



Advair® Prescribing Patterns in a State Medicaid and Child Health Insurance Program

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Background and Objective

Advair® is a combination inhaled steroid and long-acting beta agonist (LABA). This product is appropriately used for patients with chronic obstructive pulmonary disease (COPD), and as an asthma controller. National asthma treatment guidelines recommend Advair® as a treatment for patients classified with moderate to severe persistent asthma who can not be controlled with inhaled steroids.

The Food and Drug Administration (FDA) previously issued a black box warning for Advair® due to the observed increase in deaths of asthma patients using an LABA. The FDA currently recommends not to prescribe an LABA if symptom control can be achieved with inhaled steroids alone.

Advair® has become the most widely used inhaled asthma controller in recent years. This broad use implies that Advair® is prescribed as first line therapy despite current treatment guidelines and newer safety advice.

Our purpose was to describe treatment patterns of asthma patients beginning Advair® therapy. This analysis informed deliberations on policies to bring Advair® prescribing and use closer to treatment guidelines.

Methods

Advair® treated patients in the Arkansas Medicaid and State Child Health Insurance Programs were identified using administrative claims data. Asthma treatment and physician visit data were collected for all children and adults not covered by Medicare, not needing long-term care benefits, and continuously enrolled from 07/04 to 4/06.

Respiratory diagnoses were extracted for all recipients. Patients with COPD were identified and excluded.

Advair® is a registered trademark of GlaxoSmithKline (GSK). This research was conducted with no outside funding.

Methods (cont.)

Treatment patterns were examined for patients with new Advair® claims in 2005 who did not have a COPD diagnosis. Pharmacy claims for Advair®, inhaled asthma controllers, rescue medications, and systemic steroids were examined. Additionally, outpatient services and hospital admissions were also reviewed.

Results

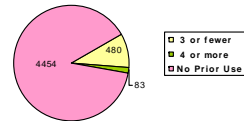
Slightly more than 6.5% of the continuously eligible recipient population (n=276,521) filled at least one prescription for an inhaled asthma controller in the study period. Approximately half of patients using an asthma controller at least once, filled a prescription for Advair®. The following table categorizes recipient counts in 2005.

Recipient Category in Year 2005	Count	%
Total population using Advair	8162	
Advair users with COPD diagnosis	1429	18%
Advair Users with asthma (7% with asthma code, 2% with no respiratory diagnosis)	6733	82%
Prior Advair users with asthma (filling at least one Advair claim from 7/04 to 12/04)	2347	29%
New Advair Users with asthma	4386	54%

Prior inhaled controller use was assessed for all asthma patients started on Advair® from January 2005 through April 2006 (n=5017). Prior use was assessed from July 1, 2004 to the date of the 2005 index Advair® claim. A small number of new Advair® patients (n=563) were treated with an inhaled steroid controller prior to starting Advair. Only 16 patients used an add-on LABA prior to their first Advair® prescription claim.

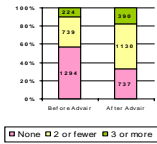
Results (cont.)

Months of Inhaled Controller Use Before Advair®

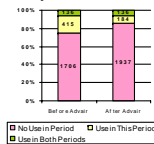


Short-acting Beta agonist and systemic steroid use are considered markers of asthma severity and symptom control. Prescription claims dispensed in the six months prior to and after Advair® start were examined for 2257 new patients starting Advair® in the first half of 2005.

Rescue Inhaler Use



Systemic Steroid Use

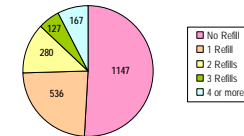


Provider encounter patterns show that 44% of patients starting Advair® had fewer than two office visits in a year. Nearly a third of patients with ED visits were seen both before and after starting Advair®.

All Cause Encounters (n=2257)	Office Visits	ER Visits	Hospital
Only Before	433 (19%)	333 (15%)	13 (1%)
Both Before and After	1267 (56%)	153 (7%)	0
Only After	129 (6%)	261 (12%)	14 (1%)
No Visits	428 (19%)	1510 (67%)	2230 (99%)

Of 2257 patients starting Advair® in the first half of 2005, 51% did not refill Advair® in the subsequent six months. Only 13% of these new Advair® non-COPD patients filled three or more prescriptions in the subsequent six months. Eighteen of the 2257 newly treated patients filled Advair® monthly.

Advair® Refills Six Months After Index Advair® Claim



Conclusions

Most patients initiating Advair® treatment in the first half of 2005 lacked markers of moderate to severe persistent asthma. The fact that 30% of patients have no claim for a rescue inhaler combined with the sporadic pattern of Advair® refills suggests that it may be used for treatment of exacerbations.

This pattern of use does not follow treatment guidelines or safety recommendations from the FDA and GSK. Arkansas Medicaid and SCHIP recipients may be at increased risk for life-threatening events because of Advair® use outside of accepted recommendations.

Given the apparent inappropriate use and higher risks and costs of Advair® relative to other asthma controllers, the Arkansas Medicaid program instituted Advair® prior authorization requirements for patients who lack markers of moderate or severe asthma, or who do not show a refill pattern suggestive of adherence to controller therapy.