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Managing the Cost of Specialty Pharmaceuticals

Executive Summary

- ▶ In 2001, total health care expenditures increased 8.7% while pharmaceutical expenditures increased 16.9%, making the case for closer management of pharmaceutical cost and reimbursement
- ▶ For the ambulatory care practices facing decreasing reimbursement and increasing care complexity often due to the advent of specialty pharmaceuticals, this management imperative is even stronger.
- ▶ Using the example of Remicade® (a monoclonal antibody used in the treatment of Crohn's disease) in an ambulatory GI program, this study provides a model for improving purchasing, inventory management, preauthorization, administration, coding, and billing
- ▶ Charge capture was improved by coding items in addition to the drug itself.
- ▶ Reimbursement was also improved by correctly coding the drug dose units according to the method used by each payer.
- ▶ Through the implementation of these practices, the program turned a \$140K loss into a projected \$200K profit.

THE COST OF HEALTH CARE in the United States continues to soar. Total health care spending climbed to \$1.4 trillion in 2001 (Levit et al., 2003). This represents 14.1% of the gross domestic product (GDP), an 0.8% increase from 2000. The growth in health care expenditures outpaced the growth in GDP in 1999, 2000, and 2001. It is projected that by 2011, health care spending will double to \$2.8 trillion and represent 17% of the GDP (Duff, 2002).

Pharmaceutical costs increase at a rate faster than that of total health care costs (Shah, Vermeulen, Santell, Hunkler, & Hontz, 2002). In 2001, total health care expenditures increased by 8.7% (Levit et al., 2003). During that same period, total expenditures on pharmaceuticals rose by 16.9% (Ingram, 2003). In fact, the growth in spending for pharmaceuticals exceeded the growth in spending in all other health care sectors. Ambulatory practice sites are directly affected. For 2003, the projected increase in pharmaceutical expenditures at ambulatory practice sites was 13.5% to 15.5% (Shah, Hoffman, Vermeulen, Hunkler, & Hontz, 2003).

The growth in pharmaceutical expenditures at ambulatory practice sites is caused by several factors. Price increases account for only a small percentage of this growth. One of the most significant contributors is the rapid increase in the number of pharmaceuticals in development or seeking approval. A significant number of these are specialty pharmaceuticals, defined as drug therapies that require complex delivery systems and cost greater than \$5,000 per patient per year (Morrow, 2003). Specialty pharmaceuticals are typically prescribed to treat rare, complex, or chronic disease. In 2001, eight new biologics, or one-third of all new drugs, were released. According to Morrow (2003), specialty pharmaceuticals, including

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new biologic and other costly chronic therapies, represent approximately \$17 to \$20 billion of the total annual spending on pharmaceuticals.

Another factor contributing to the increased costs of pharmaceuticals in ambulatory practice sites is the shift in health care from hospitalization to new technologies and treatments, including specialty pharmaceuticals. In addition, the number of people who are diagnosed with chronic diseases for which specialty pharmaceuticals are available to treat is growing rapidly. Specialty pharmaceuticals are often injectable or infusible medications that must be administered in a clinical setting by skilled health care providers. As a result, there has been an increased utilization and intensity of care provided in ambulatory settings, which drives the cost of ambulatory care even higher.

Other factors contribute to the growth of pharmaceutical spending. New pharmaceuticals are arriving on the market faster. The review time for priority new drug approval by the Food and Drug Administration is the shortest since 1995 (Shah et al., 2002). In 1997, the FDA approved direct consumer marketing. This has resulted in increased consumer awareness of and demand for the use of specialty pharmaceuticals.

Managing Pharmaceutical Costs

Managing the cost of specialty pharmaceuticals is a significant issue for ambulatory practice sites. In fiscal year (FY) 2002, the cost of pharmaceuticals represented 14% of the total clinical operating budget for the department of medicine's ambulatory practice sites at University Hospitals of Cleveland. This level of expenditure represented a doubling, as a percentage of the total clinical operating budget, over the preceding fiscal year and led to an analysis of pharmaceutical usage patterns in individual clinics within the department.

University Hospitals of Cleve-

land is a 947-bed, tertiary academic medical center in a large metropolitan setting. It serves as the flagship hospital for University Hospitals Health System, which has 150 locations including satellite hospitals, ambulatory centers, and physician practice sites throughout Northeast Ohio.

The department of medicine uses the doctor's-office model for its primary care and select specialty clinical practices based at the hospital. Specialties include general internal medicine, gastroenterology (GI), pulmonary, cardiology, rheumatology, and a multi-specialty clinic that includes infectious diseases, endocrinology, nephrology, and hypertension. Each clinic has a separate operating budget. (The hematology-oncology, geriatrics and special immunology sections are hospital-based and not included in this discussion.) In 2002, these programs accounted for 90,000 ambulatory encounters.

Pharmaceutical expenditures in the general internal medicine, pulmonary, and cardiology programs remained flat during the evaluation period (FY 2000 to FY 2002). In that same period, pharmaceutical expenditures in the multi-specialty clinic rose from 4.5% to 14.7% of its total operating budget. In the GI clinic, pharmaceutical expenditures rose from 2.5% to 55% of its total operating budget. In the latter two programs, patient volume, patient mix, and standard formulary use and cost remained constant. The contributing variable to these large increases in pharmaceutical expenditures in specific clinics was the introduction of specialty pharmaceuticals. These include Thyrogen® and Sandostatin LAR® in endocrinology and Remicade® in GI. None of these medications was administered in the clinics just 5 years ago. While exact figures are unknown, the rheumatology clinic experienced similar increases in pharmaceutical expenditures with the release of Hyalgan® and Synvisc®

in the late 1990s.

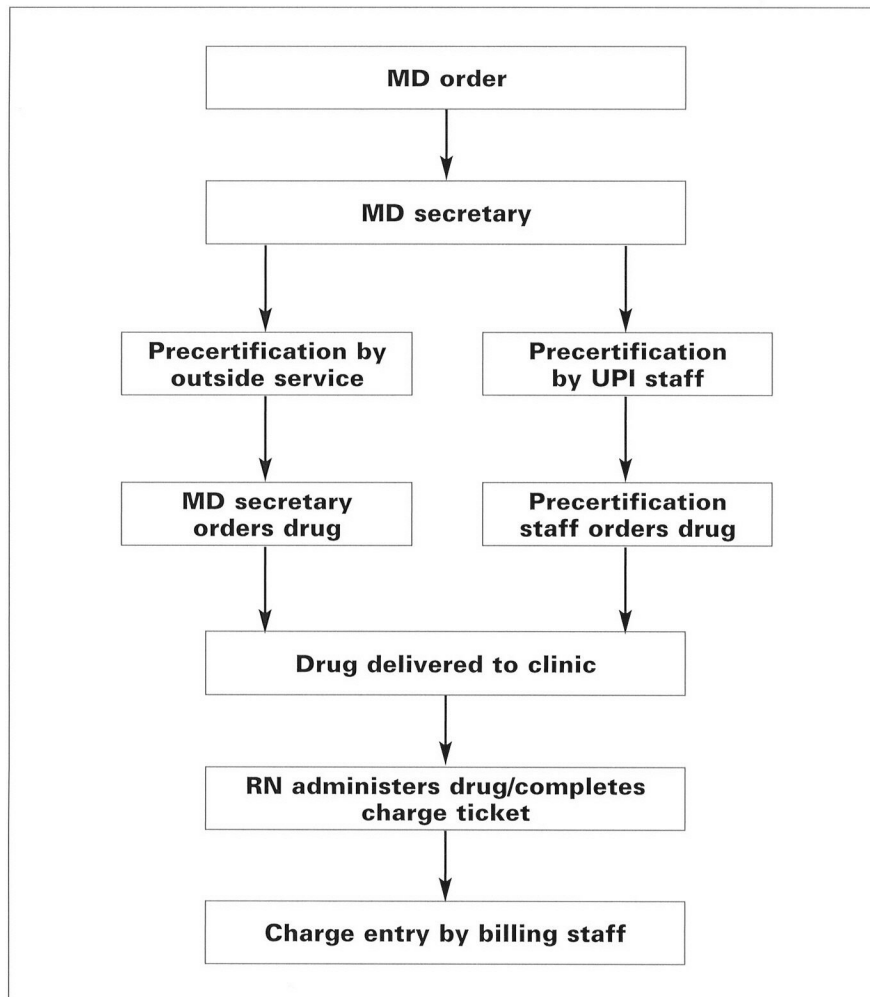
The department's first experience with specialty pharmaceuticals came with the release of Remicade®, a monoclonal antibody used to treat Crohn's disease. The GI program started administering it soon after its release in August 1998. At that time, the department did not have a formal process for the purchase, precertification, billing, or tracking of medication use and reimbursement (see Figure 1).

Challenges

The hospital's pharmacy supplies the clinics with the majority of its medications; however, since Remicade was nonformulary, it was ordered from an outside pharmacy. The department investigated several suppliers to obtain the best price and chose an out-of-state wholesaler recommended by the manufacturer. It was decided not to stock the medication due to its cost and the undetermined usage pattern. The medication was ordered as needed for individual patients. This presented several problems. Since the wholesaler was from out-of-state, if there was anything wrong with a vial of medication, or if the physician changed the dose, additional medication could not be obtained until at least the next afternoon. Thus, care was delayed and the patient inconvenienced. In addition, orders were shipped to the storeroom, which serves the entire hospital. On occasion, shipments were lost or temporarily misplaced. After further investigation, a local pharmacy was located that could supply the medication at a cost only slightly higher than the out-of-state wholesaler with the advantage of direct delivery to the clinic by pharmacy personnel. They also offered same-day delivery if needed.

Another issue occurred with the use of an out-of-state wholesaler. The physician's secretary initiated the precertification, ordered the drug, and scheduled

Figure 1.
Specialty Pharmaceutical Acquisition Process:
Pre-Intervention



the patient. This secretary is not located in the clinic area and therefore did not know when the drug was received. The nurses receive the infusion schedule only 1 day in advance. If the medication had not been delivered for a patient on the schedule, the secretary had to be notified to check on the order status. At times, the patient had to be rescheduled. Occasionally, medication was borrowed from one patient to supply another. Eventually, the nurses worked more closely with the physician's secretary in coordinating patient scheduling.

The initial ordering process

was also problematic. The physician's secretary ordered the drug without a purchase order (PO). The nurses received the medication and sent the packing slip to accounts payable. It was difficult reconciling what was ordered and received with what was billed. This process was changed to centralized ordering with a PO, which can be tracked to individual patients.

The precertification process also presented problems. Initially, an outside precertification service was used. If obtaining precertification was difficult, the patient was referred to University

Physicians, Inc. (UPI) precertification staff. On several occasions, the service only verified insurance coverage but did not obtain precertification. Thus, getting these claims paid was difficult. As a result, this service was discontinued and precertifications are performed by UPI precertification staff.

The biggest challenge was billing. There was no specific HCPCS code for Remicade until January 2000. In addition, coding is complicated. Remicade is supplied in 100 milligram vials. The typical dosage ranges from 300 to 600 milligrams, or 3 to 6 vials. However, the medication is not coded in number of milligrams administered or vials used. It is coded in 10 milligram units. There are 10 units per vial. The department initially billed in number of vials used. Some insurance companies reimbursed according to number of vials used; however, many interpreted this number as number of units administered. As a result, the department received one-tenth the level of reimbursement that it should have on those claims. Collections from June 2000 to September of 2001 did not cover costs and the department lost \$141,384. Many of the charges were recoded and resubmitted for payment, with varying results depending on the insurance company involved and the length of time from the date of service. An additional \$95,761 was collected from these charges to decrease the net loss to \$45,623. Table 1 summarizes these financials, and for ease of comparison to Table 2, the potential annual loss for 700 infusions (100 patients X 7 infusions/year) pre-intervention.

Another issue that affected overall program profitability was the inexperience in billing for specialty pharmaceutical infusions. Remicade is typically infused over a 2-hour period; however, personnel did not code for infusion hours. At charge entry, this effort was not recognized as a separate

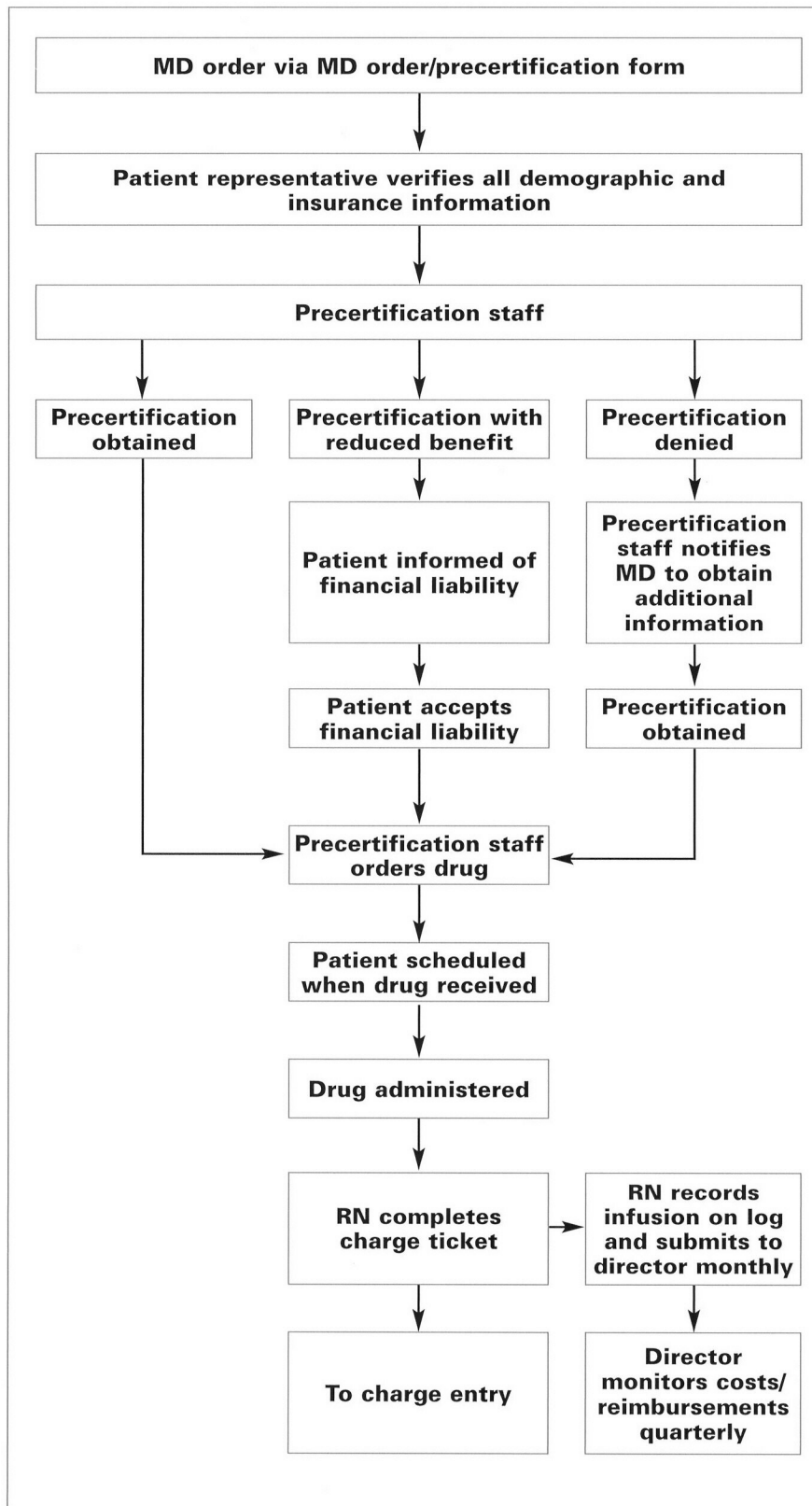
**Table 1.
Remicade Infusion Financials:
Pre-Intervention**

	Description	Weighted Average of One 1,400 mg Infusion	Total X 198 Infusions Administered (Actual)	Net Profit for 100 Patients X 7 Infusions/Year (Projected)
Total Reimbursement	Remicade 400 mg, 2-hour infusion, supplies	\$2,132	\$422,136	
Total Cost	Remicade 400 mg plus supplies	\$2,290	\$453,420	
Personnel Costs	Precertification staff, 1 hour per precertification	\$14.42	\$2,855	
	RN staff, 2 hours per infusion	\$58	\$11,484	
Profit/Loss		(\$230.42)	(\$45,623.16)	(\$161,294)

**Table 2.
Remicade Infusion Financials:
Post-Intervention**

	Description	Weighted Average of One 300 mg Infusion	Totals X 700 Infusions (100 Patients X 7 Infusions/Year)
Total Reimbursement	Remicade 300 mg, 2-hour infusion, supplies	\$1,957.75	\$1,370,425
Total Cost	Remicade 300 mg plus supplies	\$1,588.00	\$1,111,600
Personnel Costs	Precertification staff, 1 hour per precertification	\$14.42	\$10,094
	RN staff, 2 hours per infusion	\$58.00	\$40,600
Profit/Loss		\$297.33	\$208,131
Capital Expenditure	IV pump X 2, Infusion chair X 2		-\$5,620
Net Profit for 100 Patients X 7 Infusions/year			\$202,511

Figure 2.
Specialty Pharmaceutical Acquisition Process:
Post-Intervention



billable service. In addition, personnel were not aware that the IV infusion kit and the normal saline used for the medication admixture had to be billed separately. Both the clinical staff and coders were taught to convert vials to units and to bill for all services rendered. In addition, this educational effort was underpinned with a simplification of charge documents.

Cost-Containment Program

As a result of the experience with Remicade, and with the continued use of new specialty pharmaceuticals, the department of medicine developed a comprehensive program to minimize cost and maximize reimbursement for administering specialty pharmaceuticals (see Figure 2). All staff, including physicians, pre-certification specialists, nurses, and coders, are expected to follow the same process in the administration of specialty pharmaceuticals.

The first step was developing a single form for use as a worksheet by all staff processing the order. Without exception, this form must be used for all new orders and for changes in existing orders such as increased dose or frequency of administration. It includes patient demographics, physician orders, patient diagnosis (or medical necessity), and insurance information. The physician and the nurse initiate the form. Then, it is sent to the pre-certification staff, which pre-certifies the medication or notifies the physician if additional information is needed. Depending on the patient's insurance coverage, the pre-certification staff calls the patient to discuss co-payments, deductibles, or payment options. Once pre-certification is obtained and the patient receives financial counseling, the form is returned to the nursing staff, which orders the medication and schedules the patient for administration after the medication is received. Once the medication is administered, the nurses complete the charge ticket.

Both nurses and coders are taught unique coding aspects of each specialty pharmaceutical that is administered. Some charge tickets have been revised to include these unique codes or modifiers.

The next step in the process is tracking and accountability. The nurses maintain a log of all specialty pharmaceuticals they administer. This log is forwarded to the clinical director monthly. The director compares what was administered to what was billed in IDX. If there is a discrepancy, she forwards this information to the nurse for correction of charge tickets or to the billing manager for correction of charge entry. Quarterly the director determines the profitability of each specialty pharmaceutical used.

This process is applied to all specialty pharmaceuticals in use. Table 2 includes a margin analysis of 100 Remicade infusions post-management intervention. The margin analysis includes the patient mix based on insurance type and calculates a per infusion weighted average reimbursement for the 100 projected patients. The average included reimbursement for all aspects of the service: medication, IV infusion first hour, IV infusion X 1 additional hour, and supplies (300 milligrams or 30 units were used as the average dosage in the calculations). The cost of each infusion was also calculated. All costs were considered including precertification staff, RN staff, medication, and supplies. (Physician salaries were not included in the costs.) Based on projected volume, a discounted price with a 60-day term was negotiated with a local supplier. Using the above data, it was determined that a per-infusion profit of \$297.33 could be realized. An annual profit based on the projected 100 patients at an average 7 infusions per year minus the capital expenditure of two IV pumps and infusion chairs was projected at \$202,511.

There are several advantages

to using this system. First, the department is able to use specialty pharmaceuticals as soon as they receive FDA approval. This is essential for a tertiary medical center where patients come for treatment of uncommon or complicated illnesses. In the majority of cases, these specialty pharmaceuticals improve the patients' overall health status and their ability to perform activities of daily living. For some patients, complications related to their disease or inpatient care can be avoided. Another advantage is that the department can identify billing or coding problems and determine the profit/loss of a given service early in the process. Both help to maximize reimbursement. Patients also benefit financially as the process minimizes out-of-pocket expenses. In addition, patients are given cost information that allows them to make an informed decision before proceeding with treatment.

Conclusion

Managing specialty pharmaceuticals is an important economic issue for ambulatory practices. The availability, use, and cost of specialty pharmaceuticals will continue to grow. Managers should focus on a system of checks and balances, incorporating margin analysis, drug acquisition, precertification, claims processing, and reimbursement (Johnson, 2003). Providers must remain diligent in their efforts to identify opportunities to control costs and maximize reimbursement in a fiscally responsible manner.

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exposes them to some of the trials and joys of nursing leadership.

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