AMCP Format for Formulary Submissions, Version 4.0

The product dossier is a key resource used in the evaluation of medical treatments for formulary placement. The *AMCP Format for Formulary Submissions* serves as a template in helping manufacturers understand the information that is needed by pharmacy formulary decision makers to assist in the drug evaluation process. The recently updated version of the *AMCP Format* (Version 4.0) helps to provide further clarification and direction on many of the challenging topics faced by managed care organizations today, such as comparative effectiveness research, companion diagnostics tests, biosimilars, preapproval dossiers, and economic modeling.

In 2015, 30 of the 45 novel drug approvals were medications that could be considered specialty medications. As specialty medications become a greater focus for managed care organizations, there is an increased emphasis on defining value and providing a thorough analysis of the medical treatments brought to market. By providing pharmaceutical manufacturers with the appropriate guidance on dossier content, it will help to improve product dossier content, making the manufacturer more apt to address the current needs in the marketplace.

Because of the large impact that specialty medications have on the medical and pharmacy budget, a timely evaluation of medical therapies is necessary to render a decision that benefits the member and the payer. If used by the pharmaceutical manufacturer, the preapproval dossier will be useful in allowing the formulary decision makers the ability to begin the initial assessment before U.S. Food and Drug Administration (FDA) approval in order to better understand the estimated impact of a favorable decision by the FDA.

A key element of current specialty strategies by health care decision makers is the effect of biosimilars on the specialty landscape. Although there are still many unanswered questions with regards to biosimilars and their effects, the updated dossier clarifies for the pharmaceutical manufacturer the data necessary to provide an appropriate drug evaluation. It is anticipated that biosimilars will continue to be evaluated, to the extent possible, under the same standards as the innovator product, given the nature of the approval and manufacturing processes.

Comparative effectiveness research (CER) and economic modeling are important tools used by formulary decision makers in the evaluation of pharmaceutical products. In the absence of head-to-head clinical trials and the abundance of randomized placebo controlled trials, formulary managers are left to use other analyses to compare products and understand the true effect of a product on the health care system. Previously, it was not uncommon for manufacturer-provided economic models to come with a preconceived stigma of bias because of the lack of transparency and flexibility in the model. The updated version of the *AMCP Format* addresses the need for transparent models to be available to formulary decision makers that explain the assumptions made by the manufacturer and allow for customization of the assumptions to better apply to the populations that the decision makers manage. The updated *AMCP Format* does not dictate which types of CER should be conducted, but it does emphasize the importance of such research to formulary decision makers and the need for these types of analysis to be incorporated as they come available.

Initial impressions of the updated *AMCP Format* are positive in that it addresses the anticipated changes in the managed care landscape now and in the future. If pharmaceutical manufacturers use the updated *Format* as a guide in their dossier creation process, they will create dossiers that better equip formulary decision makers to do thorough evaluations of their products.

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DISCLOSURES

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