ABSTRACT

OBJECTIVE: To consider the extent, nature, and range of risk arrangements between physician groups and health maintenance organizations (HMOs) for self-administered injectable (SAI) drugs; to examine types and frequencies of SAI drug-use management strategies adopted by physician groups; and to explore the relationship between locus and level of financial risk for SAI and physician group strategy adoption.

METHODS: We used a multiple case-study design to select physician groups and their health maintenance organization (HMO) contractual partners in 4 markets in the United States (Northwest, Northeast, Midwest, Southwest). Physician groups in these markets were chosen based on size (≥50 physicians) and experience with drug risk (≥1 year). Physician groups were asked to identify their 3 major HMO contractual partners in each market. Telephone interviews were conducted from January 2000 to June 2001, with the resulting purposive sample of 37 individuals representing 20 physician groups.

RESULTS: We found that the level and locus of SAI financial risk were related to the adoption of management strategies. Physician groups with higher financial risk for SAI adopted more strategies than lower-risk groups. Groups with SAI financial risk in the pharmacy-risk budget (PRB) averaged 1.5 strategies per group. Groups with SAI financial risk in both the MSC and PRB fell in-between, averaging 4.5 strategies per group. The most frequently adopted strategy was designing evidenced-based therapeutic guidelines, i.e., protocols based on evidence from the peer-reviewed literature used to guide physicians in the treatment of typically chronic conditions (9 groups, 45% of sample). The second most common strategy involved adapting the existing utilization management system to process SAIAs (7 groups, 35%) and the establishment of office procedures for internal authorization (5 groups, 25%). The least frequently used strategies were determining amount paid to out-of-group physician providers (1 group, 5%) and hiring personnel (e.g., pharmacists) in claims or utilization management departments to implement and manage SAI programs (1 group, 5%). We also identified potential factors that increased the likelihood of strategy adoption and that could slow the rate of SAI cost increases.

CONCLUSION: Our findings suggest that adoption of SAI drug-use management strategies may be more likely to occur when there is a minimum level of risk for SAI drug costs. Likewise, both the adoption of strategies and the opportunity to slow the rate of SAI cost increases may be more likely to occur when 3 additional factors are present: a contractual environment conducive to controlling SAI drug costs, the ability to implement SAI drug-use management strategies, and power in negotiations with drug manufacturers to reduce SAI prices. A sustainable and affordable SAI financial risk management program maximizing these factors while minimizing the financial burden for patients will require collaboration among all stakeholders, payers, providers, drug manufacturers, and patients.

KEYWORDS: Self-administered injectable drugs, Physician group, Risk, Drug-use management strategy

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The advent of high-cost, self-administered injectable drugs (SAIs) represents an important emerging issue within one of the fastest-growing subcomponents of drug costs. An SAI is defined as a prescription for an injectable medication written by a provider, filled by a pharmacy, and administered at home by the patient or caregiver. (While these drugs also may be administered in a variety of settings [physician’s office or clinic], this study focuses on those drugs self-administered at home.)

Injectable drugs that can be self-administered have made possible the treatment of conditions for which there were formerly very limited or no therapeutic options. For example, self-administered injectable interferons, especially in combination with ribavirin, have dramatically increased the percentage of hepatitis C patients with positive clinical and virological outcomes. The Medical Advisory Board of the National Multiple Sclerosis Society recommends initiation of the self-administered injectables beta interferons or glatiramer acetate, following a diagnosis of multiple sclerosis with a relapsing course. Rheumatoid arthritis (RA) can be treated with etanercept, adalimumab, or anakinra, all of which are SAIs. SAs are now also used to treat, anemia, neutropenia, deep-venous thrombosis previously requiring hospitalization for treatment, infertility, growth hormone deficiency, migraines, and diabetes.

These medical advances, however, come at a price. Table 1 shows the average monthly cost for commonly used SAI medications. Expenditures for biotechnology products such as SAIs are expected to grow faster than oral prescription drug costs, which are projected to increase by 70% over the next 5 years.

Authors

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Importantly for patients, the cost of an individual course of treatment with SAIs far exceeds that of oral medications. The average cost per prescription of the top 50 new drugs introduced between 1992 and 2000 was $86.48. Of those drugs, the 4 that were SAIs had an average cost of $900.12 per prescription. The average wholesale price for SAIs for multiple sclerosis for 1 month ranges from $900 to $1,300. Etanercept (Enbrel), an SAI used to treat RA, has an average wholesale price of more than $1,100 for 1 month of treatment.13

Because SAIs are often used to treat chronic conditions, these costs take on even greater significance for both patients and the health care system. Depending on insurance coverage, patient costs for SAIs can represent a significant burden. For example, in mid-May 2002, federal health officials announced that Medicare would cover interferon beta-1a (Avonex) for multiple sclerosis but not 3 other commonly prescribed MS medications and not other injectable drugs that Medicare beneficiaries self-administer more than 50% of the time.14

SAI drugs have existed since the introduction of insulin, but the more recent introduction of several high-cost SAIs highlight the dilemma that advances in biotechnology pose to the health care system, namely, how to balance cost and care. These challenges are not unique to SAIs since oral drugs represent the fastest-growing component of health care costs, but the cost per treatment with SAIs far surpasses the average cost per treatment with most oral drugs.

Of particular concern is the appropriate distribution of financial risk among physician groups, insurers (e.g., health maintenance organizations [HMOs]), and patients. In the case of oral prescription drugs, one method has been the transfer of risk for drug costs from HMOs to physician groups. However, given the potentially enormous financial losses involved, some physician groups were less willing or less able to assume contracts carrying risk for oral prescription drugs. Other groups, convinced that such risk could be managed profitably with the adoption of specific management strategies, were more willing to assume such contracts.15 Evidence suggests that physician groups in California had been trying to shift back to HMOs their financial risk for injectable drugs administered in the physician’s office,16 and, effective July 1, 2003, California law required HMOs to offer to take back the financial risk from physician groups for injectables.17

As with oral prescription drugs, the rapid growth of SAI drug costs has made the distribution of financial risk for SAIs a contentious issue. In many cases, HMOs have transferred financial risk for SAIs to physician groups. However, there are no empirical studies examining how physician groups have responded to the cost pressures associated with existing SAI drug-risk arrangements and the extent to which they have adopted strategies to manage significant increases in SAI drug costs and utilization. This is important given that a premise underlying managed care is that assumption of financial risk will spur changes in physician group behavior to manage the risk,21 such as the adoption of innovations.

Some studies have examined risk arrangements for oral drugs among health plans and physician groups.22,23 One case study of a northern California multispecialty physician group found that adoption of multiple SAI drug-use management strategies resulted in cost-savings of $271,000 over the initial 6-month period, 32% of the SAI drug budget.24 However, no study has looked exclusively at SAIs and management strategies across physician groups.

Studying current SAI drug-risk arrangements is central not only for understanding the dynamics of this increasingly important area of health care spending but also for its potential to shed light on the broader, critically important policy issue of how financial risk for increasingly expensive prescription drugs should be spread among key stakeholders in the health care system. Given the absence of any systematic analysis of SAI drug-risk arrangements in the literature, we undertook the current study with 3 goals in mind: first, to consider the extent, nature, and range of SAI-risk arrangements between physician groups and HMOs; second, to examine the types and frequencies of SAI drug-use management strategies adopted by physician groups; and third, to explore the relationship between locus and level of financial risk for SAIs and the number of strategies adopted by the physician group.

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**TABLE 1**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity</th>
<th>Indication</th>
<th>Average Cost Per Montha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avonex 30 mcg</td>
<td>4 vials</td>
<td>Multiple sclerosis</td>
<td>$943.98</td>
</tr>
<tr>
<td>Betaseron 0.25 mg</td>
<td>15 vials</td>
<td>Multiple sclerosis</td>
<td>$1,099.99</td>
</tr>
<tr>
<td>Copaxone</td>
<td>1 kit of 30 prefilled syringes</td>
<td>Multiple sclerosis</td>
<td>$940.99</td>
</tr>
<tr>
<td>Rebul 44 mcg/0.5cc</td>
<td>12 pack of prefilled syringes</td>
<td>Multiple sclerosis</td>
<td>$1,209.99</td>
</tr>
<tr>
<td>Enbrel 25 mg</td>
<td>8 vials</td>
<td>Rheumatoid arthritis</td>
<td>$1,089.99</td>
</tr>
<tr>
<td>Humira</td>
<td>2 vials</td>
<td>Rheumatoid arthritis</td>
<td>$1,159.87</td>
</tr>
<tr>
<td>Peg-Interon 120 mcg</td>
<td>4 kits</td>
<td>Hepatitis C</td>
<td>$1,223.96</td>
</tr>
<tr>
<td>Pegasis 180 mcg</td>
<td>1 kit</td>
<td>Hepatitis C</td>
<td>$1,349.95</td>
</tr>
<tr>
<td>Procrit 20,000 units</td>
<td>4 vials</td>
<td>Anemia</td>
<td>$1,003.92</td>
</tr>
<tr>
<td>Epogen 4,000 units</td>
<td>12 vials</td>
<td>Anemia</td>
<td>$587.88</td>
</tr>
<tr>
<td>Lovenox 100 mg</td>
<td>20 x 1 ml syringes</td>
<td>Deep venous thrombosis</td>
<td>$1,081.89†</td>
</tr>
</tbody>
</table>

† Price for a 4-week or 30-day supply.
‡ Price for 10 days of therapy.
Methods

Case-Study Methodology and Sample Selection
This study was conducted as part of a larger study conducted from January 2000 through June 2001 that examined drug-risk arrangements between physician groups and their HMO contractual partners.23 We used a multiple case-study design to select physician groups and their HMO contractual partners in a 2-stage process.

In stage 1, we selected 4 markets, each composed of a single metropolitan area, within which the physician groups under study were chosen. One goal was to identify markets with significant managed care penetration (i.e., greater than 30% of market share). We accomplished this by reviewing markets selected by the Center for Studying Health System Change for its Community Tracking Studies and markets described by the University Health System Consortium.24 We then considered geographic diversity in selecting markets. To protect confidentiality, the markets are described by region of the country in which they are located: Northwest (NW), Southwest (SW), Midwest (MW), and Northeast (NE).

In stage 2, physician groups in these markets were chosen based on size (≥50 physicians) and experience with drug risk (≥1 year). Physician groups were then asked to identify their 3 major HMO contractual partners in each market.

Telephone interviews with the resulting purposive sample of 37 individuals representing 20 physician groups were conducted between January 2000 and June 2001. One or two individuals in each physician group were interviewed using a semi-structured protocol that lasted an average of 60 to 90 minutes and included both closed and open-ended questions (see Survey). Interviewees included medical directors (12), pharmacy directors (14), clinical pharmacy specialists or managers (2), finance officers (2), and chief executive officers or other physician group executives (7). Respondents reported the locus of SAI drug risk in 3 categories (medical services capitation, pharmacy-risk budget (PRB), or the pharmacy-risk budget (PRB)). The MSC is the monthly capitation payment (per member per month) that is paid to the physician group by the HMO for all medical services. When SAI drug costs were part of the PRB, the level of SAI drug risk was equal to that of oral medications. For example, in a physician group with HMO-risk contracts placing the group at 50% risk for oral prescription drug costs, if the SAI drug costs were part of the PRB, the SAI risk level also was considered equal to 50%. In some cases, physician groups had a combination of contracts from their HMO partners such that SAI drug-risk was placed in both the MSC and the PRB.

Level of SAI drug risk. Physician groups were classified as having one of 3 types of SAI drug risk: no risk, shared risk, or full risk. Physician groups reporting that the HMO assumed full risk for SAI drug costs were categorized as “no risk.” If the physician group reported SAI drug risk in the MSC, then the group was assumed by the researchers to have assumed responsibility for all SAI drug costs and was therefore categorized as “full risk.” (In this study, when level of risk was 100%, risk always resided in the MSC. However, it is possible that risk could be at 100% and reside in the PRB, in which case, the physician group assumed all of the risk for SAI costs. No physician group in the current study met this criterion.) The remaining physician groups were assigned to the “shared risk” category. These groups reported either: (1) a combination of individual “no-risk” and “full-risk” contracts, (2) contracts stating that risk was to be shared between a particular HMO partner and the physician group, or (3) a combination of (1) and (2).

Sample characteristics. Table 3 summarizes the individual group and market-level characteristics of the study sample. The sample included 5 physician groups in the NE and MW markets, 4 groups in the SW, and 6 groups in the NW. The total number of physicians in each group ranged from 55 to 1,200 (mean: 737, median: 500; 19 of 20 groups reporting). The number of enrollees ranged from 50,000 to 630,000 (mean: 214,473, median: 215,000; 17 of 20 groups reporting).
TABLE 2) Definitions of SAI Drug-Use Management Strategies in Physician Groups

<table>
<thead>
<tr>
<th>Strategy Type</th>
<th>Strategy Subtype</th>
<th>Definition of Strategy Subtype</th>
<th>Number of Physician Groups Adopting the Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1(a). Quantify SAI costs</td>
<td>Capitation deductions</td>
<td>Determine amount health plan deducts from medical capitation payment for SAIs</td>
<td>2</td>
</tr>
<tr>
<td>1(b). Determine extent of cost burden</td>
<td>Pharmacies, out-of-group providers, home health providers</td>
<td>Determine amount physician group pays pharmacies, out-of-group providers, and home health providers through direct billing to claims department*</td>
<td>3, 1, 5</td>
</tr>
<tr>
<td>2. Establish SAI authorization processes</td>
<td>Implement therapeutic guidelines for authorizations</td>
<td>Utilize evidence-based guidelines for SAI prescribing (e.g., multiple sclerosis and rheumatoid arthritis)*</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Use existing utilization management (UM) system</td>
<td>Adapt existing UM system to process requests for SAI authorizations</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Establish office procedures for internal SAI authorization</td>
<td>Establish processes physicians and staff follow to obtain authorization from the physician group’s UM department for SAIs that are the physician group’s financial responsibility</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Hire personnel</td>
<td>Hire personnel in claims/UM department to implement and manage SAI authorization program</td>
<td>1</td>
</tr>
<tr>
<td>3. Negotiate price and monitor amount paid for SAI</td>
<td>Pharmacy network</td>
<td>Determine price paid for each SAI using HMO capitation deductions</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Pharmacies</td>
<td>Develop network(s) of local pharmacies or contract with a pharmacy vendor to supply SAIs at a lower price</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Home health providers</td>
<td>Negotiate lower SAI price with local pharmacy (by physician group)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical companies</td>
<td>Negotiate a lower price with SAI manufacturer directly (by physician group)</td>
<td>3</td>
</tr>
<tr>
<td>4. Establish, monitor pharmacy claims system for SAIs</td>
<td>Establish claims processing system for direct billing to internal claims department</td>
<td>Establish process by which pharmacies, out-of-group providers, and/or home health providers bill and receive reimbursement from the physician group directly for SAIs</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Monitor individual SAI costs via claims system</td>
<td>Establish a system to monitor each individual SAI cost through internal claims processing system</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Monitor overall SAI costs via claims system</td>
<td>Establish a system to monitor overall SAI costs through internal claims processing system</td>
<td>4</td>
</tr>
<tr>
<td>5. Establish SAI auditing processes</td>
<td>Monitor compliance with internal guidelines and internal prior-authorization process</td>
<td>Monitor compliance with internal prior-authorization process and guidelines for SAIs (by individual or department within physician group)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Audit capitation deduction reports for patient eligibility, and duplicate and over-charges for medications</td>
<td>Review medical services capitation deductions related to SAIs for verification of patient eligibility, duplicate or over-charges for medications, and correct interpretation of contracted financial responsibility</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Audit bills from pharmacies, out-of-group providers, and home health providers</td>
<td>Review outpatient pharmacy, out-of-group providers, and home health bills related to SAIs for verification of patient eligibility, duplicate or over-charges for medications, and correct interpretation of contracted financial responsibility</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Prospective auditing of patient eligibility by UM department</td>
<td>Verify patient’s insurance coverage (by UM department in the physician group before SAI authorized)</td>
<td>4</td>
</tr>
<tr>
<td>6. Develop SAI contracting arrangements</td>
<td>Establish different SAI-risk arrangements with HMO</td>
<td>Transfer risk for SAI costs to HMO (shared risk or no risk for physician group)</td>
<td>2</td>
</tr>
</tbody>
</table>

* This strategy subtype represents 3 possible strategies: determine amount paid to pharmacies, out-of-group providers, or home health providers.
TABLE 3  Sample Characteristics, SAI-Risk Relationships, and Number of Adopted Strategies

<table>
<thead>
<tr>
<th>ID</th>
<th>Number of Physicians</th>
<th>Enrollees (thousands)</th>
<th>Locus of SAI Risk</th>
<th>Level of SAI Risk</th>
<th>Number of Adopted Strategies</th>
<th>Market Summary§</th>
</tr>
</thead>
<tbody>
<tr>
<td>NE 1</td>
<td>≥1,000</td>
<td>&gt;200</td>
<td>PRB</td>
<td>shared</td>
<td>none</td>
<td>Dominated by 3 large, nonprofit insurers, 2 of which were locally based. Collaborative working relationships between physician groups and HMOs. Consolidated on delivery side and high degree of horizontal cooperation between groups. All but 1 organization had drug-risk contracts with a management service organization (MSO) for the purposes of negotiating risk contracts. The characteristics of the risk contracts themselves varied considerably.</td>
</tr>
<tr>
<td>NE 2</td>
<td>≥1,000</td>
<td>&gt;200</td>
<td>PRB</td>
<td>shared</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>NE 3</td>
<td>≥1,000</td>
<td>&gt;200</td>
<td>PRB</td>
<td>shared</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>NE 4</td>
<td>500-999</td>
<td>missing*</td>
<td>PRB</td>
<td>shared</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>NE 5</td>
<td>&gt;1,000</td>
<td>missing†</td>
<td>PRB &amp; MSC</td>
<td>shared</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>SW 1</td>
<td>&lt;500</td>
<td>100-199</td>
<td>MSC</td>
<td>full</td>
<td>16</td>
<td>Most heavily capitated market, with more partial capitation than any other market. Groups derived substantially higher percentages of income from Medicare-risk contracts than in other markets. Relations between groups and HMOs more adversarial than in other markets, and physician groups were not as horizontally integrated. Mix of shared and global drug-risk contracts.</td>
</tr>
<tr>
<td>SW 2</td>
<td>&lt;500</td>
<td>&lt;100</td>
<td>MSC</td>
<td>full</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>SW 3</td>
<td>≥1,000</td>
<td>&gt;200</td>
<td>MSC</td>
<td>full</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>SW 4</td>
<td>500-999</td>
<td>100-199</td>
<td>MSC</td>
<td>full</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>MW 1</td>
<td>&lt;500</td>
<td>missing†</td>
<td>N/A‡</td>
<td>none</td>
<td>none</td>
<td>Market witnessed a decline in HMO penetration over the course of the study period. Unique market due to the presence of a large coalition of health care purchasers who leveraged the size of their combined enrollee populations to purchase health care. Drug-risk arrangements for oral medications were almost exclusively various forms of full-risk or global capitation contracts.</td>
</tr>
<tr>
<td>MW 2</td>
<td>500-999</td>
<td>&lt;100</td>
<td>PRB</td>
<td>shared</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>MW 3</td>
<td>&lt;500</td>
<td>&gt;200</td>
<td>PRB</td>
<td>shared</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>MW 4</td>
<td>&lt;500</td>
<td>&lt;100</td>
<td>PRB</td>
<td>shared</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>MW 5</td>
<td>500-999</td>
<td>100-200</td>
<td>PRB</td>
<td>shared</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>NW 1</td>
<td>&lt;500</td>
<td>&gt;200</td>
<td>MSC</td>
<td>full</td>
<td>7</td>
<td>Market unique in that there were no Medicare-risk contracts. This shift in risk generated increased interest for health plans to collaborate with physician groups in managing drug costs. Collaboration among physician groups in creating standardized clinical practice guidelines and in publishing a formulary guide. Primarily global capitation or full-risk contracts for oral drug costs.</td>
</tr>
<tr>
<td>NW 2</td>
<td>&lt;500</td>
<td>&gt;200</td>
<td>MSC</td>
<td>none</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>NW 3</td>
<td>500-999</td>
<td>≥100</td>
<td>PRB</td>
<td>shared</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>NW 4</td>
<td>&lt;500</td>
<td>&lt;100</td>
<td>PRB &amp; MSC</td>
<td>shared</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>NW 5</td>
<td>500-999</td>
<td>100-199</td>
<td>PRB &amp; MSC</td>
<td>shared</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>NW 6</td>
<td>&lt;500</td>
<td>&gt;200</td>
<td>PRB &amp; MSC</td>
<td>shared</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

* No data provided.
† Respondents could only report number of patient visits per year, not number of enrollees.
‡ Because these groups have no SAI risk, the locus of risk is not applicable.
§ The descriptions of each market include information on the defining characteristics of that market rather than common attributes across markets.

Level of SAI Risk:
PRB = Pharmacy risk budget.
MSC = Medical services capitation.

Results

Level of SAI drug risk. Out of a total of 20 physician groups, 18 assumed some financial risk for SAI drug costs. Table 4 shows that 5 physician groups (25% of sample) reported that they were at full financial risk for SAIs. Thirteen groups (65%) shared financial risk with their HMO contractual partners, while the remaining 2 groups (10%) reported no financial risk for SAIs. The level of SAI drug risk borne by the physician group appeared linked to the number of strategies adopted, with higher-risk groups adopting more strategies than lower-risk groups. Groups with full financial risk adopted an average of 9.2 strategies per group compared with 2.3 strategies per shared-risk group and 1 strategy per no-risk group. The average number of strategies for the entire sample was 3.9 per group.

There was also a clear regional variation in the distribution of the level of SAI drug risk across physician groups. All of the SW groups had full risk for SAIs, while all of the NE groups had shared risk for SAIs. The majority of the groups in the NW and MW markets had shared risk for SAIs. There did not appear to be any relationship between level of managed care penetration in each market and the level of SAI risk among physician groups within each market: the markets with the highest and lowest levels of managed care penetration included groups with primarily shared-risk contracts for SAIs.

Locus of SAI drug risk. Table 5 reveals that physician groups were divided with respect to the locus of SAI drug risk. Eight groups (40% of sample) reported that risk was in the PRB, 5 (25%) groups reported it in the MSC, and 4 (20%) reported it in both the MSC and PRB. Two groups (10%) had no SAI risk, and one group (5%) did not know where its SAI drug risk resided.
TABLE 4 SAI Drug-Use Management Strategies by Level of SAI Financial Risk

<table>
<thead>
<tr>
<th>Level of SAI Financial Risk</th>
<th>Number of Physician Groups</th>
<th>Number of Strategies</th>
<th>Average Number of Strategies per Physician Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full risk</td>
<td>5</td>
<td>46</td>
<td>9.2</td>
</tr>
<tr>
<td>Shared risk</td>
<td>13</td>
<td>30</td>
<td>2.3</td>
</tr>
<tr>
<td>No risk</td>
<td>2</td>
<td>2</td>
<td>1.0</td>
</tr>
</tbody>
</table>

TABLE 5 SAI Drug-Use Management Strategies by Locus of SAI Financial Risk

<table>
<thead>
<tr>
<th>Locus of SAI Financial Risk</th>
<th>Number of Physician Groups*</th>
<th>Number of Strategies</th>
<th>Average Number of Strategies per Physician Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSC</td>
<td>5</td>
<td>46</td>
<td>9.2</td>
</tr>
<tr>
<td>PRB and MSC</td>
<td>4</td>
<td>18</td>
<td>4.5</td>
</tr>
<tr>
<td>PRB</td>
<td>8</td>
<td>12</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Level of SAI Risk:

- No risk = HMO assumed full risk for SAI drug costs.
- Shared risk = the physician group reported either: (1) a combination of individual “no-risk” and “full-risk” contracts; (2) contracts stating that risk was to be shared between a particular HMO partner and the physician group; or (3) a combination of (1) and (2).
- Full risk = the physician group assumed responsibility for all SAI drug costs.

Locus of SAI Risk:

MSC = Medical services capitation.
PRB = Pharmacy risk budget.

Strategy adoption appeared related to the locus of SAI drug risk. Groups with SAI drug risk in the MSC, on average, adopted 9.2 strategies per group. In contrast, groups with SAI drug risk in the PRB averaged 1.5 strategies per group. Groups with SAI drug risk in both the MSC and the PRB fell in-between, with an average of 4.5 strategies per group.

As with patterns of strategy adoption, the locus of SAI drug risk also varied by market. All 4 of the SW physician groups (100% of market) had risk in the MSC. In contrast, in the NE and MW, the majority of physician groups had SAI drug risk in the PRB (80% of groups in the NE and 60% of groups in the MW). The locus of SAI drug risk appeared more evenly spread in the NW: 3 groups (50%) had SAI drug risk in both the PRB and MSC, 2 in the PRB (33%), and 1 in the MSC (16%).

Frequency and distribution of SAI drug-use management strategies. Sixty percent (12 groups) of surveyed physician groups adopted at least 1 strategy. Among those physician groups that adopted any strategies, the average was 6.5 per group. The most common category of strategies adopted was establishing an SAI authorization process (11 groups, 55% of sample). The next most common categories of strategies included strategies to negotiate and monitor SAI prices (7 groups, 35%), including negotiating directly with the drug manufacturer (3 groups, 15%), followed by establishment and monitoring of a pharmacy claims system for SAIs (5 groups, 25%), establishment of SAI auditing processes (5 groups, 25%), efforts to quantify SAI drug costs (5 groups, 25%), and changes to current SAI contracting arrangements (i.e., transferring risk for SAI drug costs back to the HMO—2 groups, 10%).

With respect to individual strategies, the most frequently used strategy was designing evidenced-based therapeutic guidelines that formed the basis for authorizations for SAIs. For example, a guideline might suggest the use of etanercept in the treatment of RA when a patient meets the following inclusion criteria: a diagnosis of RA by a rheumatologist (i.e., the patient meets 4 out of 7 criteria listed by the ACR [American College of Rheumatologists]); has inadequate response, failed therapy, or has contraindications to specific alternative drugs; and no history of tuberculosis (Table 6). This strategy was followed in frequency of use by measures to adapt the existing utilization management system to process SAI requests efficiently (7 groups, 35% of sample), the establishment of office procedures for internal authorization (5 groups, 25%), and determining the amount the physician group paid for SAIs to home health agencies (5 groups, 25%).

The least frequently used strategies were: determining the amount the group paid to out-of-group physician providers (1 group, 5% of sample) and hiring personnel (e.g., pharmacists) in the claims or utilization management departments to implement and manage an SAI program (1 group, 5%). Every strategy was adopted by at least 1 physician group. No group described a drug-use management strategy beyond the 21 described in the survey protocol even though all were offered the opportunity to do so in the open-ended portion of the survey.

The extent of SAI management strategy adoption varied by market. No physician groups in the NE adopted any SAI management strategies, while 3 of 5 groups (60%) in the MW adopted one or more strategies. In the NW, 5 of the 6 groups (83%) adopted strategies, compared with all 4 (100%) of the SW groups.

The dependent variable (number of management strategies adopted) and the independent variables (locus and level of SAI drug risk) were independently conceptualized and measured in our study. The list of management strategies used in the survey was selected from a list of strategies developed by the study authors. The independent variables, “location” of SAI risk (MSC or PRB), and “level” of SAI risk (full, shared, none), were a priori hypothesized to influence management strategy adoption.

Discussion

We found that level of SAI drug financial risk was positively relat-
ed to strategy adoption, with high-risk groups adopting more strategies than lower-risk groups. This is consistent with the theory of risk that has motivated much managed care activity, namely, that when drug-risk transfer occurs, physician groups will be motivated to adopt drug-use management innovations.

Findings from the current study corroborate and extend results from 2 prior studies that examined this relationship for oral prescription drug risk in managed care organizations. Hillman et al. compared drug spending and prescribing patterns across 9 physician groups managed by a single health plan. The authors concluded that physician prescribing behaviors and total drug expenditures could be influenced by direct financial incentives for physicians to control drug use. Using data from a physician-hospital organization from 1995 to 1999, Chernew et al. compared drug-cost growth for patients receiving services from capitated physician groups and patients using noncapitated physician groups and found that drug spending in the capitated group increased as the risk transfer was diminished.

Neither of these studies addressed the extent to which financial incentives influenced adoption of drug-use management innovations in physician groups. Further, in selecting physician groups from only 1 managed care organization, Hillman et al. and Chernew et al. limited their potential to explore the range of existing risk-arrangement strategies and their differential effects on innovation at the physician group level. Therefore, our current findings, which are based on the experiences of multiple physician groups across multiple managed care markets, represent important empirical support for the hypothesis that the assumption of financial responsibility for drug costs results in changes in adoption of drug-use management innovations for SAIs, the fastest-rising component of drug budgets.

Our findings revealed that strategy adoption was influenced by locus of risk. When the locus of risk for SAI drug costs resided in the MSC, the number of strategies adopted was higher (mean: 9.2 strategies per group) compared with groups where the locus of risk was located in the PRB (mean: 1.2 strategies per group). We would suggest that placement of risk in the MSC permitted physician groups to capitalize on their ability to implement SAI drug-use management strategies.

Locus in the MSC increased strategy adoption because, once in the MSC, physician groups could adapt available drug utilization strategies to their management of risk for SAI costs, namely, establishing an SAI authorization process, developing and monitoring a claims adjudication process for SAIs, and negotiating and monitoring the prices paid for SAIs. Physician groups were less able to implement strategies if the locus was in the PRB because the pharmacy benefit was controlled by the health plans, reducing the ability of medical groups to change the authorization or claims processes or prices paid for SAIs.

Despite pressure to control SAI drug costs, 40% of groups in the sample did not adopt any SAI drug-use management strategies. Among the 60% of groups that did adopt at least 1 strategy, the average number of adopted strategies was 6.5 per group, well below the 21 possible strategies presented in the survey. We posit 3 reasons for fairly low levels of strategy adoption. First, prescription drugs, which have accounted for a smaller portion of health care organizations’ budgets than hospital and physician services, have, until recently, received less attention from medical group management.

A second explanation for low adoption rates may be related to the physician groups’ lack of power to negotiate better injectable medication prices with drug manufacturers or better risk arrangements with HMOs. Only 3 groups (15% of the sample) negotiated better prices with manufacturers, and only 2 groups (10%) negotiated different contractual arrangements, i.e., transferred SAI risk to HMOs. We did not determine how many physician groups attempted to negotiate risk sharing with HMOs.

An effective financial risk-management strategy for physician groups would involve risk sharing of SAI drug costs with HMOs, but this strategy is, of course, part of the ongoing tug of

<table>
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<tr>
<th>TABLE 6 Guideline for Approval of Etanercept (Enbrel) Therapy</th>
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<tbody>
<tr>
<td>Please include the following information to expedite the approval process for Enbrel:</td>
</tr>
<tr>
<td>1. Request by rheumatologist: _____Yes</td>
</tr>
<tr>
<td>2. Inclusion criteria:</td>
</tr>
<tr>
<td>Patient has diagnosis of rheumatoid arthritis (RA) by American College of Rheumatology (ACR) criteria (see guideline) _____Yes</td>
</tr>
<tr>
<td>Patient has moderate to severe RA _____Yes</td>
</tr>
<tr>
<td>Patient has inadequate response, failed therapy, or contraindications to the following medications: _____Imuran _____Methotrexate _____Ridaura _____Plaquenil _____Cupramine_____Azulfidine _____Gold Therapy</td>
</tr>
<tr>
<td>Patient does not have history of TB or a positive PPD _____Yes</td>
</tr>
</tbody>
</table>

Principal Items in Survey of Physician Groups and Self-Administered Injectable Drugs

1. Who is at risk for SAIs?
   a. HMO
   b. Physician organization
   c. Shared
   d. Other

2. What kind of risk arrangement do you have for SAIs?
   a. None, HMO at full risk
   b. Physician group cap
   c. Pharmacy cap
   d. Pharmacy carve-out for SAIs
   e. Other

If group is at risk for SAIs:
3. When did you first assume risk for SAIs?
4. What were your SAI costs for the last fiscal year?
5. Since assumption of risk for SAIs, has your drug PMPM...
   a. Increased
   b. Decreased
   c. Remained the same
   d. Not applicable because SAI in med cap
   e. Other
6. Since assumption of risk for SAIs, have your total SAI costs...
   a. Increased
   b. Decreased
   c. Remained the same
   d. Other
7. Where do you project your SAI costs are going?
8. Why?

If group not currently at risk for SAIs:
9. Have you been at risk for SAIs in the past?
   a. No
   b. Yes
   c. Other
10. Why was the risk arrangement dropped?
11. Do you anticipate assuming risk for SAIs in the future?
    a. No
    b. Yes
    c. Other
12. Why?

Strategies to manage SAI cost and use
13. Do you have strategies for containing costs of SAIs?
    a. No
    b. Yes
    c. Other

Strategies to quantify SAI costs
14. Quantify costs from cap deducts
    a. No
    b. Yes
    c. Other
15. Quantify costs from out-of-group providers via claims department
    a. No
    b. Yes
    c. Other

Physician group authorization process
16. Designing therapeutic guidelines for authorization
    a. No
    b. Yes
    c. Other
17. Establishing process to use existing utilization management
    a. No
    b. Yes
    c. Other
18. Establishing office procedures for internal authorization
    a. No
    b. Yes
    c. Other

Auditing
19. Monitor compliance with guidelines and internal prior-authorization process
    a. No
    b. Yes
    c. Other
20. Audit cap deduct detail reports for patient eligibility, duplicates, and overcharges
    a. No
    b. Yes
    c. Other
21. Audit contracted pharmacy bills for patient eligibility, duplicates, and overcharges
    a. No
    b. Yes
    c. Other
22. Prospective auditing of patient eligibility by UM department
    a. No
    b. Yes
    c. Other

Pharmacy network
23. Contract for price and service with local pharmacies
    a. No
    b. Yes
    c. Other

Measures to monitor and negotiate price
24. Determine current price paid for each self-injectable drug
    a. No
    b. Yes
    c. Other
25. Contract with home health provider for best price
    a. No
    b. Yes
    c. Other
26. Contract with pharmacy for best price
    a. No
    b. Yes
    c. Other
27. Contract with drug company for best price
    a. No
    b. Yes
    c. Other
28. Evaluate ability to use “own-use” pricing with attached hospital system
    a. No
    b. Yes
    c. Other

Claims
29. Establish claims-processing system for direct billing to internal claims department
    a. No
    b. Yes
    c. Other
30. Monitor SAI expense via claims data
    a. No
    b. Yes
    c. Other
31. Monitor costs via claims system (monitoring out-of-group expenses, home health agency expenses)
    a. No
    b. Yes
    c. Other

Contracting
32. Contract different risk arrangements with health plans
    a. No
    b. Yes
    c. Other
33. Contract different risk arrangements with pharmacy, home health provider, and drug industry
    a. No
    b. Yes
    c. Other
Financial Risk Relationships and Adoption of Management Strategies in Physician Groups for Self-Administered Injectable Drugs

war between HMOs and contracted medical providers. Financial risk that can be managed by physician groups can be transferred. Less manageable financial risk should be shared, and financial risk that is not manageable by the physician medical group should be retained by the HMO and affected through benefit design and adequate premiums.

A third possibility is that adoption of strategies was related to the ability of physician groups to develop and implement strategies through possession of adequate expertise, infrastructure, and resources. The groups attempted to deal with SAI drug financial risk by adapting tools already at their disposal in the management of oral medications and other services. For example, groups were more likely to adopt strategies to establish authorization processes for SAIIs using existing utilization management departments, which had experience in implementing prior-authorization procedures for other diagnostic and medical services. The physician groups also implemented strategies related to monitoring and negotiating SAI price, relying on their existing contracting departments’ experience in negotiating contracts for pharmacy budgets and services.

Fewer groups quantified their SAI drug costs—something that might be considered an obvious first step to managing SAI expenditures. This may represent the perception that quantifying costs is not necessary to control SAI expenditures or that the magnitude of the SAI cost threat was not recognized. It may also demonstrate the lack of expertise and resources within physician groups to quantify drug costs, particularly if risk for SAI drug costs is in the MSC, where tracking and itemizing drug costs from multiple sources (e.g., pharmacies, home health providers, HMOs, out-of-network providers) is difficult.

In our study, 25% of the groups quantified SAI drug costs related to home health agencies, but only 1 group attempted to quantify SAI drug costs from out-of-network providers. In addition, several of the SAI drug-use management strategies were employed by only 1 physician group, and no unique strategies were offered by the groups during the open-ended portion of the interview. Further, while some physician groups shifted resources toward the management of SAI drug costs, as evidenced by adapting their existing utilization management processes, only 1 group (NW1) actually extended resources by hiring additional personnel to manage SAI costs. NW1 was unique among its NW market counterparts in that it had a history of using pharmacists to manage oral prescription drug risk. This group’s decision to hire a pharmacist might also be explained by its acknowledgment that it “saw medical care [including SAIIs] as a complete pie which needs to be managed and can be best controlled at the medical group level,” and hiring a pharmacist was seen as a step toward that goal.

Our findings suggest that adoption of SAI drug-use management strategies may be more likely to occur when there is at least a minimum level of risk for SAI drug costs. Likewise, both the adoption of strategies and the opportunity to slow the rate of SAI cost increases may be more likely to occur when 3 additional factors are present: a contractual environment conducive to controlling SAI drug costs, the ability to implement SAI drug-use management strategies, and power in negotiations with drug manufacturers to reduce SAI prices.

First, the responsible parties should be at some level of financial risk (either shared or full) for SAI drug costs. Although limited by the small sample size of the study, the findings support the hypothesis that increased risk is accompanied by increased levels of strategy adoption. Specifically, physician groups implemented more cost-control strategies when increasing levels of financial risk were assumed.

Second, financial risk-bearing for SAI drug costs should occur in a contractual environment in which the responsible party has the necessary control to manage the risk. In our study, the physician groups were able to manage the risk when SAI drug costs were embedded within the MSC, and more strategies were adopted due to this increased level of control. As noted in the discussion, placement of SAI drug-risk in the MSC permitted the physician groups to have control over key aspects of SAI drug utilization, such as drug authorization, price, and, potentially, formulary selection. In contrast, when SAI risk resided in the PRB, SAI authorization, price, and formulary selection were controlled by the HMO, thus limiting the group’s implementation of cost-control strategies even when needed infrastructure and expertise existed.

Third, the organization must possess the ability—adequate expertise, infrastructure, and resources—necessary to develop and implement the strategies. The most frequently used strategy, establishing SAI prior authorization, could be implemented in physician groups by drawing on existing utilization management expertise, infrastructure, and staff.

Further, the processes for negotiating and monitoring SAI prices should build upon an existing contracting department with expertise in HMO risk arrangements and drug price negotiation. In contrast, very few groups quantified SAI drug costs or hired personnel, reflecting their overall lack of expertise and resources to develop a viable SAI drug management program.

Finally, power in negotiating with drug manufacturers is key for organizations wishing to obtain discounts and rebates from manufacturers and, therefore, manage SAI drug-cost increases. In our sample, most price negotiations occurred between the physician groups and pharmacy providers, not with drug manufacturers, presumably because of the relatively small portion of market share that physician groups could leverage with the manufacturers. By giving physician groups the power to transfer risk for SAI drug costs to HMOs, which command significantly larger market share, lower SAI prices could be obtained from manufacturers by the HMOs.

Limitations

Our study has several limitations. First, we did not consider the
extent to which the length of a medical group’s experience with risk contracting was an explanatory variable.

Second, we relied upon self-report data to measure SAI drug-risk levels and innovation, and we did not pursue interviews with physician group representatives to determine qualitative characteristics and differences in the financial risk arrangements with HMOs.

Third, we did not obtain detailed information regarding the management or administration of the physician groups or query respondents about various SAI distribution methods; for example, we did not obtain information on the extent to which physician groups used group purchasing organizations to minimize SAI costs when patients received SAIs directly from physicians.

Fourth, we considered all strategies equal in importance, even though it is likely that some strategies have a larger impact on SAI drug management than others.

Fifth, the characteristics of our sample limit the generalizability of our findings. The sample itself was too small to validate results through the use of statistical hypothesis testing. Because we surveyed large physician organizations with experience of 1 year or more in managing drug risk, our results are not generalizable to smaller physician groups or those with less experience with financial risk contracting.

In addition, the variations in market characteristics among the 4 cities we studied were large and create uncertainty about the extent to which findings from these locations are applicable to other markets. For example, there may exist other contractual arrangements between physician groups and HMOs that were not found among our sample. Similarly, medical groups and HMOs operate in other states where legislation may restrict or prohibit drug-risk transfer entirely. Nonetheless, ours remains the first systematic study of SAI drug risk and the first analysis of the number and types of SAI drug-use management strategies showing a pronounced link between strategy adoption and locus and level of risk for SAIs.

We did not measure the effectiveness of any of these management strategies on actual SAI drug utilization or spending. We did not assess the extent to which HMOs negotiated purchase discounts or rebates with manufacturers on behalf of contract physician groups. Future research will also need to assess the extent to which physician groups use group purchase organizations to affect the average price of SAI drugs and how physician medical groups and HMOs use specialty pharmacies to manage SAI drug cost and care outcomes.

**Conclusion**

Policymakers intent on maximizing the benefit of each of these 4 factors: risk, environment, ability to implement, and power in negotiations (REAP) should consider whether the physician group—or any single entity—is the optimal party to bear financial responsibility for SAI costs. Physician groups, while most knowledgeable regarding the clinical factors related to SAIs, may not have the infrastructure or resources necessary for successful implementation of SAI drug-use management strategies. Physician groups certainly can assume some financial risk; indeed, we believe that their clinical expertise means they can (and should) adopt some strategies to manage risk, including authorizations and clinical guidelines, without becoming the primary bearer of financial risk.

Further, even the largest physician groups lack adequate power since they generally represent only a fraction of the covered lives needed to secure significant rebates and discounts from drug manufacturers. A sustainable and affordable SAI drug financial risk-management program—one that maximizes the REAP factors while managing the financial burden for patients—ultimately will require collaboration among public and private purchasers, health plans, providers, patients, and drug manufacturers.

**DISCLOSURES**

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