Use of Valsartan for the Treatment of Heart-Failure Patients Not Receiving ACE Inhibitors: A Budget Impact Analysis

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ABSTRACT

Background: Heart failure is a widespread and costly malady. It represents the leading single diagnosis for hospitalized patients. For many heart failure patients, angiotensin-converting enzyme (ACE) inhibitors are either not tolerated or contraindicated, but angiotensin receptor blockers such as valsartan may be a therapeutic option for them.

Objective: The aim of this study was to prepare a budget impact analysis to assist health plans in evaluating the financial impact of adding valsartan therapy to usual care for heart failure patients not receiving ACE inhibitors.

Methods: A budget impact analysis was developed for a hypothetical US health plan. Model inputs included demographic data, estimates of the prevalence of heart failure and proportion of heart-failure patients not on ACE inhibitors, prevalence of heart failure-related hospitalization, cost data, and resultant health care utilization from the Valsartan Heart Failure Trial (Val-HeFT). Costs and cost savings were reported as year-2001 US dollars.

Results: An estimated 1207 of hypothetical 250,000 enrollees were projected to have heart-failure diagnoses, with 603 (50.0%) not receiving ACE inhibitors, and 160 (26.5%) of such patients being hospitalized each year. For valsartan-treated patients, savings due to reduced hospitalizations and shorter length of hospital stay were \$1,083,938 and \$221,364, respectively. Subtracting the cost of valsartan treatment (\$629,472) from savings yielded projected net savings of \$675,830 per year. Varying patient, treatment, and payer-mix characteristics resulted in projected net savings of \$409,598 to \$1,350,617 per year.

Conclusions: Addition of valsartan therapy to usual care in this model analysis resulted in net cost savings among hypothetical heart-failure patients not receiving ACE inhibitors. Substantial cost savings were realized, regardless of variation in model param-

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Key words: heart failure, angiotensin converting enzyme inhibitors, budget impact, angiotensin receptor blockers, hospital costs.

INTRODUCTION

Heart failure is a major public health concern currently affecting almost 5 million Americans, with 550,000 new cases diagnosed in the United States each year. From 1979 to 2001, hospital discharges for heart failure rose from 377,000 to 970,000, an increase of 157%. For women aged 40 years and for men, the lifetime risk of developing heart failure is 1 in 5.2 The incidence of heart failure increases with age, with older patients often being undertreated. Given the aging of the overall US population and efforts to assure appropriate treatment for all persons, heart failure will impose an increasing economic burden on health care budgets in coming years.

The impact of heart failure on health care costs is substantial. The American Heart Association estimates the costs of heart failure to have been US \$27.9 billion in the year 2005: US \$25.3 billion in direct costs, measured by medical expenditures, and US \$2.1 billion in indirect costs, measured by lost productivity. The majority of the direct medical costs of heart failure are attributable to hospitalizations. In fact, heart failure is the single leading Medicare diagnosis-related group (DRG), and the number of hospitalizations continues to rise each year. Furthermore, ~44% of heart-

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failure patients are readmitted within 6 months of their first hospitalization. Strategies to reduce the frequency of hospitalization represent a significant opportunity for relieving the economic burden associated with heart failure. In addition to reducing costs, therapeutic approaches intended to decrease hospitalizations can also positively affect the quality of life of heart-failure patients. 10

Representing nearly 2% of health care budgets, heart failure is an important target for cost containment, especially within managed care organizations. 5,6,11 Due to its high prevalence and cost, treatment approaches that produce even modest reductions in perpatient costs may translate into substantial total cost savings. It is imperative that heart-failure treatment strategies be evaluated in terms of their impact on costs, as well as their clinical benefits.

In recent years, important advances have been made in the pharmacotherapeutic treatment of heart failure. Angiotensin-converting enzyme (ACE) inhibitors, β-blockers, and the angiotensin receptor blocker (ARB) valsartan have all demonstrated mortality and morbidity benefits.¹²⁻¹⁵ However, for many heart-failure patients, ACE inhibitors are either not tolerated or contraindicated.¹⁶

Benefits of heart-failure therapy should be weighed in the context of their impact on health care budgets, be they cost-saving or cost-adding. We focus here on the budget impact of therapy from a health-plan perspective. Of course, health plans also consider issues other than cost, but such issues are not elaborated upon in this analysis. A recently completed trial of an ARB for the treatment of heart failure, the Valsartan Heart Failure Trial (Val-HeFT), demonstrated that the use of valsartan (when added to the usual care of patients not receiving ACE inhibitors) was associated with reduced rates of heart-failure-related hospitalizations and mortality, as well as shorter duration of hospitalization.¹⁷ These clinical benefits may represent important cost savings.

To quantify these benefits, we prepared a budget impact analysis of the Val-HeFT data, presented in this paper. The analysis was intended to assist health plans in evaluating the financial impact of adding valsartan therapy to usual care for patients not receiving ACE inhibitors for the treatment of heart failure.

PATIENTS AND METHODS

A budget impact analysis was prepared to assess the financial impact of using valsartan in addition to usual care for the treatment of heart-failure patients not receiving ACE inhibitors for a hypothetical US health plan with 250,000 enrollees. Epidemiology, costs, and effectiveness data from pertinent sources were used to populate the model (Table I).^{17–24} Because this analysis was based on secondary data without identifiers, there were no human subject considerations to be reported.

US Census 2000 data were used as default data to define the age group distribution of the hypothetical health plan population.¹³ Only persons aged ≥18 years were included, to reflect the population at risk for heart failure and the approved indication of valsartan for treatment of heart failure in adults. The prevalence of heart-failure-related hospitalizations were obtained from hospital discharge data, accounting for differences by age group.¹³

Estimates from previously published studies were evaluated to determine the proportion of heart-failure patients not receiving ACE inhibitors in the model. An investigation of trends in heart-failure treatment in a sample of community-dwelling adults aged ≥65 years found that ~40% of those studied used ACE inhibitors.²⁵ In a systematic review of 37 studies on the use of ACE inhibitors in patients with heart failure, between 33% and 67% of all patients discharged from hospitals and between 10% and 36% of communitydwelling patients were prescribed ACE inhibitors.²⁰ Among older nursing-home residents, a review indicated underuse of ACE inhibitors.3 One managedcare-based study reported that 50.6% of patients with hypertension and heart failure were receiving ACE inhibitors. 21 Another study reported that 50% of heart-failure patients enrolled in managed care plans were receiving ACE inhibitors, compared with 41% of heart-failure patients enrolled in indemnity plans.²² Based on the findings of these studies, 50% was chosen as a baseline estimate of the proportion of heart-failure patients receiving ACE inhibitors in the model.

Heart-failure patients may not receive ACE inhibitors due to drug intolerance, noncompliance with prescribed medications, insufficient prescribing, or other reasons. 3,16,20-22 Various studies report that 3% to 29% of patients experienced ACE-inhibitor-related adverse events. 23 Studies comparing ACE inhibitors and ARBs have reported that ACE inhibitor intolerance or contraindication were among the main exclusion criteria. 26 Valsartan is generally tolerated well. Compared with lisinopril and amlodipine, adverse events were

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