

Improving Adherence To Seasonal Allergic Rhinitis (SAR) Practice Guidelines: Budget Impact Analysis for an Intranasal Formulation of Azelastine Hydrochloride and Fluticasone Propionate (Dymista) for U.S. Health Plans

Brooke Harrow, PhD¹; Jeffrey Hofmeister¹; Michael J. Lacey²; Cara M. Scheibling²; & John E. Schneider²

¹Meda Pharmaceuticals, Inc., Somerset, NJ; ²Avalon Health Economics, Morristown, NJ

Abstract

Background: Allergic rhinitis (AR) affects 10–20% of the US population, with treatment costs exceeding \$6 billion annually. US practice guidelines suggest treatment with a combination of intranasal corticosteroids and antihistamines. Dymista™ (azelastine HCl 137 µg/fluticasone propionate 50 µg per spray) is an intranasal formulation of azelastine hydrochloride and fluticasone propionate (AZ/FP) in an advanced delivery system indicated for the relief of symptoms of seasonal AR (SAR). Patients treated with AZ/FP experience significantly greater symptom relief in comparison to first-line therapy in trials.

Objective: To use an economic model to calculate the per-member per-month (PMPM) budget impact on a US health insurer of moving AZ/FP from third-tier to second-tier pricing and reimbursement.

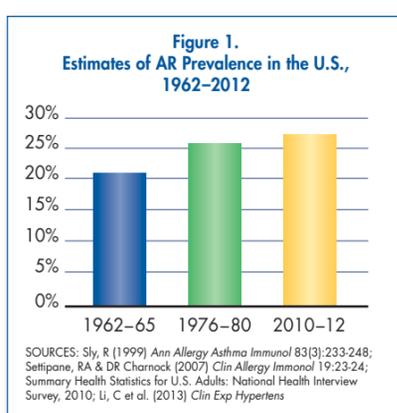
Methods: Population is SAR sufferers seeking treatment. AZ/FP is assumed to gain market share annually with second-tier pricing. Time horizon is one year and five years. Perspective is a US health plan with 500,000 enrollees. BIA is a pharmacy cost impact model using data from literature and supplied by Meda. Model assumes 10% branded drug price inflation; 80% brand to generic share shift and 50% price reduction; tiered payer rebate percentages and patient copay amounts.

Results: Estimated treated SAR population ranged from 63,165 at baseline to 68,630 in Year 5. Branded share of fluticasone-based products declined from 17% to 7%. Overall SAR treatment budget declined from \$3.2 million annually at baseline to \$3.1 million in Year 5 reflecting expected shift from branded to generic market share. According to baseline assumptions, marginal change in costs over the one-year time horizon from moving AZ/FP from third-tier to second-tier pricing are \$19,659 (<\$0.01 PMPM). Costs associated with the 5-year horizon, given changes in market shares, are \$97,342 (\$0.01 PMPM).

Conclusions: AZ/FP offers an appropriate means of adhering to AR practice guidelines and improving outcomes, and this BIA model shows that the added costs of those benefits are minimal to US payers.

Background

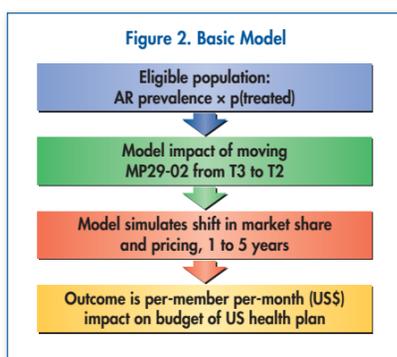
- Allergic rhinitis (AR) affects 10–27% of the US population, with treatment costs in excess of \$6 billion annually.
- AR has been shown to be associated with asthma, upper respiratory infection, and sleep disorders, and has been shown to have a substantial impact on productivity.
- AZ/FP is a novel intranasal formulation of azelastine hydrochloride and fluticasone propionate in an advanced delivery system for the treatment of AR, indicated for the relief of symptoms of seasonal AR (SAR) in patients ≥12 years of age requiring treatment with both azelastine hydrochloride and fluticasone propionate.
- AZ/FP has been studied in comparison to first-line therapies in SAR patients in direct head-to-head trials. Patients treated with AZ/FP experience significantly greater symptom relief.



Methods

Overview

- Population size:** SAR sufferers seeking treatment.
- Technology mix:** AZ/FP is assumed to gain market share annually with second-tier pricing.
- Time horizon:** one year and five years (considering patent expiry of other treatments on market).
- Perspective & target audience:** U.S. health plan with 500,000 enrollees.
- Model description:** Budget impact model is a pharmacy cost impact model, built in Excel following ISPOR guidelines.
- Input data:** parameters included 7% branded drug price inflation, 80% brand to generic share shift and 50% price reduction. Other variables included tiered payer rebate percentages and patient copay amounts. Sensitivity analyses were performed.



	Baseline Data	YEAR					
		0	1	2	3	4	5
Total Population ^a	500,000	500,000	508,367	516,874	525,523	534,317	543,258
Proportion age ^b ≥12	84.22%	421,100	428,147	435,311	442,596	450,002	457,532
Prevalence of Treated AR ^c	15%	63,165	64,222	65,297	66,389	67,500	68,630
Est. Eligible Population		63,165	64,222	65,297	66,389	67,500	68,630

^a Projected US population growth rate—2010–2012=1.7%. SOURCE: U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2012. Internet release date: December 2013.

^b U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2012. Internet release date: December 2013.

^c Bernstein JA. Allergic and mixed rhinitis: Epidemiology and natural history. *Allergy Asthma Proc* 2010;31:365-369; Tran NP, Vickery J, Blaiss MS. Management of rhinitis: Allergic and non-allergic. *Allergy Asthma Immunol Res* 2011;3(3):148-156; Small P, Kim H. Allergic rhinitis. *Allergy Asthma Immunol Res* 2011;7(suppl 1):S3-S10.

Market Dynamics

- Mometasone furoate goes generic in year 2. Branded mometasone furoate share drops 80% in year 2 (12.8% to 2.6%).
- Generic mometasone furoate enters market at 50% price discount to Nasonex.
- AZ/FP takes share equally from other branded products and generic fluticasone.

	AZ/FP Remains at Tier 3	AZ/FP Improves to Tier 2
2014	1%	2%
2015	1.1%	3%
2016	1.2%	4%
2017	1.3%	5%
2018	1.4%	5%

Other Model Assumptions

- Mean usage of SAR products:** 1.7 bottles per patient per year for all products based on unpublished market research data.
- Branded product prices** are assumed to increase 7% annually based on branded AR price change from 2013–2014.
- Budget impacts** expressed as net present value (NPV) using a 5% discount rate for years 1–5.
- Net Cost to Payer** = Payment to Pharmacy—Manufacturer Rebate (10–20% of Wholesale Acquisition Cost, WAC) + Prior Authorization Costs (~50% of T3 Rx only).

Conclusions

- AZ/FP offers an appropriate means of adhering to AR practice guidelines and improving outcomes, and the budget impact model shows that the added costs of those benefits are minimal.
- The marginal change in overall health plan costs in 2015 from moving AZ/FP from third-tier to second-tier pricing is a \$17,593 in budget reduction (i.e., savings).
- Overall total costs associated with the 5-year horizon from moving AZ/FP from third-tier to second-tier pricing are \$51,682, which translates to only \$0.01 PMPM.
- As a supplement to the basic pharmacy cost model, a model of productivity effects shows that moving AZ/FP from Tier 3 to Tier 2 resulted in a marginal reduction of 4,729 AR-symptomatic days annually and total indirect cost savings ranging from \$168,838 in year 1 to \$190,937 in year 5.

Results

- For a typical health plan with 500,000 members, the estimated treated SAR population ranged from 63,165 in 2014 to 68,630 in Year 2018 due to expected annual increase (1.7% per year) in population growth.
- Overall SAR treatment budget was generally flat, decreasing from \$1.3 million in 2014 to \$1.2 million in 2018.
- According to status quo assumptions, marginal change in overall costs in 2015 from moving AZ/FP from third-tier to second-tier pricing are (\$17,593) (Savings).
- Overall costs associated with the 5-year horizon from moving AZ/FP from third-tier to second-tier pricing are \$51,682 (\$0.01 PMPM).

	YEAR				
	2014	2015	2016	2017	2018
Overall Budget					
Status Quo	\$1,345,670	\$1,004,828	\$1,069,955	\$1,137,990	\$1,209,052
AZ/FP Tier 3 to Tier 2	\$1,328,077	\$1,013,034	\$1,101,547	\$1,198,011	\$1,260,733
NET TOTAL IMPACT	\$(17,593)	\$8,207	\$31,592	\$60,021	\$51,682
Per-Member Per Month					
Status Quo	\$0.22	\$0.16	\$0.17	\$0.18	\$0.19
AZ/FP Tier 3 to Tier 2	\$0.22	\$0.17	\$0.18	\$0.19	\$0.20
NET PMPM IMPACT	\$(0.00)	\$0.00	\$0.01	\$0.01	\$0.01

Sensitivity Analysis

Approach

- Market factors:**
 - Treated prevalence
 - Branded product price inflation
 - Discount rate
- AZ/FP factors:**
 - Share growth rate
 - AZ/FP rebate to payers (% of WAC)
- Model:**
 - Parameters of “status quo”
- Vary ±20%** from initial assumptions
- Primary outcome** = net budget impact in year 2016 (midpoint) of the model time horizon

Results

- The model is very robust and relatively insensitive to changes in key baseline assumptions and variables
- The variables that matter the most in the model are:
 - AZ/FP rebate to payers
 - AZ/FP share growth over time
 - Price inflation among branded comparators
 - Treated prevalence
 - Discount rate (% of AWP)

Supplemental Analysis: PRODUCTIVITY EFFECTS

Background

- AR has been shown in studies to have an impact on productivity
 - Work loss days (absenteeism; presenteeism)
 - School loss days
- For example, Nathan (2007) found that in the U.S., AR results in 3.5 million lost work days and 2 million lost school days annually

Approach

- Estimate total number of AR-related symptomatic days per patient:
 - Total number of AR-related episodes per year multiplied by the number of days per AR episode
 - The number of these days that occur during a standard 5 day work week
 - Proportion of week days = 68%—(5*52)/365
 - The proportion of AR symptomatic days resulting in absenteeism or presenteeism from the literature

Productivity Analysis: Value of Reduced AR Symptomatic Days due to AZ/FP

- The number of reduced AR-symptomatic days due to AZ/FP is based on reduced time to symptom relief observed in clinical studies.
- Time to symptom relief is reduced 2 days or 15% per episode (2 days/14 days per episode)
- AR symptomatic days among AZ/FP patients reduced from 77 to 66 days per year.
- Calculate the net change in AR-symptomatic days, work loss and presenteeism days annually per AZ/FP patient.
- Economic value of work-loss estimated based on US National average daily wages, benefits and expected wage inflation.
- Economic value of presenteeism was estimated at 50% of average daily wage based on the literature.



Productivity Analysis: RESULTS—From Tier 3 to Tier 2

- AZ/FP on formulary as Tier 3 results in a reduction of 4,598 AR-symptomatic days annually.
- Moving AZ/FP from Tier 3 to Tier 2 resulted in an additional reduction of 4,729 AR-symptomatic days annually.
 - Total marginal indirect cost savings ranged from \$168,838 in year 1 to \$190,937 in year 5.
 - Absenteeism costs accounted for 40% and presenteeism accounted for 60% of the value.