

management
challenges

MANAGEMENT CHALLENGES

CuraScript Specialty Pharmacy Management Guide & Trend Report

Management Challenges

Specialty drugs raise other complex access and administration issues for employers and managed-care organizations. Specialty drugs do not fit neatly within traditional benefit-design structures, creating inequities in reimbursement and access. Multifaceted and inadequately defined benefit structures have created complex billing and reimbursement issues for specialty drugs. Historically, third-party payment systems have been structured to manage drug costs in two separate segments:

- Prescription-drug coverage, traditionally for relatively low-cost, low-maintenance oral medications
- Medical coverage, historically for higher-cost, high-management injections and infusions

When biotechnology drugs and other high-cost specialty drugs began entering the market in the late 1980s, third-party payers routinely covered the costs of these drugs through medical benefits. Over the past several years, however, increasing numbers and types of specialty products have become available, and patients using specialty drugs have assumed greater degrees of self-management in home settings. Presently, some specialty drugs are covered under prescription-drug benefits, while others still fall into medical benefits, and some can be either, depending on the setting in which they are administered.

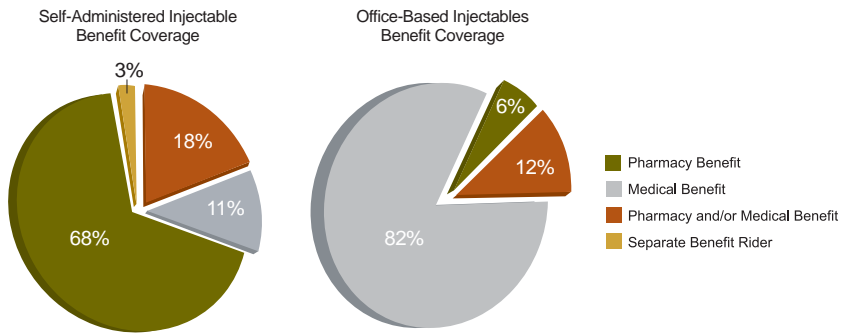
Based on a December 2004 survey of medical directors from various sized health plans, 63% of respondents indicated that they reimburse specialty products under both pharmacy and medical benefits. Sixteen percent of the respondents to this survey had already shifted coverage to the prescription-drug benefit in 2004, while 28% plan to shift reimbursement to the prescription-drug benefit in the next 12 months.¹²

¹² JPMorgan/MedPanel Medical Directors Survey, December 2004.

Similarly, 68% of the plan sponsors analyzed cover self-administered injectables only under the prescription-drug benefit, and 5% of plan sponsors cover all injectables under the prescription-drug benefit. Conversely, 82% of plan sponsors cover office-administered injectables only under the medical benefit, and 11% of health plans cover all injectables under the medical benefit. Only 3% of health plans have a separate rider for specialty-pharmacy products (Exhibit 9).¹³

Exhibit 16

Self-Administered vs Office-Based Injectables Benefit Coverage



A client may assume it has control of specialty-drug spend if it adjudicates self-administered specialty drugs through a PBM claims adjudication platform. However, true specialty spend is much higher since not all specialty drugs are adjudicated through this platform. In most circumstances, PBM claims adjudication does not include specialty drugs administered in the physician office setting.

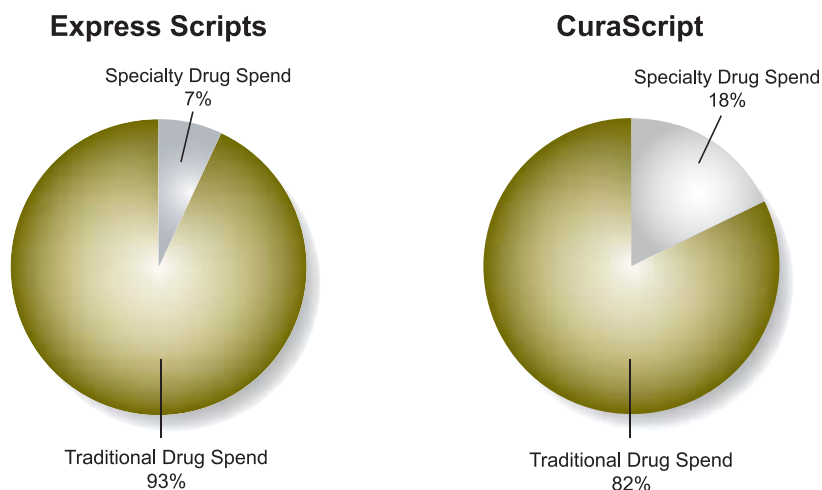
To demonstrate this, we identified all specialty drugs adjudicated through the Express Scripts pharmacy claims platform in 2004 and compared that activity to all specialty drugs adjudicated by CuraScript in 2004. Because CuraScript has the ability to provide, manage and bill clients for specialty drugs administered in the physician office setting, significantly more specialty drugs were identified within the CuraScript claims system. Since the CuraScript data captures both self-administered

¹³ Managed Care Strategies for Management of Specialty Injectable Drugs, *Serono Injectable Digest*, Volume 1, 2004.

and physician-administered specialty drugs, the data provides a more complete picture of true specialty drug spend. Based on the CuraScript data, specialty drug spend in 2004 represented 18% of total outpatient drug spend, compared with 7% captured through Express Scripts data (Exhibit 17).

Exhibit 17

*Comparison of Express Scripts vs CuraScript Specialty Drug Spend
As a Percentage of Overall Outpatient Pharmacy Spend in 2004*



In order to properly manage specialty-drug trend, it is important for clients to identify and manage these drugs across all outpatient settings. A specialty pharmacy has the ability to supply these drugs and provide the appropriate patient-management services across all outpatient settings.

WHY IS J-CODE CLAIMS PROCESSING PROBLEMATIC?

A survey of health plans found that only 11% of plan sponsors are able to process medical drug claims at the National Drug Code (NDC) level.¹⁴ This presents numerous challenges to clients.

¹⁴ Managed Care Strategies for Management of Specialty Injectable Drugs, *Serono Injectable Digest*, Volume 1, 2004.

Lack of Specificity: The NDC system uses a unique 11-digit, three-segment number to all legend and over-the-counter drugs, specifying the manufacturer, strength, dosage and package size. A Healthcare Common Procedure Coding System (HCPCS) J-Code specifies only the chemical name of the drug, not the specific product NDC, strength or package size. One J-Code can be used to represent multiple NDCs for multiple drug therapies.

For example, J-Code J1563 represents IVIG drugs. There are 38 unique NDCs covering a range of manufacturers, strengths and package sizes all represented by this one J-Code.

Delay in Availability of J-Codes: The NDC number for a new drug is available at the time the FDA approves the drug for use. J-Codes generally become available anywhere from six to 18 months after a drug enters the market. Until a J-Code for a new drug is assigned, an unclassified J-Code, such as J-3490, is appropriately used for billing. Unless manually audited, the client cannot identify the drug or strength being billed.

J-Code Unit Conversion: HCPCS J-Codes also have a complex unit conversion system that is subject to error in appropriate billing quantities, resulting in over or under billing by less experienced billing specialists. For payers to convert HCPCS J-Codes to an equivalent NDC unit and specific AWP for fee schedules, the process can be difficult and imprecise. As payers lack the ability to electronically process HCFA claims at an NDC level, the auditing of J-Code claims for accuracy is often a manual and costly process.

Implications: Lacking information regarding the specific NDC strength and conversion units, J-Codes make it difficult for clients to:

- Obtain actual NDC level utilization data
- Reimburse providers for actual drug, strength and quantity utilized by members
- Apply prospective prior authorization and utilization management tools
- Use clinical-management and step-therapy strategies
- Take advantage of generic opportunities when available

- Achieve financial savings through the use of formulary management and preferred agents
- Effectively administer drug-specific benefit design and cost-share on medical-benefit claims

WHY IS THE PHYSICIAN OFFICE BUY-AND-BILL MODEL PROBLEMATIC?

Clients have historically relied on physicians to obtain the specialty drugs, manage the inventory, administer the product and submit HCFA claims utilizing J-Codes along with CPT codes for their professional services. As clients have applied cost-management strategies to professional services fees for CPT code reimbursement, J-Code reimbursement was left relatively unchecked. Providers were able to bill at a premium well above their acquisition costs, creating an additional revenue stream for a physician practice.

As outlined above, the lack of NDC-level data in medical-benefit claims processing allows clients little control over the cost and utilization of specialty drugs provided through physician offices and clinics.

The specialty pharmacy is well-positioned to support clients with cost-containment strategies through its ability to:

- Eliminate the problems associated with J-Codes by allowing NDC level reporting
- Allow for consistent prospective-utilization management and step therapy to be implemented on physician office drug prescribing and use
- Provide data collection and reporting to allow implementation of formulary and generic substitution programs
- Provide an avenue for early identification of high-risk members in order to apply clinical-management interventions early in the disease process
- Enable clients to realign benefit design for specialty drugs

Medicare-reform legislation is beginning to address some of the issues associated with HCPCS J-Code billing and physician-office drug distribution. This effort is primarily focused on oncology practices but has ramifications in other areas of specialty-drug use. Average Sale Price (ASP) reimbursement by Medicare is a step toward realigning the prices billed for drugs on behalf of Medicare beneficiaries with physicians' drug-acquisition costs. Unfortunately, the impact of this reduction in revenue on physician practices may cause some physicians to shift costs to commercial clients and employer groups to supplement lost revenue from Medicare. Close monitoring of Medicare reform is needed to ensure that cost-containment strategies and network-management efforts are aligned. This approach will help ensure a positive impact for all clients, including government, commercial and labor segments.