Introduction

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The rapidly rising costs of health care in the United States,¹ and a corresponding failure to prolong the mean life expectancy,² are driving the push to find more efficient and effective ways to provide the best health care for the most value in making decisions in technology reimbursement.

Comparative effectiveness research (CER) is a viable method used to help improve health outcomes and decrease costs in our health care system. CER is a systematic research method that compares new drugs and therapies with established drugs and therapies. This research approach not only determines whether a therapy works, but also how well one therapy compares to another.³ The goal of CER is to achieve the right therapy for the right patient at the right time. By incorporating CER into early stages of drug development as well as in post-marketing and real-world studies, we can improve health care and de-emphasize inefficient or inferior products and services.

Currently, CER is underutilized. Under the guidance of the U.S. Food and Drug Administration (FDA), most clinical drug trials are designed using a placebo-controlled strategy. This study design fails to compare a new drug product to existing products and may lack important information necessary for formulary decisions.^{4,5} CER could be conducted prior to product introduction to understand potential gaps in therapy and help determine where a new agent may fill an unmet need, at reasonable cost. For today's formulary decision makers, the challenge remains of how to incorporate CER into their day-to-day practice of offering an affordable, balanced drug formulary to their health plan members.

During the October 2010 Academy of Managed Care Pharmacy (AMCP) Educational Conference in St. Louis, Missouri, a payer executive roundtable was convened. This roundtable consisted of 9 representatives from a broad spectrum of health plans as well as government bodies such as Medicaid. The roundtable thought leaders defined CER from

their perspectives and described how CER data is currently used in formulary decision making. A comprehensive clinical trial program consisting only of head-to-head comparative trials for liraglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes,⁶ was presented to the panel to generate feedback on what was beneficial and what was still lacking in the approach for patients with type 2 diabetes. This example was also used to discuss how CER can be used by formulary decision makers when considering a new drug. The panel then discussed opportunities and hurdles for integrating CER into the health care delivery system. This supplement to the *Journal of Managed Care Pharmacy* presents 3 articles based on the results of a roundtable discussion and is intended to advance the understanding of CER and its possible future impact on pharmaceutical development and health care in the United States.

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