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A systematic review of sevelamer in ESRD and an analysis of its potential economic impact in Canada and the United States.

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Abstract: The Kidney Disease Outcomes Quality Initiatives (K/DOQI) guidelines on bone metabolism and disease in chronic kidney disease were recently published. Despite limited evidence of clinical effectiveness and without detailed consideration of cost, these guidelines recommend the use of a nonmineral-containing phosphate binder (i.e., sevelamer) in several common clinical situations. The objective of this study is to use the example of sevelamer to outline the information that is needed to assist health care payers with the decision to fund a new and expensive therapy.

We assessed the clinical benefit of sevelamer by performing a systematic review of all randomized trials evaluating its use. To estimate the direct budget impact associated with implementation of the K/DOQI bone disease guidelines, we used laboratory and medication data available from two cohorts of dialysis patients (one treated in Canada and one in the United States) to determine the proportion of patients who meet the criteria for the use of sevelamer as described in the K/DOQI bone disease guidelines.

No randomized trials document the impact of sevelamer on survival, hospitalization, or quality of life. However, at least 51% and 64% of dialysis patients in the Canadian and American cohorts, respectively, would meet K/DOQI criteria for use of sevelamer. Extrapolating to the United States dialysis population, adoption of the K/DOQI bone guidelines would result in expenditures of approximately 781 million dollars annually on sevelamer alone.

Given their potential budgetary impact, future nephrology clinical practice guidelines should consider resource use, in addition to clinical data.

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