

CAREMARK TrendsRx[®] Alert

What's new...What's next...What to do now

June 2003

NEW DRUG APPROVAL

Xolair[®] for Injection (omalizumab)

Xolair was approved in June 2003 by the United States (US) Food and Drug Administration (FDA) for the treatment of moderate-to-severe allergic asthma in people 12 years of age and older whose symptoms are not controlled by inhaled corticosteroids. Xolair is the first biologic therapy that targets a protein produced in the body called immunoglobulin E (IgE). IgE is responsible for the release of substances that lead to allergic asthma. Genentech, Inc., Novartis Pharmaceuticals Corporation, and Tanox, Inc. collaborated on the development of Xolair. The dosing and frequency of Xolair are determined by the levels of IgE in the body and body weight. Xolair should be injected under the skin (subcutaneously) every 2 or 4 weeks. Common adverse events included flushing, itching, hives, and rash. Xolair is contraindicated in people who have had an allergic reaction to Xolair in the past.

BACKGROUND

Asthma affects over 20 million people in the US. Most people with asthma have good control of their condition. However, about 500,000 people with more severe and persistent asthma are not controlled despite currently available treatments. Xolair for Injection is a new drug that may benefit this small subgroup of asthmatics. Xolair is a unique drug that appears to be safe and effective for treating people with difficult-to-treat allergic asthma. Asthmatics using high doses of corticosteroids for allergic asthma would appear to benefit most from this drug. Because this is an injectable drug, it is anticipated that it will initially be administered in physicians' offices. The wholesale price of Xolair is expected to be \$433 per vial. For an average sized adult that would be \$433-\$866/dose or approximately \$10,000-\$15,000 per year. However, the high cost of Xolair may be offset by reduced medical costs such as emergency room visits and hospitalizations.

Caremark is one of five distributors for this product.

CAREMARK RESPONSE

Caremark recommends the coverage of Xolair under your prescription benefit.

A prescription presented under the retail or mail service benefit will be directed to Caremark Specialty Pharmacy Services.

For clients with CustomCare Mail, Caremark will verify the appropriate diagnosis to assure optimal participant selection.

Further clinical management is available focusing on the following:

- Optimization of oral and inhaled asthma drug therapy
- Evaluation of lab parameters

More extensive disease management education and support for participants is available through the Caremark CarePatterns[®] Program for Asthma.

CONTACT

For more information call your Caremark account representative.

Please Note: This document provides a brief overview of the subject. Please refer to the manufacturer's full prescribing information for a complete discussion of the product. This review is provided as a reference only, and is based in part on information derived from third parties.