2012, the policy was extended to remove coverage of prescription-only SGAs (included desloratadine and levocetirizine products).

Objectives: To assess the utilization of SGAs and SGA alternatives and to assess the rate of product switching associated with coverage changes.

Methods: Pharmacy claim data from January 1, 2010 to October 31, 2012 were analyzed using the Truven Health Advantage Suite® system. Study participants had to be continuously enrolled, ≥18 years, and have received ≥1 prescription for a desloratadine, fexofenadine, or levocetirizine product during the study period. Three reference periods were evaluated to assess utilization patterns: (1) a period during which desloratadine, fexofenadine, and levocetirizine were covered; (2) a desloratadine and levocetirizine prescription-only coverage period during which fexofenadine OTC was introduced to the market; and (3) an SGA non-coverage period. Product switching was determined by having at least one new fill for a covered SGA or SGA alternative after a coverage change.

Results: 84.6% of health plan participants taking SGAs did not switch to a prescription SGA alternative following SGA coverage discontinuation. For those who did switch, the most common therapeutic class switched to was intranasal corticosteroids (54%), which is the recommended first-line therapy for AR. More than half of the members who switched to a prescription SGA alternative were not persistent in filling the new

medication, which could suggest that those members purchased an OTC SGA or left their condition untreated.

Conclusion: The policy decision to discontinue coverage of SGAs was not associated with seeking a prescription alternative by the majority of plan members. With the potential for more medications to go OTC, this observational study illustrates that managed care organizations can efficiently manage drug costs for a fixed population by reserving scarce plan resources through appropriate benefit design management.

Keywords: antihistamines, product switching, coverage, utilization, OTC medications

What is already known about this subject

- For the treatment of allergic rhinitis, prescription and over-the-counter (OTC) products exist as options for the 58 million Americans impacted by the upper respiratory condition, including second generation antihistamines (SGAs).
- Intranasal corticosteroids have shown greater efficacy in trials, but SGAs continue to be the most heavily utilized therapeutic class.
- The decision not to cover prescription products within a therapeutic class that has OTC products and the opportunity costs associated with such a decision are of interest to payers and employers within the health insurance industry.

What this study adds

- After drug coverage was removed for SGAs, increases in alternative prescription products were minimal, and the majority of health plan participants either purchased an OTC alternative or left the condition untreated.
- The observed results from this study may be applicable to other health plans and can be used for the decision-making process for plan sponsors.

Disclosure Statement

No funding was received for this study. The authors report no conflict of interest regarding this study.

BACKGROUND

Second generation antihistamines (SGAs) are approved to treat seasonal and/or perennial allergic rhinitis (AR) and chronic idiopathic urticaria (CIU).[1] AR affects about 58 million Americans, which represents approximately 20% of the population.[2] Symptoms of AR include rhinorrhea, nasal obstruction, sneezing, and nasal itching.[3]

While the complications of AR are not life-threatening, the condition, if left untreated, is associated with impaired quality of life, decreased work performance, and the potential to exacerbate other conditions such as sleep apnea, otitis media, chronic sinusitis, and asthma.[4]

It is estimated that 82% of Americans with AR use antihistamines, with the majority using SGAs due to their low side effect profile compared to the first generation antihistamines, which are associated with increased sedation.[5] Other therapeutic classes and medications indicated for AR include: intranasal antihistamines, intranasal corticosteroids, leukotriene pathway inhibitors, and ipratropium nasal solution.[6,7] Intranasal corticosteroids are recommended over the other therapeutic classes that treat AR due to their higher efficacy in clinical trials, but many patients prefer the oral versus the intranasal route of administration for their medications, which is why SGAs are more commonly used.[8]

As policy, over-the-counter (OTC) SGAs were not covered in this health plan population (cetirizine and loratadine products were available OTC prior to the study period, while fexofenadine products became available OTC during the study period). The decision not to cover prescription products within a therapeutic class that has OTC products and the opportunity costs associated with such a decision are of interest to employers and payers within the health insurance industry.[9,10] The potential for higher costs in drug spending exists if members are unwilling to purchase the OTC options out-of-pocket and decide instead to seek brand-name prescription products in a different therapeutic class. A 2004 North Carolina (NC) Medicaid study focused on the utilization changes when loratadine (Claritin®) became available OTC and was no longer covered in their population. It appeared that NC Medicaid recipients were 2.16 times more likely to switch to a prescription-only SGA rather than use OTC loratadine.[11] While these results would indicate increased costs to plan sponsors that implemented a similar policy, the landscape of allergic rhinitis medications has changed since the study on NC Medicaid recipients results.

With the majority of SGAs available as OTC products in 2011, the policy was extended to remove coverage of prescription-only SGAs (included desloratadine and levocetirizine products) on January 1, 2012. This policy decision left health plan

participants who had been taking SGAs with three main options: purchase an OTC SGA, such as loratadine, fexofenadine (Allegra®), or cetirizine (Zyrtec®); obtain a prescription for an alternative medication, such as fluticasone propionate (Flonase®), mometasone (Nasonex®) or montelukast (Singulair®); or leave their condition untreated. The purpose of this study was to assess the utilization of SGAs and SGA alternatives and to assess the rate of product switching associated with the coverage changes.

METHODS

Study Design

Pharmacy claim data from January 1, 2010 to October 31, 2012 were analyzed using the Truven Health Advantage Suite® system. Three reference periods were evaluated to assess utilization patterns: (1) a period during which desloratadine, fexofenadine, and levocetirizine were covered, (2) a desloratadine and levocetirizine Rx-only coverage period during which fexofenadine OTC was introduced to the market, and (3) an SGA non-coverage period.

[Insert Table 1 here]

Patient Population

Study participants had to be continuously enrolled in the managed care organization and at least 18 years old. Subjects must have received ≥1 prescription for a desloratadine, fexofenadine, or levocetirizine product during the study period.

Product Switching

Product switching was determined by having at least one new fill for a covered SGA or SGA alternative (Appendix A) following the coverage change. Switches to an SGA alternative within the same therapeutic class were not counted as a switch. For example, if a health plan participant had one fill for mometasone before the coverage change then had a fill for fluticasone propionate afterwards, this would not equal a switch. The rate of product switching was calculated as the number of members who switched per total number of users for the individual SGA users and total SGA users. In order to determine the extent to which demographics were associated with medication switching, chi-square and independent samples t-tests were run on gender and age, respectively.

Fexofenadine switch determination:

Subjects must have had ≥1 fill for a fexofenadine product during the study period and ≥1 new fill for desloratadine, levocetirizine, or SGA alternative following discontinuation of fexofenadine coverage in order to be classified as a fexofenadine switch user.

Desloratadine or levocetirizine switch determination:

Subjects must have had ≥1 fill for a desloratadine or levocetirizine product during the study period and ≥1 fill for a new SGA alternative in 2012 in order to be classified as a desloratadine or levocetirizine switch user.

[Insert Table 2 here]

RESULTS

During the study period, a total of 1,549 unique participants utilized fexofenadine, desloratadine, and/or levocetirizine products. Only 15.4% of the study population had at least one fill for a new medication after discontinuation of coverage (Table 2), while 6.8% of subjects were persistent in either filling the switched-to product or filling for a medication within the same therapeutic class of the switched-to product.

[Insert Table 3 here]

54 study participants had fills for more than one of the SGAs. Of the 12% of fexofenadine users that switched to desloratadine or levocetirizine, only 8% then switched to a prescription SGA alternative in 2012.

The most common therapeutic class switched to was intranasal corticosteroids (54%), followed by intranasal antihistamines (15%). A few switch users had the same fill date for medications from separate therapeutic classes. Thus, they were classified as combination therapy in Figure 1.

[Insert Figure 1 here]

There was increased utilization of intranasal corticosteroids (10.3%) between the second quarters of 2010 and 2012, while the study population only grew by 8.3%. Annual utilization of intranasal antihistamines and leukotriene pathway inhibitors stayed relatively constant throughout the study period (Figure 2).

[Insert Figure 2 here]

No significant difference in switching rate was observed between genders, X^2 (1, n = 1,818) = .091, p = .763. Given that no violation of Levene's Test for Homogeneity was detected, a *t*-test assuming equal variances was run; no significant difference in age was observed between the two groups either, t (1,818) = -.835, p = .404. From these tests we inferred that gender and age did not influence medication switching behavior.

DISCUSSION

The majority of study participants (84.6%) taking SGAs did not switch to a prescription SGA alternative following SGA coverage discontinuation. Furthermore, over half of the members who switched to a prescription SGA alternative were not persistent in filling the new medication, which could suggest that those health plan participants purchased an OTC SGA or left their condition untreated.

For participants that bought OTC products after the policy change, there may be a slight increase or decrease in medication cost shifting depending on the OTC product selected and previous prescription SGA utilized. However, there is significant savings by eliminating the need for a patient to go to a doctor's office for a new prescription. Thus, both the health plan and its members should see cost savings (unless the health plan participant decided to leave the condition untreated). For those who switched to prescription products, the medication cost would be the same or a little less (sometimes inhalers last more than 30 days) because the same generic copayment would apply in most cases. Additionally, health plan participants may have experienced a reduced impact of allergies because the majority switched to the prescriber-preferred therapeutic class for allergic rhinitis (inhaled corticosteroids).

The choice to switch to particular medication within a therapeutic class is often correlated with the formulary status and the generic availability of the individual drug. If a medication is not on the formulary, the health plan participant is less likely to utilize that medication versus one that is on the formulary due to the increase in cost share.[12] The formulary status can explain why the top three medications switched to were fluticasone propionate (generic), mometasone (formulary brand), and montelukast (formulary brand).

Limitations

Due to the retrospective nature of the observational study, it is impossible to be certain if the SGA policy change caused a switch. A member could have coincidentally stopped an SGA and started an alternative around the time of the policy change for a variety of reasons, such as ineffectiveness in treating symptoms. Had this occurred, it could have inflated the product switch rate. Another potential source of switch rate inflation is that many of the SGA alternatives are also used to treat concomitant conditions that AR patients are likely to experience, such as asthma.[8] The persistence to an SGA prior to the switch was not evaluated partly because of the seasonal nature of AR, but mainly in order to not eliminate any health plan participants that may have been impacted by the discontinuation of coverage. Thus, it is possible that a member with only one fill for an SGA was counted as a product switcher. This happened in rare instances but the reasoning behind a switch would be difficult to determine without contacting the health plan participant or prescriber.

Another limitation is that medical claims were not utilized to determine the diagnoses of the health plan participants. There is the potential for members to be taking SGAs for chronic idiopathic urticaria, but the prevalence of this condition in the general population is low at only 1%.[13] The major downside of not using medical claims is that all of the SGA alternatives are approved for conditions other than AR, such as asthma, which could significantly increase the switch rate. An increase in switch rate could be observed if a health plan participant was prescribed an intranasal corticosteroid for asthma after the policy change even though the participant began purchasing an OTC SGA for the treatment of AR.

It should be noted that different fexofenadine products went OTC at different times between March-August 2011, which could influence the therapeutic class switched to after the benefit change. For example, if a member received a 90-day supply of fexofenadine plus pseudoephedrine in August 2011, it is highly unlikely the member would receive a prescription for one of the remaining prescription SGA products before January 1, 2012.

The financial impact of the discontinuation of SGA coverage was not assessed because it was not possible to determine the rate of absenteeism and presenteeism in the

health plan population before, during and after the study period. In the United States, approximately 4 million days of lost productivity at work and school are due to AR each year.[6] Because 84.6% of subjects did not have any claims for SGA alternatives, the potential that some members left their AR untreated exists, which would negate the money saved for the managed care health plan population.

CONCLUSION

The policy decision to discontinue coverage of second generation antihistamines was not associated with seeking a prescription alternative by the majority of plan members. Organizations within the health insurance industry can utilize the findings of this study when considering coverage of over-the-counter (OTC) medications, taking into account the limitations noted. With the potential for more medications to go OTC, this observational study illustrates that managed care organizations can efficiently manage drug costs for a fixed population by reserving scarce plan resources through appropriate benefit design management.

This study contributes to the overall value to public health by highlighting how people can be responsible for their own health management. One of the intentions of health care reform is to empower the population to be educated health care consumers. Rather than depending on a prescription from a health care provider, a patient can determine which OTC product will be the most cost-effective option to treat their condition. This process can be assisted with (or without) the help of the pharmacist on duty at no cost to the patient. Additionally, those health plan participants impacted by the policy that switched to intranasal corticosteroids may have improved control over their symptoms, which would reduce the absenteeism/presenteeism for the managed care organization's population.

TABLES AND FIGURES

Table 1. Demographics

Characteristic	SGA users (*n*=1,549)
Age (years)	42.2
Female (%)	63.8

Table 2. SGA Alternatives

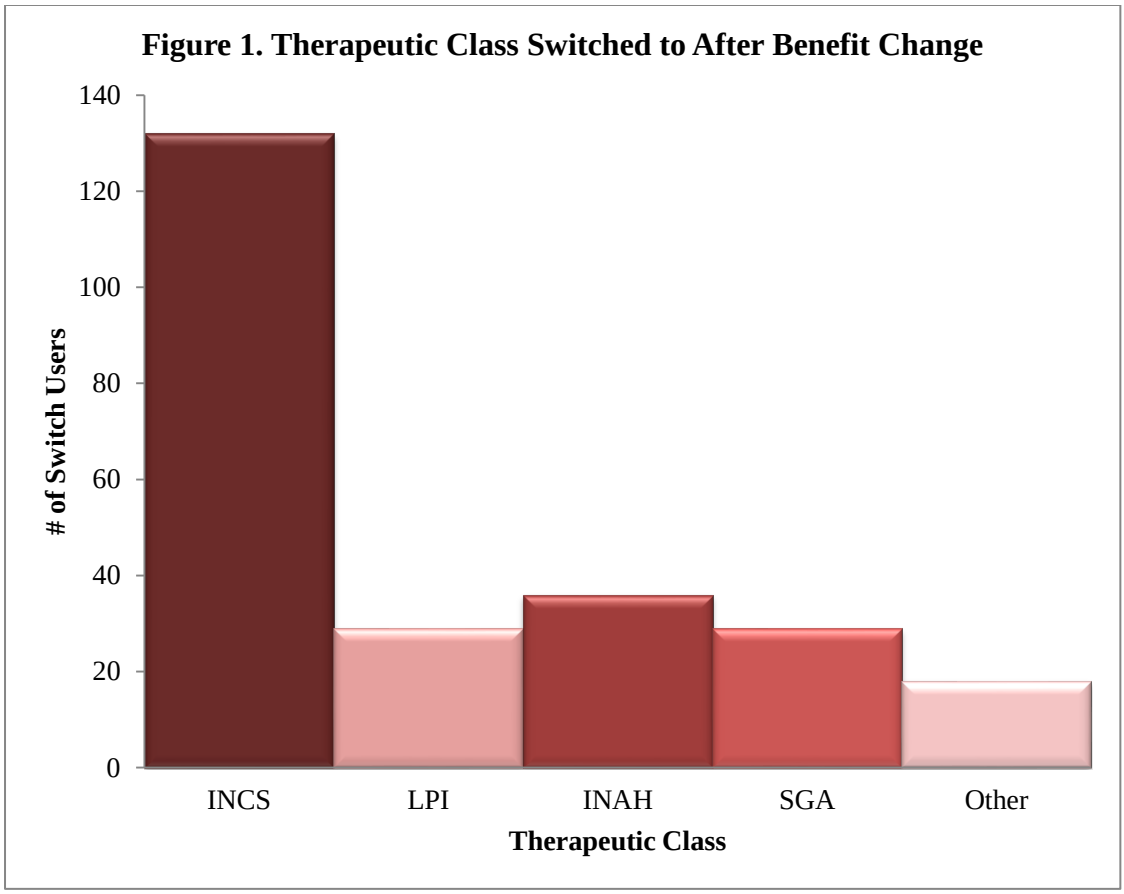
Medication Class	Generic Name
Intranasal Corticosteroids	beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone propionate, fluticasone furoate, mometasone, triamcinolone
Leukotriene Pathway Inhibitors	montelukast, zafirlukast
Intranasal Antihistamines	azelastine, olopatadine
Other	ipratropium nasal solution

Table 3. Medication Switch Rates After Benefit Change

Second Generation Antihistamine (*n*)	≥ 1 Fill for Alternative	≥ 2 Fills for Alternative
Desloratadine (79)	11.4%	6.3%
Fexofenadine (1,392)	15.9%	6.8%
Levocetirizine (135)	10.4%	4.4%
Total Unique Users (1,549)*	**15.4%**	**6.8%**

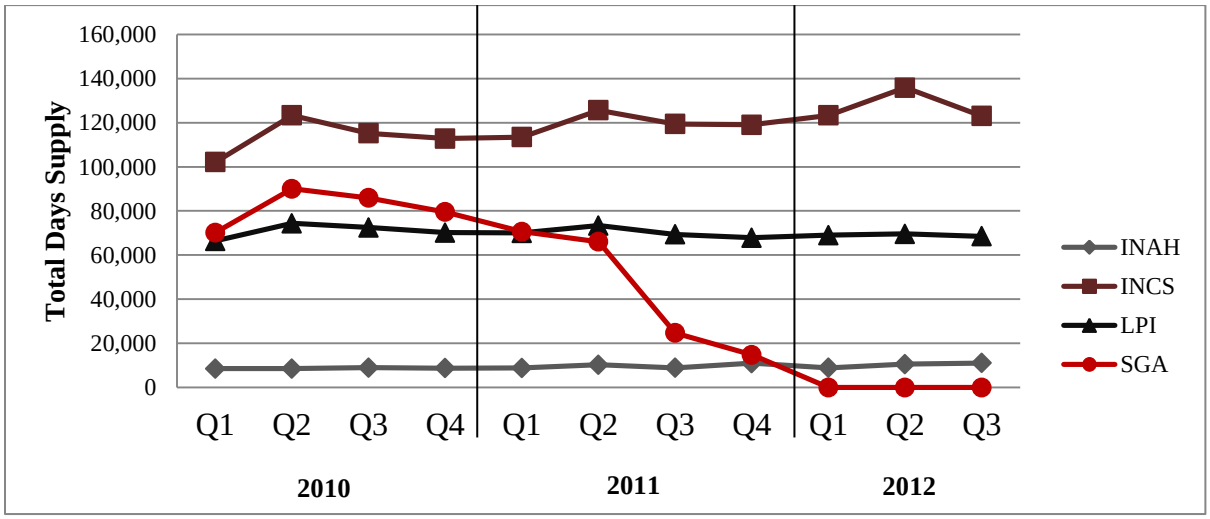
***54 users were noted as having used two or more SGAs

Figure 1. Therapeutic Class Switched to After Benefit Change



INAH = Intranasal antihistamines
INCS = Intranasal corticosteroids
LPI = Leukotriene pathway inhibitors
SGA = Second generation antihistamines
Other = Combination therapy or ipratropium nasal solution

Figure 2. Quarterly Utilization Patterns of SGAs and SGA Alternatives



Appendix A -

Two variables were used: (1) Generic names (Red Book description of the generic product); and Adjustment Type Medstat = non-adjusted (Medstat Advantage Suite standard description for the type of adjustment for the claim)

- **Second Generation Antihistamines (SGAs):**
  - Desloratadine
  - Desloratadine/Pseudoephedrine Sulfate
  - Fexofenadine HCl/PSE HCl
  - Fexofenadine hydrochloride
  - Levocetirizine dihydrochloride

- **SGA replacements:**
  - Azelastine Hydrochloride
  - Azelastine Hydrochloride/Fluticasone Propionate
  - Beclomethasone Dipropionate
  - Beclomethasone Dipropionate Monohydrate
  - Beclomethasone Dipropionate, Micronized
  - Ciclesonide
  - Flunisolide
  - Flunisolide, Micronized
  - Fluticasone Furoate
  - Fluticasone Propionate
  - Ipratropium Bromide
  - Mometasone Furoate
  - Montelukast Sodium
  - Olopatadine Hydrochloride
  - Triamcinolone
  - Triamcinolone, Micronized
  - Zafirlukast
  - Zileuton
  - Budesonide/Formoterol Fumarate

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