Assessment of Drug Therapy Management and the Prevalence of Heart Failure in a Managed Care Population With Hypertension

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ABSTRACT

OBJECTIVES: To (1) determine the prevalence of heart failure (HF) and cardiovascular risk factors within a hypertensive managed care population, (2) measure blood pressure goal attainment in patients with concurrent HF and hypertension (HTN), and (3) assess the use of drug therapy for diabetic and nondiabetic patients with concurrent HF and HTN, particularly regarding the use of angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs).

METHODS: Eligible patients were identified through a review of medical and pharmacy claims data from 10 managed care organizations (MCOs) and 2 specialty medical groups (4.6 million total members) from June 1998 through July 2001. From approximately 850,000 members in the claims database identified as hypertensive, 7,226 were randomly selected for medical chart review. Of these, 6,935 medical charts had a confirmed diagnosis of HTN but not HF, and 291 (4%) had confirmed HTN and HF. The study population—291 patients with HTN and HF—provided information on demographic characteristics, prevalence of cardiovascular risk factors and relevant comorbidities, and systolic and diastolic blood pressure. Current antihypertensive therapy prescription fill rate was evaluated using pharmacy claims.

RESULTS: Patients with diagnoses of HTN and HF confirmed in the medical chart (N = 291) were included in the present analysis. HF prevalence among hypertensive patients was 4% (291 of 7,226). Mean age of the study patients was 68.3 years, and 52.9% of the patients were female. Key cardiovascular risk factors included gender (men and postmenopausal women) (89.3%), age > 60 years (73.5%), hyperlipidemia (47.4%), and diabetes (38.8%). Of the total sample, only 30.1% of the diabetic (34 of 113) and 26.4% of the nondiabetic (47 of 178) patients with HF had their blood pressure controlled to the goal level of < 130/85 mm Hg recommended by the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI), the national guideline in effect at the time. Overall, 64.7% of HF patients for whom we had pharmacy claims were receiving an ACE inhibitor or an ARB.

CONCLUSIONS: The study results indicate a deficit in the treatment of HTN among HF patients with and without diabetes, including failure to achieve blood pressure goals < 130/85 mm Hg at the time of this study period. More aggressive quality improvement programs are necessary to educate providers and patients on the importance of treating blood pressure to nationally accepted goal using antihypertensives proven beneficial for hypertensive patients with HF.

KEYWORDS: Hypertension, Heart failure, Diabetes, Blood pressure, Pharmacotherapy, Angiotensin-converting enzyme inhibitors, Angiotensin II receptor blockers

J Manag Care Pharm. 2004;10(6):513-20

Toddy, approximately 4.9 million Americans live with heart failure (HF), and 550,000 new cases occur every year.1 The economic burden to society is staggering and is escalating. Between 1979 and 2000, hospital discharges for HF increased 165%, and the direct and indirect costs for 2003 were estimated at $24.3 billion.1

High blood pressure or hypertension (HTN) is a critical risk factor for the development of HF. Increasing blood pressure is associated with increasing chances for developing HF as well as other cardiovascular diseases.2 Precise etiology of HTN in 90% to 95% of the cases is not known, but HTN can be easily detected and controlled.1 Despite increased awareness of HTN and improved control rates seen between 1988 and 2000, recent data indicate that 47% of hypertensive individuals treated do not have their blood pressure adequately controlled.3 Another critical risk factor is diabetes mellitus. Individuals who suffer from both diabetes and HTN have almost twice the risk of developing cardiovascular disease.4

The study was based on recommendations in the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI), the latest JNC report at the time the study was conducted. JNC VI recommended initial therapy with angiotensin-converting enzyme (ACE) inhibitors and diuretics for patients with HTN and HF. The recently released Seventh Report of the JNC (JNC 7) expanded the therapeutic recommendations for HF to include beta-blockers (BBs), angiotensin II receptor blockers (ARBs), and aldosterone antagonists.5

The pathophysiology of HTN and the development of HF...
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### TABLE 1 Codes Used to Identify Hypertension and Comorbidities

<table>
<thead>
<tr>
<th>Medical Claim (ICD-9-CM)*</th>
<th>Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrhythmia</td>
<td>427.0, 427.3x, 427.6x</td>
</tr>
<tr>
<td>Benign prostatic hyperplasia</td>
<td>600</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>428.x, 398.91</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>585</td>
</tr>
<tr>
<td>Hypertension</td>
<td>401.x</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>411.xx, 413.x, 414.0x</td>
</tr>
<tr>
<td>Lower-extremity edema</td>
<td>782.3</td>
</tr>
<tr>
<td>Migraine</td>
<td>346.x</td>
</tr>
</tbody>
</table>

**Pharmacy Claim**

- Medispan Generic Product Identifier (GPI)
  - all 33-*, 34-*, 36-*, 37-*
- Universal System Classification (USC)
  - all 31(110, 120, 130, 140, 150, 151, 152, 153, 154, 400, 420, 700 and all 41xxx)
  - all 2404xx, 2408xx, 4028xx


### TABLE 2 Number of Subjects Lost Due to Each Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th></th>
<th>No. Lost</th>
<th>% Lost</th>
<th>No. Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTN claim or antihypertensive Rx claim</td>
<td>3,366</td>
<td>0.4</td>
<td>812,732</td>
</tr>
<tr>
<td>&lt;18 years of age</td>
<td>3,366</td>
<td>0.4</td>
<td>809,366</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>7,503</td>
<td>0.9</td>
<td>801,863</td>
</tr>
<tr>
<td>Patients identified via an Rx claim with no diagnosis of HTN, but who had a diagnosis that may have been the indication for the antihypertensive medication (e.g., BPH and an alpha-blocker)</td>
<td>26,808</td>
<td>3.3</td>
<td>775,055</td>
</tr>
<tr>
<td>Patients receiving BBs, diltiazem, or verapamil with ICD-9 codes for arrhythmia</td>
<td>2,934</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Patients receiving ACE inhibitors, spironolactone, carvedilol, diuretics, ARBs, ACE inhibitor or ARB/diuretic combinations, or hydralazine/nitrate and with ICD-9 codes for heart failure</td>
<td>4,878</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Patients receiving alpha-blockers with ICD-9 codes for BPH</td>
<td>2,789</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Patients receiving BBs, diltiazem, or verapamil, or clonidine with ICD-9 codes for migraine</td>
<td>4,555</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Patients receiving BBs or CCBs with ICD-9 codes for ischemic heart disease</td>
<td>9,524</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>Patients receiving diuretics with ICD-9 codes for lower extremity edema</td>
<td>4,015</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Patients identified by pharmacy claims who met more than one exclusion criteria</td>
<td>(-1,887)</td>
<td>-0.2</td>
<td></td>
</tr>
<tr>
<td>Random sample selected for chart review</td>
<td>767,829</td>
<td>7,226</td>
<td></td>
</tr>
<tr>
<td>HTN and heart failure confirmed in chart</td>
<td>6,935</td>
<td>291</td>
<td></td>
</tr>
</tbody>
</table>

HTN = hypertension; Rx = prescription; BPH = benign prostatic hyperplasia; BB = beta-blocker; ICD-9 = International Classification of Diseases–9th Clinical Modification; ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CCB = calcium channel blocker.

have been associated with the renin-angiotensin-aldosterone system (RAAS). The RAAS can be inhibited by blocking either the conversion of angiotensin I to angiotensin II with ACE inhibitors or by selectively blocking the binding of angiotensin II to the AT1 receptor subtype with ARBs.

Numerous randomized, prospective, placebo-controlled clinical trials have demonstrated the effectiveness of ACE inhibitors in improving survival in thousands of patients with HF. The evidence to support the use of ACE inhibitors in patients with left ventricular systolic dysfunction is strong and unambiguous. Based on this evidence, treatment guidelines have consistently recommended ACE inhibitor therapy in this population. ARBs have a similar antihypertensive effect but are better tolerated than ACE inhibitors in some patients; long-term benefits of ARBs on target-organ damage and cardiovascular events continue to be researched. The Valsartan Heart Failure Trial (Val-HeFT) demonstrated significant reductions in all-cause mortality and morbidity as well as in HF-related hospitalizations in valsartan patients with HF who were not receiving an ACE inhibitor, compared with placebo.

By understanding the epidemiology of hypertensive patients with HF in managed care and evaluating current treatment patterns, decision makers can assess whether or not deficiencies in therapy exist. In the study, the goal was to determine the prevalence of HF and cardiovascular risk factors within the hypertensive managed care population, blood pressure control levels in the hypertensive cohort with HF, and management of drug therapy for the same cohort with and without diabetes, particularly regarding the use of ACE inhibitors and ARBs.

### Methods

#### Study Description

This study was conducted using data from a national HTN quality improvement (QI) program involving 10 MCOs and 2 specialty medical groups. The MCOs were composed primarily of preferred provider organization (PPO) and health maintenance organization (HMO) members, but they also included smaller portions of point-of-service (POS) members. Each of the 2 specialty medical groups comprised more than 100 physicians: one was located in the Southeast United States and the other in the Midwest. The MCOs were distributed throughout the United States, except none were located in the Pacific Northwest.

The HTN QI program involved construction of a data warehouse containing medical and pharmacy claims as well as medical chart review data for hypertensive patients during the period of June 1998 through July 2001. From a population of about 4.6 million managed care enrollees, approximately 850,000 (18.5%) individuals with HTN were identified. From
these 850,000 members, 7,226 medical charts were randomly selected for review. Hypertensive patients with HF confirmed by provider documentation in the medical chart (n = 291) were included in the present analysis.

**Selection Criteria**

MCOs or specialty medical groups initially identified managed care members with HTN as those with a medical claim for HTN or an antihypertensive pharmacy claim during the period of June 1, 1998, through July 31, 2001. A medical claim for HTN was defined as an International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) code of 401.x within the first 5 diagnoses fields. Antihypertensive agents were identified in pharmacy claims using the Generic Product Identifier (GPI), Universal System Classification (USC), or American Hospital Formulary Service (AHFS) codes (Table 1). Each MCO and specialty medical group used only 1 coding system to identify patients with HTN. All 3 drug coding systems are common to all pharmacy claims.

Patients were excluded if they were aged <18 years or had end-stage renal disease, based on an ICD-9 code 585 (Table 2). The resulting population (n = 775,055) was considered hypertensive as identified by medical claims only (n = 240,382), pharmacy claims only (n = 276,842), or both medical and pharmacy claims (n = 257,831) (Table 3). From the population identified initially by antihypertensive (pharmacy) claims only, patients were later excluded if any medical claim contained a diagnosis code other than HTN (such as congestive HF, benign prostatic hyperplasia, ischemic heart disease, arrhythmia, migraine, or lower extremity edema). These 6 diagnoses were excluded in an attempt to capture only those patients with a principal diagnosis of HTN. However, the lack of a full medical history within the medical claims precludes us from categorizing patients identified using pharmacy claims only as hypertensive because some of the relevant diagnoses (excludable as well as HTN) may have occurred prior to the time frame represented in the data.

A total of 7,226 patients were randomly selected for chart review using medical claims only (n = 2,042), pharmacy claims only (n = 1,704) or medical and pharmacy claims (n = 257,831) (Table 3). Of these patients, 6,935 had a confirmed diagnosis of HTN but not HF in the medical chart, and 291 (+4%) patients were confirmed to have both HTN and HF. These 291 patients with HTN and HF constituted the study population.

**Data Collection**

Licensed nurses and pharmacists conducted the chart reviews to gather information on age, gender, HTN diagnosis, cardiovascular risk factors and relevant comorbidities, and systolic and diastolic blood pressure. Current antihypertensive therapy was evaluated using pharmacy claims. An HTN diagnosis was confirmed when at least 1 of the following terms was found in the patient chart: hypertension, HTN, high blood pressure, HBP, or TBP. A similar approach was used when diagnosing HF but using the following terms: HF, heart failure, CHF, or congestive heart failure. The type of HF was not differentiated. The documented HTN and HF diagnosis could have occurred at any time within the medical chart.

Consistent with JNC VI, the risk stratification criteria for hypertensive patients included diabetes, dyslipidemia, aged ≥60 years, sex (male or postmenopausal women), smoking, and family history of cardiovascular disease.

The JNC VI goal blood pressure definition for diabetic and nondiabetic hypertensives with HF—systolic/diastolic blood pressure <130/85 mm Hg—was the standard used for evaluating this study population. The representative blood pressure was defined as the blood pressure reading from the most recent visit during the year of interest, as long as the visit occurred after the diagnosis of HTN was made. If more than 1 blood pressure reading was documented during a single visit, the lowest was recorded as the blood pressure for that visit. If multiple positional blood pressure measurements were documented during a single visit (e.g., sitting, standing, and supine), only the sitting measurement was recorded. If there were supine and standing blood pressure measurements, but not sitting blood pressure, the supine measurement was recorded. A standing blood pressure measurement was recorded if it was the only one documented in the patient chart.

All antihypertensive side effects documented in the last 2 or more visits during the 12-month study period were recorded along with their associated antihypertensive regimen. Pharmacy claims were used to determine ACE inhibitor and/or ARB use in the study population. Descriptive statistics using the Statistical Analysis System (Version 8.2, SAS Institute, Inc., Cary, North Carolina) were generated for demographic characteristics, clinical indicators, and blood pressure control data.

**Results**

**Demographic Characteristics**

HF was present in 4% (n = 291) of the hypertensive patients selected for chart review (n = 7,226). Of the 291 hypertensive patients with HF identified by medical and pharmacy claims...
and confirmed by medical chart review, about half were between the age of 66 and 85 years (Table 4). The mean age for the study population was 68.3 years. A slight majority of the patients were female (52.9%), and, for the subjects with race reported, 72.7% were white (race was not documented in 40.9% of charts).

### Cardiovascular Risk Factors

Several major risk factors for cardiovascular disease were prevalent in the study population; the most common were sex (male or postmenopausal female) and age > 60 years (89.3% and 73.5%, respectively) (Table 4). Diabetes was prevalent in 38.8% of the study sample. About 91.1% of hypertensive patients with HF had more than 1 risk factor. One or more comorbidities were present in 76.6% of the study population, including angina (29.2%), coronary artery disease (28.9%), left ventricular hypertrophy (18.6%), peripheral arterial disease (15.5%), status postmyocardial infarction (14.4%), stroke (12.7%), nephropathy (8.6%), and retinopathy (4.1%).

### Blood Pressure Control

Overall, the proportion of patients with controlled blood pressure using the JNC VI goal of <130/85 mm Hg was 27.8%; 77.7% of patients had diastolic pressure controlled to goal (Table 5). Study subjects with and without diabetes were also analyzed. Of the total sample, 30.1% of the diabetic (34 of 113) (Figure 1) and 26.4% of the nondiabetic (47 of 178) patients with HF had their blood pressure controlled.

### Pharmacotherapy

Of the total cohort of hypertensive patients with HF (n = 291), claims data were available for 218 patients (Figure 2). Of these,
were not receiving any antihypertensive pharmacotherapy. A large majority of the patients receiving therapy (77.1%) were prescribed more than one therapeutic agent. The most commonly prescribed agents were diuretics (65.1%), ACE inhibitors (53.2%), calcium channel blockers (CCBs [37.2%]), and BBs (30.3%). Side effects were rarely reported in the medical charts and were even more rarely attributed to a particular antihypertensive drug. Of the 49 side effects captured in the chart review, shortness of breath (n = 7), edema (n = 6), dizziness (n = 5), and hyperkalemia (n = 5) were the most prevalent.

**Recommended Best Practices**

One third of patients with and without diabetes were not being prescribed appropriate therapy according to recommended best practice. Of all study patients receiving drug therapy (n = 218), 113 and 25 patients were receiving ACE inhibitors and ARBs, respectively (Figure 3). Three patients were receiving both agents. Of the 78 diabetic patients receiving antihypertensive therapy, 39 and 14 patients were receiving ACE inhibitors and ARBs, respectively. Of those who were nondiabetic (n=140) and on antihypertensive medication, 74 were receiving ACE inhibitors and 11 were receiving ARBs.

**Discussion**

The present study was designed to assess blood pressure control and management of drug therapy for patients with concurrent HF and HTN within a managed care setting. The study revealed opportunities to improve the management of hypertensive patients with HF. High blood pressure, a long-known risk factor for HF, is easily detectable but is poorly controlled in the United States, in general, and among diabetics, in particular. The study found that more than two thirds of the study population did not have their blood pressure controlled to target. Receiving cardioprotective therapy is a critical factor in the care of hypertensive patients with HF. We found that, although a slight majority of the cohort was receiving an ACE inhibitor, 1 of every 3 hypertensive patients with HF was not receiving either an ACE inhibitor or an ARB.

The 4% prevalence of HF in the study sample is higher than the estimated national average of 1.7% of the total U.S. population, most likely because the study subjects were older, hypertensive, and probably insured. Additionally, the study population presented other major risk factors, which have been known to significantly increase the potential for cardiovascular complications.

Approximately 28% of patients in the study achieved blood pressure control of <130/85 mm Hg. Using data from the Third National Health and Nutrition Examination Survey, Geiss et al. estimated the prevalence of elevated blood pressure among adults with diagnosed diabetes and examined the extent to which elevated blood pressure was being treated and controlled. Results showed that, among those with elevated blood pressure, 71% were aware and 57% were treated, but only...
12% had mean blood pressure <130/85 mm Hg. These findings, coupled with ours, suggest an unmet need for improving blood pressure control among these patients.

The majority of the study patients were being prescribed ACE inhibitors and diuretics, following JNC VI and JNC 7 compelling indications for HTN and HF. In lower numbers, they were also receiving BBs and ARBs, which are now recommended therapies by the JNC 7 Report. CCBs were the third most frequently prescribed antihypertensive therapy; however, with the exception of amlodipine, CCBs have been associated with an increased risk of cardiovascular events in the treatment of HF. Because CCBs are among the recommended therapies for hypertensive patients with diabetes, we analyzed the data further and found that 23% of all diabetics in the study were on CCBs and 35% of CCB users were diabetic. A recently published study of 1,220 managed care members with chronic HF also reported a similar level of CCB prescriptions filled (32%). The study could not determine the reasons for this pattern of use of CCBs in HF patients or the clinical implications it may have in this high-risk patient population.

We also observed that one third of study patients with HF were not receiving the benefits of angiotensin pathway blockade. Schmedtje et al. similarly reported that 52% of patients with chronic HF received prescriptions for ACE inhibitors and 9% received prescriptions for ARBs. One possible explanation for the subutilization of ACE inhibitors, which has been previously reported, is patient intolerance of the drug. Although as many as 67% of HF patients discharged from hospitals are prescribed ACE inhibitors, studies of outpatient visits report ACE inhibitor use of 39%, and those of community-dwelling patients indicate ACE inhibitor use between 10% and 40%.

There is increasing evidence that ARBs can improve the clinical outcomes of patients with cardiovascular disease. Valsartan, the only ARB with a U.S. Food and Drug Administration (FDA)-approved indication for HF patients, is an alternative and effective therapy for patients who are intolerant of ACE inhibitors, according to the analysis of the subgroup of HF patients not receiving ACE inhibitors in the Val-HeFT. More recently, candesartan demonstrated significant reductions in cardiovascular deaths and hospital admissions for HF in the CHARM trial, but it does not have an FDA-approved indication. The Heart Failure Society of America (HFSA) recommends the use of ARBs when HF patients are intolerant of ACE inhibitors.

The study findings reveal the presence of a vulnerable patient group within managed care that requires appropriate therapies that are cardioprotective and effective in providing better outcomes. Although national guidelines are a source of reference for adequate treatment, health plans may benefit from the inclusion of appropriate indicators that will measure and help monitor the quality of care that hypertensive patients with HF are receiving.

Study patients with diabetes are considered a high-risk group for cardiac events and, consequently, have a goal blood pressure of <130/85 mm Hg, according to JNC VI, and a more stringent blood pressure goal of <130/80 mm Hg in the recent JNC 7 and American Diabetes Association (ADA) recommendation. Diabetic patients constituted more than one third of our study group. Previous studies indicate that diabetic patients are more...
likely to receive recommended therapy but seldom reach blood pressure control goal levels. Although treatment for diabetic patients was comparable to our overall study population, blood pressure control of 30% is of equal concern for this high-risk group. Other managed care studies have documented similar findings. More importantly, however, one third of the study patients with diabetes were not receiving ACE inhibitors, as recommended by JNC VI best practice, or ARBs as recommended by the ADA when patients are intolerant of ACE inhibitors. The JNC 7 Report states that antihypertensive therapies based on ACE inhibitors or ARBs favorably affect the progression of diabetic nephropathy and reduce albuminuria. Patients with diabetes as a comorbidity should be treated following established guidelines to ensure the best possible outcomes.

MCOs may implement educational programs to improve the care of hypertensive patients with HF. Continuing education teleconferences may be a cost-effective method for health plans with geographically dispersed physician sites. Lunch-and-learn sessions provide a similar alternative for those plans with large physician practices. Academic detailing visits, which are more resource consuming, are a good option for physicians with large pools of hypertensive patients with HF; as they provide a more suitable setting for physician profiling discussions and the delivery of individual patient profiles.

Limitations
Medical and pharmacy claims databases were used to identify patients as hypertensive. For the approximately one third of patients who were identified as using pharmacy claims only, an HTN diagnosis could not be confirmed. However, confirmation of an HTN diagnosis was achieved for all patients in the study population (N = 291) at the chart review step. Because the sample pool excluded patients receiving antihypertensive drugs for indications other than HTN (such as HF), the study population with HF was relatively small. Consequently, the results may not be generalizable to a wider population. Given its cross-sectional design, the study observed levels of blood pressure control and the type of antihypertensive therapy being used in a hypertensive population with HF at a specific time. Therefore, no observations over time or temporal associations could be established.

The study was conducted on administrative (claims) data from mid-1998 through mid-2001, and it is possible that more recent data may show some improvement in the proportion of these higher-risk patients who are using ACE inhibitors or ARBs. Because there was no patient follow-up, issues of treatment compliance and patient outcomes were not studied. We also did not examine the use of appropriate doses of ACE inhibitors and ARBs, which may have affected the percentage of patients receiving adequate treatment. Clinical data gathered in the study did not include ejection fraction or type of HF; an important indicator for adequate treatment in HF patients. Since the data collected for the study occurred within the context of a national HTN QI program, we did not collect clinical detail about the type or severity of HF in the chart reviews. Possible undercoding within the administrative data may have potentially excluded hypertensive patients with an HF diagnosis.

Conclusions
The study results indicate that among subjects with HTN and HF, a deficit in the treatment of HTN exists. More than two thirds of the patients in the study did not have their blood pressure controlled to the JNC VI goal target level. Also, almost one third of patients did not receive the clinical benefit of angiotensin pathway blockade through the use of ACE inhibitors or ARBs. The data suggest a medical deficit in the treatment of this patient population with or without diabetes. More aggressive QI programs are needed to educate providers and patients of the importance of using antihypertensives proven to be beneficial for hypertensive patients with HF and titrating these antihypertensives to doses sufficient to achieve target blood pressure goals.

Acknowledgments
We would like to acknowledge the following individuals for their assistance in this study and with preparation of this manuscript: Annamaria Cerulli, MPH, independent consultant, Hoboken, New Jersey; Eileen Farrelly, MPH, senior consultant, Applied Health Outcomes, Palm Harbor, Florida; Samantha Hibler, project coordinator, Health Economics and Outcomes Research, Novartis Pharmaceuticals Corporation, East Hanover, New Jersey; Scott McKenna, DO, MPH, vice president of quality improvement, and Scott Sabrsula, RPh, director of pharmacy, Firstcare, Austin Texas.

Disclosures
Funding for this research was provided by Novartis Pharmaceuticals Corporation and was obtained by author James H. Jackson IV. Author Feride...
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Frech is employed by Novartis. Jackson and authors Revital Ronen, Lawrence Mullany, Barbara Lennert, and Vrush Jhaveri disclose no potential bias or conflict of interest relating to this article. The principal study findings were presented at the 6th Annual Scientific Meeting of the Heart Failure Society of America, Boca Raton, Florida, September 23, 2002. Jackson served as principal author of the study. Study concept and design were contributed by all authors. Analysis and interpretation of data and drafting of the manuscript were the work of Jackson and Frech; critical revision of the manuscript was the work of all authors. Statistical expertise was contributed by Jackson, Annamaria Cerulli, and Eileen Farrelly.

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