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Scientific, Clinical, and Economic Rationale for Combination Therapy in Managing Asthma: A Paradigm for Managed Care

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This Special Report supplement to *The American Journal of Managed Care* features the proceedings of the roundtable conference titled, "Scientific, Clinical, and Economic Rationale for Combination Therapy in Managing Asthma," held July 8, 2000, in Denver, Colorado, as well as a review article. The panel included experts in asthma, allergy, pulmonology, family practice, clinical pharmacy, and managed care.

Despite the availability of effective medications, too many patients with asthma do not have their disease under adequate control. The number of asthma-related deaths, hospitalizations, and emergency department visits increases annually, as does the cost of care. I and many of my colleagues strongly believe that appropriate utilization of available asthma medications, including earlier use of inhaled steroids and combination therapy with inhaled steroids and second controllers where indicated, would be of significant help in controlling asthma and in saving healthcare dollars.

At present, there are 2 basic national-level documents that address appropriate medications for asthma: the 1997 National Heart, Lung, and Blood Institute (NHLBI) Asthma Guidelines and the National Committee on Quality Assurance Health Plan Employer Data and Information Set (HEDIS) 2000 Asthma Performance Measure. There is also extensive literature on etiology, pathophysiology, diagnosis, and treatment of asthma.

The 1997 NHLBI Asthma Guidelines were developed by a panel of asthma experts and reflect a clinically based and perceived evidence-based approach to optimal therapy. The HEDIS 2000 Performance Measure, "Use of Appropriate Medication in Patients with Asthma," is based on administrative data (ie, prescription refill rates and utilization of medical services) that were used to prepare a risk-stratified approach to classifying and treating asthma. The HEDIS Performance Measure was specifically developed to outline acceptable therapy for plan-evaluation purposes, whereas the NHLBI Asthma Guidelines were developed to provide clinical guidance and recommendations for optimal therapy to a more general audience.

There are several possibilities why clinicians continue to see asthma treatment failures. They include: 1) Not enough providers follow NHLBI Asthma Guideline recommendations, either out of choice or lack of education. 2) It is often difficult for physicians to include continuing medical education meetings in their schedules, or if physicians do attend, they may have difficulty incorporating what they have learned into daily clinical practice. 3) Many physicians do not have the time or the resources (such as physician-extenders, disease management programs, and asthma

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education programs) to adequately educate their patients.

Patient compliance strongly influences asthma control. Because asthma is an episodic disease, physicians may face difficulties in educating patients that current symptoms do not always reflect disease progression, and that although patients may be clinically well, they may still have a progressive disease and may have an acute exacerbation at any time.

Although there is no single therapeutic strategy for all stages of asthma with no side effects, with 100% patient compliance, and with minimal cost, appropriate therapeutic options are available. Physicians must remember that the population with asthma is heterogeneous, and a heterogeneous medication response should be expected.

Several methods are available to assess asthma treatment outcomes, including short- to medium-term clinical well-being, pulmonary function testing, assessment of inflammation and remodeling, long-term symptom progression, and pharmacoeconomic considerations.

Clinical well-being—in terms of days, weeks, or months and rates of exacerbation—is a time-honored way to assess asthma treatment outcomes. Although pulmonary function testing has been a traditional assessment approach, it is not the only approach.

During the roundtable conference, participants addressed the following questions related to asthma management in a managed-care setting. How well does pulmonary function assess inflammation, which is viewed as a basic factor in asthma? What about the hierarchy of pulmonary function testing response? Inflammation and remodeling are important, but what is the nature of the inflammatory response and how does it change depending on progression of the disease? Do all asthma patients have the same kind of inflammatory response? How significant is remodeling? Is it clinical? Is it histologic? Can a histologic phenomenon become clinically significant with special stimuli? How is remodeling assessed clinically?

In contrast to short- or medium-term clinical well-being that is assessed in days, weeks, and months, long-term symptom progression is assessed in terms of years and decades. What is the clinical course of a patient's asthma over a long period of time? How important is early intervention with antiinflammatory therapy? Which therapeutic strategies provide the best long-term outcomes?

In addition to clinical outcomes, economic outcomes are measures of treatment success or failure. Pharmacoeconomic outcomes are important to pharmaceutical companies, healthcare payers, and the government, which is in the process of establishing a national outcomes database. Do the pharmacoeconomic data on asthma management indicate cost- and clinically effective therapies?

The presentations, discussions and review included in this Special Report address those issues and may provide valuable insights into asthma treatment as it continues to evolve.