Enhancing Value-Based Decision Making: Allergic Rhinitis

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Supplement
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Enhancing Value-Based Decision Making: Allergic Rhinitis

Part I: Evaluating the Efficiency of Treatment in the Allergic Rhinitis Market

Target Audience:
Managed care pharmacists and other health care practitioners

Learning Objectives
Upon completion of this session, the participant will be able to
1. describe the components of a cost-effectiveness analysis and a cost-efficiency frontier;
2. identify key issues and items that make allergic rhinitis a significant burden on managed care organizations, patients, and society;
3. describe the most highly prescribed medications within the 3 classes of products approved for treatment of allergic rhinitis, compare efficacy, and cite guidelines that support their use; and
4. illustrate the cost-efficiency frontier for allergic rhinitis and determine the most cost-efficient class of medications (and individual products) for treatment.

Part II: Cost Efficiency of Intranasal Corticosteroid Prescribing Patterns in the Management of Allergic Rhinitis

Target Audience:
Managed care pharmacists and other health care practitioners

Learning Objectives
Upon completion of this session, the participant will be able to
1. describe the IMS NDTI database,
2. define the mean prescribed sprays per day for the leading INS agents,
3. based on the mean prescribed sprays per day, determine the cost per day for the leading INS agents, and
4. define an economic model that could help determine the most cost-effective INS within any health care setting.
Evaluating the Efficiency of Treatment in the Allergic Rhinitis Market

TODD A. LEE, PharmD, PhD; CHRISTINE H. DIVERS, PhD, MS; and CHRISTOPHER W. LEIBMAN, PharmD, MS

ABSTRACT

BACKGROUND: In the present era of increasing health care expenditures, economic comparisons of therapeutic products play an important role in ensuring that limited health care resources are used appropriately.

OBJECTIVE: To provide a model for the comparative analysis of alternative treatments, in terms of both cost and efficacy, in allergic rhinitis that will provide decision makers in a managed care environment an additional tool to help maximize health care benefit per dollar spent. We also review current treatments in the allergic rhinitis market and their impact on cost, availability, and utilization.

SUMMARY: Efficacy estimates were derived from published reviews, meta-analyses, and guidelines, and cost data are based on average wholesale prices. Our results indicate that when cost and efficacy data are plotted on a cost-effectiveness plane, the intranasal corticosteroids appear to be the most efficient use of health care resources. Moreover, budesonide aqueous nasal spray was found to be the most efficient treatment for allergic rhinitis when compared with 3 other leading intranasal corticosteroids used at their recommended starting doses, the less-sedating/nonsedating antihistamines, and a leukotriene receptor antagonist.

CONCLUSION: Evaluating products on an efficiency frontier platform, which integrates both the effectiveness and cost of products, will allow health plan decision makers to ensure the appropriate allocation of health care resources.

KEYWORDS: Allergic rhinitis, Intranasal corticosteroids, Antihistamines, Leukotriene receptor antagonists, Cost efficiency

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Health care expenditures have increased dramatically over the last decade, leading to heavy reliance on managed care organizations (MCOs) to make decisions regarding the appropriate allocation of health care resources across an expanding number of health care conditions with an increasing number of treatment options. With prescription treatments encompassing a quickly growing portion of this overall budget, MCOs have developed a new level of scrutiny toward individual treatment regimens and have focused attention on identifying cost-effective treatments (i.e., treatments that provide maximum health benefit per dollar spent).

In an effort to ensure value-based decision making, the Academy of Managed Care Pharmacy has produced guidelines on factors for consideration in making reimbursement policy decisions. Many MCOs request information on the clinical and economic benefit of new medications before making reimbursement decisions. With continued interest in value-based decision making, pharmacoeconomic analyses are often used to help in the establishment of MCO treatment policies. Pharmacoeconomic methods provide tools to compare the value of treatment interventions, with the goal being to identify the most efficient means of expending health care resources.

Identifying efficient treatment options involves incorporating information on both the costs and effects of interventions. We briefly review cost-effectiveness analysis and highlight how it can be used to identify treatments that represent an efficient use of health care resources. We then use the allergic rhinitis (AR) market to apply these concepts to a real-world example.

The Cost-Effectiveness and Cost-Efficiency Frontier

Cost-effectiveness analysis is a form of economic evaluation that provides information on the value of an intervention or therapy in relation to its costs when compared with an alternative. The analysis is intended to compare 2 or more interventions with each other and provide information on the differences in costs and effects between the comparators. The results are summarized in a ratio that provides information on the incremental costs per unit of effect. This ratio is referred to as the incremental cost-effectiveness ratio (ICER) because it is assessing incremental differences between alternative treatments.

Results from a cost-effectiveness analysis comparing, for example, a new treatment with usual care, are often presented on a cost-effectiveness plane (Figure 1). The cost-effectiveness plane is a graphical representation of all possible results of a cost-effectiveness analysis and is divided into 4 quadrants. ICERs falling into the northwest (NW) and southeast (SE) quadrants require no decision to be made. These are quadrants where 1 of the treatments is more effective and less costly, so it dominates the other treatment. In the SE quadrant, the new treatment domi-
Evaluating the Efficiency of Treatment in the Allergic Rhinitis Market

A cost-effectiveness plane of all possible results of a cost-effectiveness analysis divided into 4 quadrants. Differences in effectiveness are represented on the x-axis and differences in costs are represented on the y-axis. TX = treatment.

A hypothetical example of the average cost (average wholesale price) and average effectiveness (as determined from published clinical studies, reviews, and meta-analysis) of 6 interventions. The interventions are labeled A to F and are representative of comparable treatments available for a similar condition. The most cost-effective intervention is treatment B, as it is the line with the smallest incremental cost-effectiveness ratio (lowest slope) when drawing a line from the origin to the placement of the product on the plot.

To represent the ICER on the cost-effectiveness plane, the point estimate of the difference in effects is plotted on the x-axis, and the point estimate of the difference in costs is plotted on the y-axis. A line can be drawn from the origin to this point, and the slope of that line represents the ICER. ICERs in the NE and SW quadrant require a decision to be made regarding the cost-effectiveness of an intervention, i.e., whether the gain in effectiveness is worth the extra cost.

The aforementioned description of the cost-effectiveness plane considered the case in which 1 intervention is being compared with a single comparator (i.e., new treatment versus usual care). As a result, the incremental difference between the interventions and the standard of care is plotted on the cost-effectiveness plane.

The cost-effectiveness plane can also be used to graphically represent several interventions, which can then be compared with each other. A cost-effectiveness plane that contains several interventions presents the average cost and average effectiveness of the interventions. The estimates for these comparisons fall in the NE section of the cost-effectiveness plane because they represent average values and will therefore be positive cost-and-effect estimates. These values in and of themselves are not particularly informative as decision makers are faced with selecting between alternatives; it is the incremental benefit that is the important factor.

However, the slope of the lines connecting the interventions represents the ICER, and a line from the origin to each of the treatments could be considered the ICER of the intervention compared with doing nothing. By graphing the average cost-and-effect estimates for the interventions, it is possible to identify the cost-efficiency frontier. The cost-efficiency frontier represents the combination of interventions with the most ICERs. It is identified by connecting the interventions that lie below and to the right of the other interventions. This frontier could be used by decision makers to make the most efficient use of their resources, i.e., by first choosing the best intervention as shown on the cost-efficiency frontier and then moving to the next-best alternatives on the frontier as needed until they have achieved the desired clinical outcome and exhausted their budget for this particular disease state.

We highlight many of the aforementioned issues with a hypothetical example. Figure 2 represents the average cost and effectiveness of 6 interventions. The interventions are labeled A through F and are used in the treatment of a similar condition. The average effectiveness of each treatment is plotted on the x-axis and the average cost on the y-axis. The most cost-effective intervention is treatment B because it has the line with the lowest slope (smallest ICER) from the origin to its place on the plot. No other intervention has a lower ICER; thus, a decision maker would be best served to choose this intervention compared with the other interventions. If, after choosing this intervention, the health care payer has not reached the budget constraint, then the next most efficient use of resources would be to choose treatment F because it represents the next lowest ICER as we move from treatment B to the next option. Thus, treatment B and treatment F lie on the cost-efficiency frontier and should be chosen in that order until exhausting the budget for this disease state in order to use resources in the most efficient manner.
The example above describes a framework for comparing several interventions when deciding how to allocate health care resources. One common use of the cost-efficiency frontier is within economic evaluations that include several treatments, where the goal is to identify the most cost-effective treatment options. Another setting in which the cost-efficiency framework can be used is to summarize the costs and effects of treatments within a given health condition, from multiple sources, to identify the best use of health care resources. This is not a formal method of comparing the value of the interventions but a more qualitative method for comparing the relative cost-effectiveness of interventions. This is particularly true in conditions such as AR, where the quality and comparability of the studies on the economic outcomes of the interventions is variable. However, using the available data can still provide a qualitative comparison of treatment interventions and frequently is the only data available to managed care decision makers.

- Allergic Rhinitis as a Case Study

Burden of Disease

Symptoms of AR can be seasonal or perennial and include runny nose, nasal congestion, sneezing, and itching. AR may not appear to be a significant disease category in the health care industry because it is not associated with a high rate of morbidity and mortality, but the prevalence of AR has been estimated to be approximately 20 to 40 million in the U.S. population. These estimates encompass 10% to 30% of adults and 40% of children. AR is also among the top 10 diagnoses for physician office visits and is the fifth most common chronic illness reported in the United States. Direct medical costs (prescriptions and ambulatory care visits) related to the treatment of AR are on the rise ($0.8 billion in 1987, $1.2 billion in 1990, $3.4 billion in 1996, and $4.5 billion in 1997). There are also indirect costs associated with AR, which encompass missed work or school days and costs to employers, including decreases in productivity and work performance. These indirect costs were estimated to range from $2.4 billion to $4.6 billion in 1995. Not surprisingly, AR symptoms are associated with decreased health-related quality of life as well as their effects on patients’ sleeping habits, energy levels, and ability to focus.

In addition to its economic burden to the MCO, AR exerts a significant burden on the patient and on society.

Despite the fact that direct costs of AR are not generally associated with hospitalizations, prescriptions and office visits impart a significant burden to the health care payer, and this disease state has received a great deal of attention in recent years by MCOs. When focusing merely on prescription utilization for the 2 most prescribed medications treating AR (antihistamines and intranasal corticosteroids [INSs]), it is clear there has been a sharp increase in expenses incurred by MCOs over the last few years. For example, per-member-per-year (PMPY) costs for prescription antihistamines increased from $8.33 in 1998 to $18.98 in 2002, while PMPY costs for INSs increased from $3.59 in 1998 to $5.86 in 2002. In terms of direct sales, prescription medication costs in 1997 were $1.6 billion for antihistamines and $0.8 billion for INSs and by 2000 had increased to more than $3.5 billion for antihistamines and $1.6 billion for INSs.

In addition to the overall cost of this disease, several recent marketplace dynamics have increased the attention on expenditures for AR. Most remarkably, these include the movement of loratadine (Claritin) to over-the-counter status and a new medication class achieving an indication for AR. These recent dynamics have led many MCOs to develop new treatment guidelines for the management of AR. Here, we apply AR to the framework previously outlined and examine the efficient treatment of AR using existing data.

### Allergic Rhinitis Treatment

The components of the cost-effectiveness plane and the cost-efficiency frontier for AR are based on the relative efficacy of AR therapies and their costs. Examination of clinical study reviews, meta-analyses, and current guidelines were used as investigational sources to assess differences in product efficacy among the AR treatment classes. Cost was based on the most recent average wholesale price (AWP) for each product. This analysis focuses on the most highly prescribed classes of therapy for treating the symptoms of AR: INSs, less-sedating antihistamines (LSAs), and leukotriene receptor antagonists (LTRAs).

The INSs evaluated in this report are the 4 most commonly prescribed and are the leading INSs by market share (in alphabetical order): budesonide aqueous nasal spray (BANS, Rhinocort, TANS = triamcinolone acetonide nasal spray.

### Table 1

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adult Dosage</th>
<th>Cost/Month ($)</th>
<th>Cost/Day ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BANS</td>
<td>1 spray/nostril qd</td>
<td>35.66</td>
<td>1.19</td>
</tr>
<tr>
<td>FPNS</td>
<td>2 spray/nostril qd or 1 spray/nostril bid</td>
<td>68.26</td>
<td>2.28</td>
</tr>
<tr>
<td>MFNS</td>
<td>2 spray/nostril qd</td>
<td>68.73</td>
<td>2.29</td>
</tr>
<tr>
<td>TANS</td>
<td>2 spray/nostril qd</td>
<td>70.31</td>
<td>2.34</td>
</tr>
<tr>
<td>LSAs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cetirizine</td>
<td>5 mg or 10 mg qd</td>
<td>63.29</td>
<td>2.11</td>
</tr>
<tr>
<td>Desloratine</td>
<td>5 mg qd</td>
<td>72.66</td>
<td>2.42</td>
</tr>
<tr>
<td>Fexofenadine</td>
<td>60 mg bid or 180 mg qd</td>
<td>73.37</td>
<td>2.45</td>
</tr>
<tr>
<td>LTRA</td>
<td>Montelukast</td>
<td>10 mg qd</td>
<td>93.90</td>
</tr>
</tbody>
</table>

INSs = intranasal corticosteroids. BANS = budesonide aqueous nasal spray. FPNS = fluticasone propionate nasal spray. MFNS = mometasone furoate nasal spray. TANS = triamcinolone acetonide nasal spray. LTRA = leukotriene receptor antagonist. bid = twice a day. Source: Cost information according to average wholesale price listings from First Data Bank as of October 15, 2003.

Montelukast 10 mg qd 93.90 3.13

LSAs = less-sedating antihistamines. LTRA = leukotriene receptor antagonist. bid = twice a day.

Source: Cost information according to average wholesale price listings from First Data Bank as of October 15, 2003.
The Allergic Rhinitis Efficiency Frontier

![Graph](image)

Differences in effectiveness (overall effectiveness of the products based on clinical studies, reviews, and meta-analysis, not magnitude of differences between products or an empirical value based on assessments of individual symptom scores) and costs (average wholesale price) of intranasal corticosteroids (INSs), less-sedating antihistamines (LSAs), and a leukotriene receptor antagonist are represented on the graph.

Budesonide aqueous nasal spray (BANS) appears to be the most efficient treatment (average wholesale price) of intranasal corticosteroids (INSs), less-sedating antihistamines (LSAs), and a leukotriene receptor antagonist are represented on the graph.

The cost of these AR treatments could be compared by placing each product on a hypothetical horizontal line, separated by its corresponding daily cost. The least costly product per day of treatment is montelukast, and it would be placed the highest on the hypothetical horizontal effectiveness line.

**Treatment Effectiveness**

Recent reviews and guidelines have demonstrated similar efficacy among the available INSs in the treatment of AR symptoms. This meta-analysis reviewed randomized controlled clinical trials of INSs versus LSAs and concluded that INSs were more effective than LSAs at relieving the nasal symptoms of AR. In a separate review of controlled clinical studies, Nathan, who evaluated the efficacy of LTRAs versus LSAs and versus INSs, found that LTRAs were sometimes more effective than placebo, were no more effective than LSAs, and were less effective than INSs in the treatment of AR. Therefore, based on individual research reports, reviews, and meta-analyses, recent guidelines established by the World Health Organization in collaboration with the Allergic Rhinitis and Its Impact on Asthma (ARIA) Workshop have classified INSs as the most effective pharmacologic treatment for AR.

**Cost**

As stated previously, the AWP for each product was obtained from the First Data Bank (as of October 15, 2003) to differentiate each product by cost per month as well as per day (Table 1). The monthly/daily cost for the INS, dosed at their recommended starting doses is as follows: BANS, $35.66/month or $1.19/day; FPNS, $68.26/month or $2.28/day; MFNS, $68.73/month or $2.29/day; and TANS, $70.31/month or $2.34/day. The monthly/daily cost of the NSAs are: cetirizine, $63.29/month or $2.11/day; desloratadine, $72.66/month or $2.42/day; and fexofenadine, $73.37/month or $2.45/day. Lastly, the monthly/daily cost of the LTRA montelukast is $93.90/month or $3.13/day.

**Allergic Rhinitis Cost-Efficiency Frontier**

Once the efficacy and cost of the most highly prescribed treatments for AR have been determined, their respective hypothetical line diagrams can be combined graphically to evaluate the 2 components together (Figure 3). The x-axis differentiates efficacy of the INSs, LSAs, and LTRAs. Weiner et al. evaluated and compared the effectiveness of LSAs and INSs in the treatment of AR symptoms. This meta-analysis reviewed randomized controlled clinical trials of INSs versus LSAs and concluded that INSs were more effective than LSAs at relieving the nasal symptoms of AR. In a separate review of controlled clinical studies, Nathan, who evaluated the efficacy of LTRAs versus LSAs and versus INSs, found that LTRAs were sometimes more effective than placebo, were no more effective than LSAs, and were less effective than INSs in the treatment of AR. Therefore, based on individual research reports, reviews, and meta-analyses, recent guidelines established by the World Health Organization in collaboration with the Allergic Rhinitis and Its Impact on Asthma (ARIA) Workshop have classified INSs as the most effective pharmacologic treatment for AR.

These guidelines are similar to those published in 1998 by the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology that declared that INSs were the most effective medication class for controlling symptoms of AR.

Efficacy results for the INSs, LSAs, and LTRAs can be compared by placing each product on a hypothetical horizontal line separated only by the results of their reviewed efficacy measures. Because montelukast may be as effective as the LSAs in the treatment of AR symptoms, these products would appear at a similar point on the effectiveness line. In contrast, INSs are considered more clinically effective than the LTRAs and LSAs for treating AR symptoms and would therefore be grouped together farther to the right on the hypothetical horizontal effectiveness line.
the products while the y-axis separates cost. The 4 leading INSs (as a class) have been shown to be the most effective treatment for AR and are placed to the right on the x-axis and are separated only by their individual costs on the y-axis. The LSAs have been shown to be less effective than INSs and are therefore placed to the left of the INSs on the x-axis (less clinically effective) and are separated only by price. Because the LTRA, montelukast, has been shown to be less efficacious than INSs and no more effective than LSAs, it is also placed on the x-axis in the area of the LSAs (less clinically effective than INSs) and positioned on the y-axis according to its cost relative to the other products. This graphical representation combining the 2 measures of efficacy and cost illustrates the AR efficiency frontier.

Discussion

Health care decision makers are increasingly requiring information on both the clinical and economic outcomes associated with treatments before making reimbursement decisions. Cost-effectiveness analysis provides a tool with which to incorporate both pieces of information when assessing the value of a treatment.

When several competing alternatives exist for the treatment of a condition, it is possible to determine which of those treatments provides for the most efficient use of health care resources. This can be done by plotting the costs and effects of the intervention on a plane and determining which interventions are on the cost-efficiency frontier; this may be particularly useful when there are limited cost-effectiveness analyses comparing treatments in the condition of interest. We use the example of AR treatments to show how concepts can be used to compare, even qualitatively, the available treatments while considering both their effectiveness and costs.

The comparison of AR treatments presented here combines information on both the costs and effectiveness of treatments. As highlighted previously, INSs (e.g., BANS, FPNS, MFNS, TANS) are more effective in the treatment of AR than LSAs (cetirizine, desloratadine, fexofenadine) or the LTRA (montelukast). Additionally, the treatments can also be differentiated by their cost. Among the INSs, the cost per day varies from $1.19 for BANS to $2.34 for TANS. When this information is combined and plotted on a cost-effectiveness plane, BANS appears to represent the most efficient treatment choice for AR.

An important issue to consider is the impact of recent changes in the market dynamics of AR treatments on estimates of the most efficient use of resources. From a societal perspective, the shifting of products from prescription-only to over-the-counter would not impact identification of the most efficient treatments unless there were major changes in the cost of the products following the switch. However, many MCOs are interested in identifying efficient treatments from the perspective of the MCO. Thus, the costs to the MCO are often the only costs included in such an analysis. Consequently, the switch of a product to over-the-counter status could have an important impact on the identification of the most efficient treatment, depending on the perspective of the analysis.

For example, if the comparison is conducted from the managed care perspective and policy changes—including over-the-counter switch, prior authorization, or copayment tier movements—result in no cost per day for an over-the-counter product (i.e., it is not covered), then that product shifts downward on the y-axis of Figure 3 and will lie on the cost-efficiency frontier regardless of effectiveness. This, however, does not consider the potential for additional physician visits due to reduced effectiveness or beneficiary satisfaction, both of which could also influence decision making.

Despite a limitation of our cost-efficiency frontier analysis (qualitative versus quantitative efficacy scale), the application-based example used here is a useful approach to review treatment alternatives within a disease category. The efficacy conclusions and the effectiveness scale presented used qualitative measures, and the placement of products on the x-axis was a reflection of overall effectiveness of the 3 product classes determined from clinical reviews. These measures do not reflect the magnitude of differences between products and was not an empirical assignment dependent on assessments between individual symptom scores. Therefore, although there may be slight differences in individual LSAs,LTRAs, or INSs in treating specific symptoms of AR, the products evaluated received overall effectiveness ratings based on conclusions from reviews and meta-analyses of clinical studies.

This method allows the evaluator the freedom of lateral movement on the x-axis of our cost-efficiency frontier graph between products depending on individual preferences or feelings about a treatment for specific symptoms compared with the other products. If each clinical study used the same standardized efficacy measurement for each analyzed symptom, it would be possible to create a quantifiable effectiveness scale for the purposes described in this review.

Conclusion

Plotting the cost and effectiveness of alternative products on a cost-effectiveness plane provides for a simple graphical representation of the relative value of the products for treatment of a given disease. The simplicity of the present approach using clinical reviews and meta-analyses combined with recent cost data for each product in AR can be easily applied to any disease category in order to provide an MCO decision maker with additional information during the selection process for appropriate treatments. Importantly, one must still consider the data sources and information used in constructing the graph and the limitations of those data sources when making decisions. However, whether these representations are populated with sound quantitative information or based on qualitative comparisons, they provide decision makers with yet another tool when deciding on treatment alternatives.

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AstraZeneca, and is a consultant to AstraZeneca. Lee served as principal author of the study. Study concept and design were contributed by all authors. Analysis and interpretation of data, statistical expertise, and drafting of the manuscript were the work of Lee and Leibman, critical revision of the manuscript was the work of all authors.

REFERENCES

Cost Efficiency of Intranasal Corticosteroid Prescribing Patterns in the Management of Allergic Rhinitis

DEBI REISSMAN, PharmD; TOM PRICE, BA; and CHRISTOPHER W. LEIBMAN, PharmD, MS

ABSTRACT

BACKGROUND: Effective treatment of seasonal or perennial allergic rhinitis often requires use of topical intranasal corticosteroids (INSs). Despite differences in recommended starting dosages, the 4 leading INSs by market share are packaged in bottles containing 120 metered-dose sprays.

OBJECTIVE: To determine the relative prescribed dosages of the leading INSs and compare economic differences resulting from these prescribing behaviors.

METHODS: The IMS National Disease and Therapeutic Index (NDTI) was used to identify prescribing habits for the 4 leading INSs: fluticasone propionate nasal spray (FPNS), mometasone furoate aqueous nasal spray (MFNS), triamcinolone acetonide nasal spray (TANS), and budesonide aqueous nasal spray (BANS). The NDTI uses a national, randomly drawn, 2-stage stratified cluster-sampling methodology. Physicians are sampled during the first stage, with 2 workdays per month subsampled from each physician in the second stage. Each physician reports on all patient contacts during the 2 consecutive days, offering a continuing compilation of statistical information about patterns and treatment of disease encountered by office-based physicians. In a given month, the NDTI reports on 1,180 unique physicians.

RESULTS: From January 1, 2002, to December 31, 2002, 58% of prescriptions for FPNS were for 4 sprays daily with 37% for 2 sprays daily, MFNS: 44% for 4 sprays and 52% for 2, TANS: 65% for 4 sprays and 31% for 2, and BANS: 29% for 4 sprays and 68% for 2. These equated to mean prescribed daily dosages of 3.47 sprays per day for FPNS, 3.33 for MFNS, 3.50 for TANS, and 2.73 for BANS. Because each INS is packaged in a bottle with 120 metered-dose sprays, the differences in dosage offer varying days of supply per unit filled. BANS offered the most days of treatment (44 days), followed by MFNS (38 days) and FPNS and TANS (means of 35 and 34 days, respectively) per single prescription filled. Cost per day of treatment was calculated by multiplying the prescribed dosage with the average wholesale price of the products. BANS had the lowest cost per day of treatment at $1.54, with each other INS costing at least an additional $0.26 daily (MFNS $1.80; FPNS $1.88; TANS $1.97).

CONCLUSION: Based on physician prescribing patterns of INSs from the NDTI database, BANS offers more days of treatment at a lower cost per day than other leading INSs.

KEYWORDS: Allergic rhinitis, Intranasal corticosteroids, Budesonide, Fluticasone propionate, Mometasone furoate, Triamcinolone acetonide, Prescribing patterns, Cost-efficiency, Model simulation

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Clinical studies and comparison trials have found that all of these INSs demonstrate approximately the same level of efficacy for treating the symptoms of AR.\textsuperscript{8,10,12,13} They have also been found to be safe and generally well tolerated.\textsuperscript{8,10,12,13}

Of these INSs, FPNS, MFNS, TANS, and BANS are the leading INSs by market share (approximately 96% of the market).\textsuperscript{14} All 4 of these INSs are dispensed in bottles containing 120 metereddose sprays. However, the recommended once-daily adult starting dosage, based on manufacturer’s prescribing information, varies: FPNS is 2 sprays per nostril (200 µg total dose), MFNS is 2 sprays per nostril (200 µg total dose), TANS is 2 sprays per nostril (220 µg total dose), and BANS is 1 spray per nostril (64 µg total dose). Because of these differences, there may be an economic advantage of certain INSs over others based on actual prescribing patterns.

Access to a centralized database containing physician-reported patient data would provide the necessary records for examination of prescription and drug utilization information as it pertained to specific products and diseases. The National Disease and Therapeutic Index (NDTI) database\textsuperscript{15} is one such database that provides data on how products are actually being prescribed in clinical practice to help determine prescribing patterns and identify utilization. Modeling monetary units onto the data results generated from the NDTI on the 4 leading INSs can provide information about real-world prescribing patterns and treatment costs for each product. Economic differences identified between the 4 leading INSs can then be evaluated to help establish the efficiency frontier for AR (for a detailed description, see Part I of this supplement), providing a value-based strategy for the treatment of AR.

The aim of this study was to determine the relative prescribed dosages of the leading INSs and to compare economic differences resulting from these prescribing behaviors.

**Methods**

NDTI,\textsuperscript{15} a product of IMS Health, was used to identify prescribing patterns for the 4 leading INSs by market share: FPNS, MFNS, TANS, and BANS.

**National Disease and Therapeutic Index**

The NDTI database has been available since 1958 and continually updates and compiles statistical information about patterns and treatment of disease encountered by office-based physicians. Information is gathered from all primary specialties involved in direct patient care.

The NDTI panel of physicians currently consists of more than 3,600 physicians in a variety of therapeutic areas. Of these physicians, there are currently 150 participating allergists who are primary specialists within allergy, allergy and immunology, immunology, and pediatric allergy. These physicians are drawn from 9 different census regions: New England and Middle Atlantic (East), East North Central and West North Central (Midwest), South Atlantic, East South Central, West South Central (South), and Mountain and Pacific (West).
Mean Cost-per-Day Calculations—Using BANS as an Example:

- 68% of patients prescribed BANS received 2 sprays per day.
- 29% of patients prescribed BANS received 4 sprays per day.
- 3% of patients prescribed BANS received 8 sprays per day.

BANS mean cost/day = \((0.68 \times \$1.12) + (0.29 \times \$2.24) + (0.03 \times \$4.49)\).

BANS mean cost/day = \$1.54.

All calculations used the AWP of the INSs based on prices reported by First Data Bank as of January 15, 2003. BANS = budesonide aqueous nasal spray; FPNS = fluticasone propionate nasal spray; MFNS = mometasone furoate nasal spray; TANS = triamcinolone acetonide nasal spray.

AWP = average wholesale price. INSs = intranasal corticosteroids.

The NDTI database uses a national, randomly drawn, 2-stage stratified cluster-sampling methodology. During the first stage, a sample population of physicians is generated from American Medical Association and American Osteopathic Association physicians who are recruited for participation based on location and therapeutic specialty. In the second stage, 2 workdays per month are sampled from each physician. All patient contact during the 2 consecutive days is reported by each physician. In a given month, the NDTI database reports on 1,180 unique physicians, and data are collected on at least 2,454 workdays. Some of the information this database provides includes information about current and long-term trends in drug therapy/utilization, medical conditions for which they are prescribed, and drug profiles, patient profiles, and physician profiles. The NDTI database also has the capacity to estimate the actual number of patients using a precise product for a specific disease.

**Prescribed Dosage Analysis**

The number of days of treatment was calculated by taking the number of metered sprays in each INS bottle (120 for all 4 INSs) divided by the actual NDTI provider data from prescriptions written to evaluate the mean number of days of treatment per prescription by product.

**Model Simulation**

A model simulation was run based on prescriber-reported dosing generated from the IMS NDTI from January 1, 2002, to December 31, 2002. The scenario run used the average wholesale price (AWP) of the INSs based on prices reported by First Data Bank as of January 15, 2003. The model scenario reports in cost per product per day. Since the 4 leading INSs are indicated for treatment of both perennial and seasonal AR, treatment lengths vary by patient and by disease severity. For this reason, a more accurate population cost metric is cost per treated day.

The models are based on cost only and do not provide information on the efficacy and safety of the INS products evaluated.
The efficacy and safety of these products have been reviewed in the literature and found to be similar.\textsuperscript{8,10,12,13} Key model assumptions were that (1) results from the NDTI can be generalized to the target population and (2) utilization of products is equal to prescribed doses.

**Cost Analysis**

The cost per day per dosage (cost per 2, 4, and 8 sprays daily) was calculated from the AWP for INS dosages per spray bottle. For example, the cost per day for a 2-sprays-per-day dosage = AWP/(sprays per bottle/2). The cost per day of each INS (calculated from the patients in which the prescribed dosage was known [>90% of patients]) = (percentage of patients prescribed 2 sprays daily x cost per day for 2 sprays) + (percentage of patients prescribed 4 sprays daily x cost per day for 4 sprays) + (percentage of patients prescribed 8 sprays daily x cost per day for 8 sprays).

**Results**

**Prescriptions Written**

The actual provider data from prescriptions written examines real-world prescribing habits. The percent of patients who received written prescriptions for BANS, FPNS, MFNS, and TANS by dosages are shown in Figure 1. The mean prescribed sprays per day for BANS (2.75) was less than for FPNS (3.47), MFNS (3.14), and TANS (3.57). BANS patients were prescribed the lowest starting dosage of 1 spray per nostril each day more often than the other leading INSs. Evaluation of the mean days of treatment supply per prescription showed that BANS provided the greatest number of treatment days, as written most commonly by physicians in the NDTI database, per bottle compared with FPNS, MFNS, and TANS (Figure 2).

**Cost Analysis**

The AWP of each of the 4 leading INSs as of January 15, 2003, was $65.01 for FPNS, $68.73 for MFNS, $66.21 for TANS, and $67.29 for BANS. The cost per day by dosage is similar for all 4 INSs; however, when the actual percentage of patients who were prescribed each dosage is factored into the model scenario (Figure 3), at $1.54 per day, BANS was found to have the lowest cost per day of treatment compared with FPNS, MFNS, and TANS (Figure 4). The mean cost per day for FPNS, MFNS, and TANS was at least $0.26 more than for BANS.

**Discussion**

Although all 4 leading INSs come in a bottle containing 120 metered-dose sprays, prescription duration varies because the prescribed daily dosage of these products varies. While the acquisition cost of these bottles is similar, when actual prescribed dosages and percentage of patients actually prescribed these dosages were factored into the model scenario analysis, differences in the costs per treated day were revealed. BANS patients were prescribed the lowest possible dosage of 1 spray per nostril more often than the other 3 INSs investigated. Because all 4 INS bottles contain the same number of metered-dose sprays (120), BANS provides more days of treatment supply per prescription than the other INSs, which leads to a lower cost per day of treatment.

This is an important result since patients and physicians are faced with numerous options for treating AR; however, in the current economic climate, where health care resources are limited, there is a need to evaluate the best option for maximizing benefit per unit cost. The results of this cost analysis, or cost-minimization analysis (analysis to determine lowest cost alternative when the consequences of treatment, efficacy and safety, are equivalent),\textsuperscript{17} show that even for products with similar efficacy and safety profiles, potential economic differences do exist.

As described in Part I of this supplement, the information from this cost-minimization analysis can be applied to develop an efficiency frontier for AR to help in making value-based treatment decisions. This is of particular importance given that the 4 leading INSs have been shown repeatedly to have similar safety and efficacy profiles and differ primarily on sensory attributes (i.e., taste, scent).\textsuperscript{18-21} Awareness of the economic differences of these products in addition to patient preference could lead to more cost-efficient prescribing patterns for the management of AR.

It is important to note that the model scenarios in this study were based solely on the prescribing behaviors reported through the NDTI and on AWP prescription costs as reported by First Data Bank. Although we were able to successfully identify prescribing patterns, we did not have any patient-level data on the rationale for

![Figure 4](image-url)
treatment selection, patient history, or diagnosis. This study also used cost per day as the economic unit of comparison among products versus other cost-unit measures. This study evaluated INS prescriptions for all patients with AR and did not separate patients into subgroups by type of symptoms, disease severity, or duration. Thus, the cost-per-day unit of measure appeared most appropriate. For future comparisons of products, depending on the patient population and other pertinent variables of the products, a different economic unit of measure may be more appropriate.

## Conclusion

Evaluation of INS prescribing patterns shows that patients are prescribed the lowest starting dosage of BANS (1 spray per nostril daily) more often than the other 3 leading INSs. In addition, results of the model scenario show that BANS had the lowest daily cost for the treatment of AR compared with FPNS, MFNS, and TANS.

## DISCLOSURES

Funding for this research was provided by AstraZeneca LP and was obtained by author Christopher Leibman. Authors Leibman and Tom Price are employed by AstraZeneca LP. Author Debi Reissman is a paid consultant with several pharmaceutical companies, including AstraZeneca. Reissman served as principal author of the study. Study concept and design, analysis and interpretation of data, and statistical expertise were the work of Leibman and Price. Drafting of the manuscript was primarily the work of Leibman, and its critical revision was the work of Reissman and Leibman.

## REFERENCES


Continuing Education
Enhancing Value-Based Decision Making: Allergic Rhinitis

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This continuing education program is made available through an educational grant from AstraZeneca LP.

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Posttest Answers: Part I

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1. Health care expenditures are stabilizing and beginning to return to their all-time lows.
   a. True
   b. False

2. Identifying efficient treatment options for each specific disease should include measures of both the costs and effects of each intervention available.
   a. True
   b. False

3. Cost-effective analysis results are summarized into a ratio that provides information on
   a. the true cost of a product compared with its average wholesale price.
   b. the effect of a product when there is more than one competitor.
   c. unit costs per total effect on patient outcomes.
   d. incremental costs per unit effect.

4. Cost-effective analysis is often plotted on a 3-dimensional graph that includes measures for cost, efficacy, and patient acceptance.
   a. True
   b. False

5. The slope of the line from the origin of the cost-effectiveness plane to specific interventions represents
   a. the total cost for treatment of a disease with a single product.
   b. the cost-effectiveness ratio for changing to a different product for treatment of a disease.
   c. the incremental cost-effectiveness ratio.
   d. the incremental cost for treating the disease per time period examined.

6. Approved treatments for allergic rhinitis are
   a. intranasal corticosteroids.
   b. antihistamines.
   c. leukotriene receptor antagonists.
   d. a and b
   e. b and c
   f. a, b, and c

7. Prescriptions for intranasal corticosteroids and antihistamines have decreased over the last 5 years.
   a. True
   b. False

8. Recent reviews and meta-analyses evaluating the most effective treatment of allergic rhinitis have found that
   a. antihistamines are superior to intranasal corticosteroids.
   b. leukotriene receptor antagonists are superior to intranasal corticosteroids.
   c. intranasal corticosteroids are superior to antihistamines but not leukotriene receptor antagonists.
   d. intranasal corticosteroids are superior to both antihistamines and leukotriene receptor antagonists.

9. Place the following allergic rhinitis treatment products in the order of increasing cost per day:
   a. BANS, cetirizine, FPNS, TANS, MFNS
   b. montelukast, fexofenadine, MFNS, FPNS, BANS
   c. MFNS, TANS, desloratadine, fexofenadine, BANS
   d. BANS, MFNS, TANS, montelukast, fexofenadine

10. Which treatment product is most cost effective in the allergic rhinitis efficiency frontier?
    a. triamcinolone acetonide nasal spray
    b. montelukast
    c. mometasone furoate nasal spray
    d. desloratadine
    e. budesonide aqueous nasal spray
    f. fexofenadine
Continuing Education
Enhancing Value-Based Decision Making: Allergic Rhinitis

Part II: Cost Efficiency of Intranasal Corticosteroid Prescribing Patterns in the Management of Allergic Rhinitis

Please indicate the correct answers on the Record of Completion.

1. INS agents available in the United States all have the same recommended dosing schedule.
   a. True
   b. False

2. Differences in prescribed dose of an INS can lead to economic differences across the available products.
   a. True
   b. False

3. Allergic rhinitis affects _______ million Americans annually.
   a. 10-20 million
   b. 20-40 million
   c. 40-60 million
   d. 60-80 million

4. Prescription costs for antihistamines and INS agents in the United States exceeded
   a. $3 billion in 1999.
   b. $1 billion in 1999.
   c. $3 billion and $1 billion, respectively, in 1999.
   d. $5 billion in 1999.

5. The economic burden of allergic rhinitis in the United States is estimated to be
   a. $3 billion in direct costs.
   b. $5.3 billion in direct costs.
   c. $7.7 billion in direct costs.
   d. $7.7 billion in indirect costs.
   e. b and d

6. Treatment guidelines for allergic rhinitis state that INS agents are recommended as first-line treatment for moderate to severe intermittent and persistent symptoms.
   a. True
   b. False

7. BANS is the only INS with a recommended starting dose of 1 spray per nostril per day.
   a. True
   b. False

8. The NDTI is a database that continually updates and compiles statistical information about patterns and treatment of disease encountered by office-based physicians.
   a. True
   b. False

9. Based on the model results, the mean prescribed spray per day were
   a. BANS (3.75), FPNS (3.47), MFNS (3.14), TANS (2.57).
   b. BANS (3.75), FPNS (2.47), MFNS (3.14), TANS (3.57).
   c. BANS (2.75), FPNS (3.47), MFNS (3.14), TANS (3.57).
   d. BANS (3.75), FPNS (3.47), MFNS (2.14), TANS (3.57).

10. Based on the mean prescribed spray per day,
    a. BANS had the highest cost per day of therapy.
    b. MFNS had the highest cost per day of therapy.
    c. BANS had the lowest cost per day of therapy.
    d. FPNS and TANS had the same cost per day of therapy.
Enhancing Value-Based Decision Making: Allergic Rhinitis

Participant’s name: ______________________________________________________ Date: ____________________

Your assistance in the evaluation process is greatly appreciated. Please return this form with the posttest answers.

Scale For Questions 1–8

1 = Not at all
2 = Not very well
3 = Somewhat well
4 = Well
5 = Very well

Scale For Questions 9 and 10

1 = Poor
2 = Fair
3 = Good
4 = Very good
5 = Excellent

Using the scale above for questions 1-8, please rate how well you will be able to accomplish the following objectives based upon successful completion of the program.

Using the scale above for questions 9 and 10, please indicate the number that best expresses your opinion.

**Part I - Objectives:**

1. describe the components of a cost-effectiveness analysis and a cost-efficiency frontier ______

2. identify key issues and items that make allergic rhinitis a significant burden on managed care organizations, patients, and society ______

3. describe the most highly prescribed medications within the 3 classes of products approved for treatment of allergic rhinitis, compare efficacy, and cite guidelines that support their use ______

4. illustrate the cost-efficiency frontier for allergic rhinitis and determine the most cost-efficient class of medications (and individual products) for treatment ______

**Part II - Objectives:**

5. describe the IMS NDTI database ______

6. define the mean prescribed sprays per day for the leading INS agents ______

7. based on the mean prescribed sprays per day, determine the cost per day for the leading INS agents ______

8. define an economic model that could help determine the most cost-effective INS within any health care setting ______

9. What is your overall rating of this program? ______

10. How would you rate the pertinence of this program material to your practice? ______

11. To what degree was there promotional bias (check one):
   a. Not at all ______
   b. Somewhat ______
   c. A great deal ______

12. To what degree do you anticipate changes in patient care as a result of the material presented? (circle one)
   1 No change 2 3 4 5 Significant change

13. Please indicate the length of time it took to complete this program: (circle selection)
   Hours: 1 2 3
   Minutes: 0 15 30 45

14. Please rate the difficulty factor for completing this CE program: (circle selection)  Easy  Moderate  Difficult

15. Please rate your willingness to recommend this program to colleagues: (circle selection)
   Very willing  Willing  Not willing

16. Please indicate which venue you prefer for obtaining continuing education: (circle selection)
   Written monograph  Slides  Videos  Internet-based

Live sessions  Other:__________________________________________