

# Florida Allergy, Asthma & Immunology Society

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January 28, 2014

To: Whom It May Concern

From: The Florida Allergy, Asthma & Immunology Society

RE: Restricted access to Advair™ in children aged 4-11 years of age

As of January 1, 2014 the dual controller asthma inhalers, Symbicort™ and Dulera™, became the preferred controllers of their class prescribed for all patients with asthma whose insurance carriers are using Express Scripts as their pharmacy benefits manager. According to the national guidelines for the diagnosis and treatment of asthma, an inhaled corticosteroid combined with a long-acting bronchodilator is clearly indicated as a preferred treatment option for the patient with asthma poorly controlled on an inhaled corticosteroid alone.

While the individual components of these inhalers (budesonide, mometasone, formoterol) are approved for use in a child, these specific drug combinations and devices mentioned above are only approved for ages 12 and above. The FDA requires efficacy and safety studies in the prescribed age group to obtain approval. It is not acceptable to assume that combination products will have the same efficacy and safety as the individual components. Many of the patients we serve are younger than the age indications clearly stipulated by the manufacturer's package inserts.

We believe that restricting access to Advair™, the alternative combination inhaler approved for use in patients' age 4 years and above, is inappropriate in the case of children 4-11 years of age. The delay in initiating an acceptable treatment option created by restricted access and prior authorization potentially places pediatric patients at greater risk for asthma exacerbations.

The practicing physician should not be required to utilize off-label medications when an alternative approved drug is available. We believe that treatment failure with a drug that is not approved for use in a child is inappropriate and should not be required to obtain an approved, available option.

Your prompt attention to this urgent matter is greatly appreciated.

Sincerely,

Neil Gershman, MD  
President, Florida Allergy, Asthma & Immunology Society

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