Medicare Coverage of Tumor Necrosis Factor α Inhibitors as an Influence on Physicians’ Prescribing Behavior

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Background: Rheumatoid arthritis is a chronic debilitating disease that affects 1% of the population. Tumor necrosis factor α inhibitors, such as etanercept and infliximab, have revolutionized the treatment of rheumatoid arthritis by averting disability but at great financial expense, generally borne by third-party payors. Prior to implementation of the Medicare Modernization Act, Medicare reimbursed for the infusion drug infliximab but not for the self-injectable drug etanercept. To determine the impact of this differential Medicare drug coverage on physicians’ prescribing behavior in clinical practice, we analyzed patterns of prescribing etanercept and infliximab for patients with rheumatoid arthritis who had public insurance compared with those who had private insurance.

Methods: We conducted an observational cohort study of 1663 patients with rheumatoid arthritis newly prescribed etanercept or infliximab after enrollment in the National Databank for Rheumatic Diseases. Univariate and multivariable analyses of patient demographic and disease characteristics were conducted to characterize predictors of the biologic drug prescribed.

Results: Treatment groups who received etanercept and infliximab differed in 6 of 8 demographic variables and in 8 of 10 disease variables. However, stratification by type of insurance reduced many of these differences. In multivariable analyses, type of insurance plan and demographic factors were strong predictors of differential prescribing of etanercept compared with prescribing of infliximab, whereas disease characteristics generally were not. Patients with public insurance were 30% more likely to receive infliximab than those who were privately insured (P<.001).

Conclusions: Public insurance predicted prescription of infliximab, reflecting preferential Medicare reimbursement for infusion drugs. Financial considerations are influential in physicians’ prescription decisions. Differential drug coverage has an impact on patient care and health care costs because it influences physicians’ prescribing behavior.

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The cost of both drugs is high. Mean annual acquisition costs for etanercept have been reported to be between $10 159$ and $12 648$; for infliximab, they have been reported to be between $12 610$ and $13 470$. However, additional costs associated with infliximab make it relatively more expensive than etanercept. The total annual cost of infliximab has been reported to be approximately $17 658$ because of infusion costs and a product labeling requirement for concurrent use of methotrexate.
Despite similar drug efficacy, insurance reimbursement policies may provide incentives for differential prescribing. The former Medicare policy was to reimburse for physician-administered drugs under Part B—including both infusion and injectable (intramuscular) drugs—but not to reimburse for self-injectable (subcutaneous) drugs. Thus, at least for Medicare beneficiaries, physicians may have had an incentive to prescribe the infusion drug infliximab rather than the self-injectable drug etanercept. The Medicare Modernization Act (effective January 1, 2006) allows beneficiaries to choose a new drug coverage option that will partially offset the cost of the self-injectable drug etanercept. However, under the standard drug plan, people with incomes over 150% of the federal poverty level will face more than $3600 in out-of-pocket costs.

In-office infusion centers have been established by some rheumatology practices to provide a service to patients who would otherwise need to go to a hospital for infliximab infusion. Operation of practice-based infusion centers generates revenue. Thus, those physicians affiliated with an infusion center may have a personal financial incentive to prescribe infliximab.

This article reports our analysis of etanercept and infliximab prescribing patterns in an observational cohort of patients with RA as a case study of the impact of economic incentives on physicians’ prescribing behavior. Because of differential reimbursement for self-injectable drugs compared with intravenous drugs, we expected that prescribing would be associated with type of insurance. We considered that prescribing might also be associated with demographic characteristics because these characteristics may themselves be associated with either an insurance plan or a patient’s drug preferences (eg, employed individuals may prefer home injection over in-office infusion, or an older person might not have the manual dexterity to self-inject). In addition, geographic variation in medical care is another factor to consider in characterization of prescribing patterns. However, we did not expect disease variables to be predictive of the drug prescribed because the reported efficacy of the 2 biologic drugs is similar. Thus, we hypothesized that controlling for insurance plan would account for differences in patient characteristics observed between the treatment cohorts.

METHODS

STUDY DESIGN AND POPULATION

We conducted a retrospective cohort study by using data from the National Databank for Rheumatic Diseases, a longitudinal database of semi-annual patient self-reported data representing patients referred by practicing rheumatologists nationwide. Since 1998, the National Databank for Rheumatic Diseases has collected data on demographics, functional disability, disease severity, quality of life, comorbidity, and medication use. More than 12 000 patients with RA contribute to the database, described extensively elsewhere.

STUDY SAMPLE AND OUTCOME VARIABLE

Patients were included for analysis if they were enrolled in the databank before December 2002 and if they initiated treatment with either etanercept or infliximab between June 2000 and December 2003. The Food and Drug Administration approved both etanercept and infliximab for treatment of RA in November 1998 and November 1999, respectively. We selected June 2000 as the earliest date of initiation because by that time use of both biologic drugs was well established. To characterize prescribing patterns as they occurred in routine practice, we excluded patients for analysis if their enrollment was through a pharmaceutical company-sponsored drug safety registry. The 160 patients who subsequently switched to a different biologic drug were also excluded. The source data set consisted of 1920 patients with RA. Of this group, the subset of 1663 patients with complete data on the variables of interest comprised the analytic sample. The patients were referred from the practices of 413 rheumatologists.

The outcome of interest in all analyses was the initially prescribed biologic drug.

PREDICTIVE VARIABLES

Eighteen items (8 demographic and 10 disease characteristics) measured in patient self-reported questionnaires were considered for inclusion as explanatory variables in development of a predictive model for choice of biologic drug. We analyzed the data reported in the last questionnaire before biologic drug initiation.

The 8 demographic factors included in the analysis were type of insurance, age, sex, race, marital status, income, education, and employment status. Analysis of type of insurance was performed in 2 ways. First, insurance was broadly categorized as either private or public. Patients coded as privately insured were self-identified as having either private insurance or insurance through a health maintenance or preferred provider organization. Patients coded as publicly insured were self-identified as having Medicaid, Medicare health maintenance organization (“Medicare health maintenance”), or Medicare fee-for-service (“Medicare”) insurance. Second, because drug coverage benefits varied among the types of public insurance, we further categorized public insurance into 2 groups: (1) public insurance with a generous prescription benefit plan that was likely to cover etanercept (Medicaid) and (2) public insurance with either a modest prescription benefit plan (Medicare health maintenance) or no prescription benefit plan (Medicare).

Age was considered in model development both as a continuous variable and as a dichotomous variable (<65 years vs ≥65 years). This cutoff was chosen to account for the effect of Medicare eligibility at age 65 years. We used these 2 specifications of age to look for independent additive effects.

The 10 disease characteristics included in the analysis were duration of disease, functional disability score (Health Assessment Questionnaire), global severity score, Short Form-36 (SF-36) physical component score, SF-36 mental component score, pain scale, and 2 comorbidity scores (1 whether the respondent ever had comorbidities and 2 presence of current comorbidities, treatment with methotrexate, and treatment with prednisone).

To investigate geographic differences in biologic drug prescription, we assigned patients by their 3-digit ZIP codes to 1 of the 10 Center for Medicare and Medicaid Services (CMS) regions.

STATISTICAL ANALYSES

We tested our hypotheses about the associations between the candidate predictive variables and the prescription of etaner-
cept or infliximab by comparing the characteristics of patients prescribed the drugs by use of the t test for continuous variables and \( \chi^2 \) tests for categorical variables. We then stratified patients by whether they had public or private insurance and statistically compared the demographic and disease characteristics of these subgroups.

We used multivariable logistic regression models to identify independent predictors of biologic prescription choice. All 18 candidate variables were considered for inclusion in the predictive model. The final model was specified by use of a backward-selection algorithm, sequentially removing the variable with the highest \( P \) value, refitting the model with remaining terms, and using a significance level of \( P \leq .20 \) as the criterion for inclusion in the model.

We assessed univariate and multivariable associations between public (vs private) insurance and biologic drug prescribed. We further assessed whether these associations were modified by having a prescription drug benefit that would likely cover etanercept. We did so by using privately insured patients as the reference group and by calculating the odds ratios (ORs) for infliximab prescriptions for publicly insured patients grouped by whether their public insurance was likely to have a prescription drug benefit plan that would cover etanercept.

To assess for geographic variation in prescriptions among the publicly insured, we performed univariate analyses of prescription by CMS region. To determine whether geographic variation influenced the predictive multivariable model we performed a conditional logistic regression analysis of the entire sample by CMS region.

Statistical analyses were conducted with Stata statistical software (version 8.0; StataCorp, College Station, Tex).

### Results

Of the patients in the overall sample, 704 (42.3%) were prescribed etanercept, and 959 (57.7%) were prescribed infliximab (Table 1). Eight hundred eighty-one patients (53%) had private insurance; 782 (47%) had public insurance, with the following distribution: 76 (4.6%), Medicaid; 69 (4.1%), Medicare health maintenance; and 637 (38.3%), Medicare.

Univariate analyses of demographic characteristics indicated that patients who received etanercept were less likely to have public insurance (29.0% vs 60.3%; \( P < .001 \)) than were patients who received infliximab (Table 1). In addition, analyses indicated that 5 of the remaining 7 demographic characteristics of patients who received etanercept differed significantly from those of patients who received infliximab (Table 1). Compared with the infliximab cohort, patients receiving etanercept on average were 6.9 years younger (\( P < .001 \)) (see age distribution in the Figure) and were less likely to be 65 years or older (17.8% vs 47.3%; \( P < .001 \)). Patients receiving etanercept were more likely to be married (75.9% vs 71.3% for those receiving infliximab; \( P = .04 \)), had a \$10,800 higher average annual income (\( P < .001 \)), received 0.5 years more of education (\( P < .001 \)), and more often had paid employment (47.7% vs 26.4%; \( P < .001 \)).

Univariate analyses also indicated that 8 of the 10 disease characteristics of patients who received etanercept
differed significantly from those who received infliximab (Table 1). They had had their disease for 2.1 fewer years \((P<.001)\). They also had 0.16-point lower Health Assessment Questionnaire functional disability scores \((P<.001)\), 0.3-point lower global severity scores \((P=.02)\), 2.1-point higher SF-36 physical component scores \((P<.001)\), 1.4-point higher SF-36 mental component scores \((P=.02)\), and lower comorbidity scores. Finally, they had a lower probability of being prescribed methotrexate (51.4% vs 66.4%; \(P<.001)\).

Stratification by public vs private insurance tended to narrow the differences in both the demographic and disease characteristics of those prescribed the 2 drugs (Table 1). Although still statistically significant, the 6.9-year difference in age between overall treatment groups narrowed among the privately insured to only 1.0 year and among the publicly insured to 4.5 years. Differences in years of education were also reduced. Within insurance-stratified cohorts, statistically significant differences between treatment groups in percentage married, income, and percentage with paid employment were eliminated. Income differences dropped to $3000 among privately insured and to $2600 among publicly insured patients. A new difference emerged among publicly insured patients in proportion of white vs nonwhite patients treated with each drug.

Of the 8 disease characteristics significantly different in univariate analyses, 3 were no longer significant after stratification: disease duration, global severity, and current comorbidity. Differences in Health Assessment Questionnaire scores, SF-36 physical and mental component scores, and ever having a comorbidity were reduced. The 0.16 difference in Health Assessment Questionnaire scores fell to 0.08 among privately insured patients and to 0.05 among the publicly insured. In contrast, group differences widened for pain score and for the proportion of patients prescribed methotrexate.

In comparison with the reference group of patients with private insurance, the univariate OR for the association between public insurance and prescription of infliximab was 3.72 (95% confidence interval [CI], 3.00-4.60) (Table 2). When we stratified publicly insured patients by whether their insurance was more or less likely to have a prescription benefit plan that covered etanercept, we found that the OR for prescription of infliximab for publicly insured patients who were likely to have a prescription benefit plan was 1.80 (95% CI, 1.12-2.91), and it was 4.07 (95% CI, 3.24-5.13) for publicly insured patients who were less likely to have a prescription benefit plan. The univariate OR for the association between public insurance and prescription of infliximab was 3.72 (95% CI, 3.00-4.60) (Table 2).

**Table 2. Unadjusted Odds Ratios (ORs) of Prescription of Infliximab Relative to Etanercept in Publicly Insured Patients**

<table>
<thead>
<tr>
<th>Type of Insurance</th>
<th>Unadjusted OR (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Public (vs private)</td>
<td>3.72 (3.00-4.60)</td>
</tr>
<tr>
<td>Prescription benefit</td>
<td>1.80 (1.12-2.91)</td>
</tr>
<tr>
<td>No prescription benefit</td>
<td>4.07 (3.24-5.13)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; HMO, health maintenance organization; PPO, preferred provider organization.

*Public insurance: Medicaid, Medicare HMO, or Medicare; private insurance: private, HMO, or PPO; public insurance with prescription drug benefit: Medicaid; public insurance with modest or no prescription drug benefit: Medicare HMO or Medicare.

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Figure. Distribution of age, stratified by biologic drug prescription (etanercept, A, and infliximab, B).
Table 3. Adjusted* Odds Ratios (ORs) for Infliximab Use Relative to Etanercept

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance coded as public or private</td>
<td>2.01 (1.34-3.02)</td>
</tr>
<tr>
<td>Age, &gt;65 y</td>
<td>1.91 (1.26-2.87)</td>
</tr>
<tr>
<td>Age, in decades</td>
<td>1.13 (0.99-1.30)</td>
</tr>
<tr>
<td>Education, y</td>
<td>0.94 (0.80-0.98)</td>
</tr>
<tr>
<td>Public insurance, prescription benefit</td>
<td>1.15 (0.68-1.94)</td>
</tr>
<tr>
<td>Public insurance, no prescription benefit</td>
<td>2.02 (1.47-2.78)</td>
</tr>
<tr>
<td>SF-36 physical component score (in 5-point increments)</td>
<td>0.94 (0.89-0.99)</td>
</tr>
<tr>
<td>Treatment with methotrexate</td>
<td>2.01 (1.62-2.49)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; SF-36, Short-Form 36.
*Adjusted for other variables in the fully specified model. Predictive variables in full model: age (dichotomous and continuous), education level, type of insurance, SF-36 physical component score, and treatment with methotrexate. Variables that did not meet criterion for inclusion, that is, \( P > .20 \), were sex, race, marital status, income, paid employment, disease duration, Health Assessment Questionnaire score, global severity score, SF-36 mental component score, pain score, comorbidity (ever and now) scores, and prednisone use.

Table 4. Adjusted* Odds Ratios (ORs) for Infliximab Use Relative to Etanercept Stratified by Center for Medicare and Medicaid Services (CMS) Region†

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance coded as public or private</td>
<td>1.95 (1.28-2.96)</td>
</tr>
<tr>
<td>Age, &gt;65 y</td>
<td>1.91 (1.26-2.87)</td>
</tr>
<tr>
<td>Age, in decades</td>
<td>1.13 (0.99-1.30)</td>
</tr>
<tr>
<td>Education, y</td>
<td>0.94 (0.80-0.98)</td>
</tr>
<tr>
<td>Public insurance, prescription benefit</td>
<td>1.89 (1.37-2.58)</td>
</tr>
<tr>
<td>Public insurance, no prescription benefit</td>
<td>0.93 (0.88-0.99)</td>
</tr>
<tr>
<td>SF-36 physical component score (in 5-point increments)</td>
<td>1.93 (1.55-2.42)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; SF-36, Short-Form 36.
†Stratified by the 10 CMS regions: I, Boston, Mass; II, New York, NY; III, Philadelphia, Pa; IV, Atlanta, Ga; V, Chicago, Ill; VI, Dallas, Tex; VII, Kansas City, Kan; VIII, Denver, Colo; IX, San Francisco, Calif; X, Seattle, Wash.

insured patients who were unlikely to have a prescription drug plan.

Univariate assessment of biologic drug prescription to publicly insured patients by CMS region revealed a relative increase in infliximab prescription in the Kansas City, Kan, region (OR, 2.75; 95% CI, 1.27-5.97) and relative decrease in infliximab prescription in the New York, NY, region (OR, 0.26; 95% CI, 0.11-0.64) compared with the other 8 regions (data not shown).

In multivariable analysis, 6 variables (type of insurance, the dichotomous and continuous age terms, education level, SF-36 physical component score, and treatment with methotrexate) were significant independent predictors of biologic drug prescription choice (Table 3). The variables that most favored prescription of infliximab over etanercept were treatment with methotrexate (OR, 2.03; 95% CI, 1.64-2.51), age (>65 years) (OR, 2.01; 95% CI, 1.34-3.02), and public insurance plan (OR, 1.82; 95% CI, 1.45-2.47). Increases in the continuous variable representing age also influenced infliximab prescription (OR, 1.14 for a change of 10 years; 95% CI, 1.00-1.31). Education level and the SF-36 physical component score were also statistically significant. The full predictive model achieved a C statistic of 0.72. Conditional logistic regression stratified on the 10 CMS geographic regions did not significantly alter the predictive model (Table 4).

When we repeated the multivariable analysis with publicly insured patients grouped by whether their public insurance was likely to have a prescription drug benefit plan that would cover etanercept, we found that, compared with those with private insurance, the OR for prescription of infliximab for publicly insured patients who were more likely to have a generous prescription benefit plan was 1.15 (95% CI, 0.68-1.94), which was not significantly different from the reference private insurance group (Table 3). In contrast, the OR for prescription of infliximab among publicly insured patients who were likely to have little or no prescription drug coverage increased to 2.02 (95% CI, 1.47-2.78).

Type of insurance was an important predictor of the drug prescribed in both univariate and multivariable analyses. Independent of other explanatory variables, patients who had public insurance had a 30% greater chance of being prescribed infliximab than those who had private insurance. (This 30% relative risk differs from the 1.82 OR because the probability of having a prescription for infliximab in the private insurance group is greater than 10%.) Further evidence for this finding comes from the fact that when we stratified the variable representing public insurance by a measure of the likelihood that it had a prescription drug plan that covered etanercept, we found that etanercept was most often prescribed to those with either private insurance or those with public insurance that was likely to have a prescription drug plan that covered etanercept, and less often to those with public insurance that was unlikely to have such a prescription drug plan. As we predicted, univariate, stratified, and multivariable analyses also indicated that physicians are factoring demographic characteristics into their prescribing decisions. Geographic differences in prescription of infliximab to publicly insured patients were noted; however, this variation did not account for the findings of the predictive model.

Our univariate finding that 8 of 10 disease characteristics differed significantly between those who received etanercept and infliximab might suggest that physicians are also using clinical variables in their biologic drug prescription choices. However, both stratification by insurance status (which reduced or eliminated most of these differences) and multivariable analysis (in which few dis-
Preferential prescribing of infliximab rather than etanercept provides yet another example of how Medicare’s unequal reimbursement for different treatments affects physicians’ choice of therapies. For example, when Medicare increased its fees for breast-conserving surgery with radiation relative to mastectomy, the probability that women received breast-conserving surgery with radiation treatment of their breast cancer increased. More generally, the preferential prescribing provides additional evidence for the claim that financial incentives are an effective means for modifying physician behavior. Physicians are considered to be rational economic actors in the model by McGuire and Pauly, guided by the counterbalancing forces of profit maximization and achievement of a target income level.

However, motivations underlying the preferential prescribing of infliximab are most likely multifactorial and may be reinforcing. Physicians may have patients’ financial interest in mind when prescribing better-reimbursed, high-cost therapies rather than less well reimbursed, lower-cost therapies, and they may gain intangible professional rewards from acting as the financial agent for their patients. Given the evidence that compliance with filling and taking prescriptions is enhanced when drugs are affordable, such prescribing can also confer clinical benefits. At the same time, physician proprietors of practice-based infusion centers may, in part, make prescription choices with their own financial interest in mind. These centers provide additional profits for the practice when patients are treated with reimbursed infusion drugs. Indeed, based on the literature on financial incentives, this behavior is anticipated.

LIMITATIONS

The data used in this analysis were all derived from patient self-reports; we did not have prescription information from physicians. The fact that the area under the receiver operating characteristic curve for our multivariable predictive model was 0.72 indicates that although the curve was predictive, we were not able to capture all of the explanatory factors that go into physicians’ prescribing decisions. For example, we were limited by our inability to assess physicians’ practice style, whether physicians had an economic stake in infusion centers, patient preferences, and patient dexterity. We also were limited by our inability to obtain information on supplemental health insurance or drug coverage. Nevertheless, there was a strong signal that insurance plan affected prescribing decisions.

IMPACT OF MEDICARE CHANGES

Although it remains to be seen how the Medicare Modernization Act will alter the current patterns of prescription, given the $2850 “donut hole” for which patients would be liable, the impact is likely to be modest. In our sample, the average income of publicly insured patients receiving infliximab was $33,500, which is more than 150% of the federal poverty level for a family of 4. The out-of-pocket expense of over $3600 for etanercept would be greater than 10% of income. Although recent cuts in reimbursement for cost of infusion drugs may reduce the financial incentives to physicians who are associated with practice-based infusion centers, savings from the cuts may be offset by increased payment for infusion services.

In conclusion, insurance plan and demographic factors were strong predictors of physician prescribing of the biologic drugs etanercept and infliximab, whereas disease characteristics generally were not. The recent Medicare policy of preferential reimbursement for infusion therapies vs self-injectable drugs inadvertently may be increasing health care costs by promoting use of the costlier of 2 equivalent drugs.

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Author Contributions: Dr Morgan DeWitt had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Role of the Sponsors: The funding organizations had no role in the design and conduct of the study; in the collection, management, analysis, and interpretation of the data; or in the preparation, review, or approval of the manuscript.

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Error in Table. In the Original Investigation by Morgan DeWitt et al titled “Medicare Coverage of Tumor Necrosis Factor α Inhibitors as an Influence on Physicians’ Prescribing Behavior,” published in the January 9 issue of the ARCHIVES (2006;166:57-63), some errors occurred in Table 1 on page 59. Under the column heading “Private Insurance,” for infliximab, the correct value for n is 381. Under the column heading “Public Insurance,” for etanercept, the correct value for n is 204. For infliximab, the correct value for n is 578.