ORIGINAL STUDY

Addressing Costs and Continuity of Care through Innovative Solutions for Infused Therapies: A Collaborative Experience with Infliximab

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Background: Infused therapies are becoming more common as pharmaceutical and biotechnology companies increasingly focus their research and development efforts on biologic agents.

Objective: To understand how collaborative efforts among a health plan, providers, and specialty pharmacies can improve the efficiency of delivering infused therapies, using the example of a pilot program in southern Ohio for the administration of infliximab.

Methods: In October 2008, the authors conducted one-on-one, in-person interviews with representatives of a health plan, a specialty pharmacy, and the 3 largest gastroenterology practices in a southern Ohio community that collaborated to develop an innovative pilot program for delivering infliximab for patients with inflammatory bowel disease in a cost-effective manner in the office setting. The 2 health plan and 1 specialty pharmacy representatives were directly involved with the development and implementation of the program. Gastroenterology practice representatives included 3 practice managers, 2 infusion nurses, 2 billing managers, and 1 precertification specialist.

Results: The interviews revealed the opportunities and challenges associated with managing infused therapies, as well as the potential unintended consequences of unilateral action by health plans. As a result of changes introduced by a local health plan in southern Ohio, 3 of the largest gastroenterology practices in the region decided to discontinue in-office infliximab infusions for their patients and send them to local hospital outpatient infusion centers. However, before the implementation of this policy, a new collaboration between the health plan, the 3 practices, and the health plan's specialty pharmacy enabled these practices to continue to provide this medication in their offices. This collaboration avoided cost increases to all involved by preventing the shift of patients to hospital outpatient departments and allowing patients to continue their care in the office setting.

Conclusion: It will become increasingly important for payers to develop and support cost-effective ways to provide physicians and patients with access to infused medications. This pilot program shows the benefits of collaboration among healthcare stakeholders to identify innovative solutions for delivering appropriate office-based infusion therapy. The specific approach that is most appropriate for a specific health plan will depend on the unique local market circumstances.

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Growth in specialty pharmaceuticals (including biologic therapies) continues to outpace traditional small molecules,[1] and many of the newly developed specialty products will be infused. At the start of the fourth quarter of 2009, at least 19 infused specialty therapies were waiting for approval by the US Food and Drug Administration or were in phase 3 clinical trials.[2] Therefore, managing the costs associated with infused therapies continues to increase in importance for private and public health insurance plans. The required involve-

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KEY POINTS

- Growth in specialty pharmaceuticals, including biologic therapies, continues to outpace traditional small molecules, and many of the new medications currently in development will be administered by infusion.
- Infused therapies usually require the involvement of a healthcare professional.
- It is therefore critical that specialty products, such as infliximab, are distributed and administered efficiently to deliver quality patient care while controlling costs.
- This case study demonstrates a successful collaborative effort between gastroenterology offices, a specialty pharmacy, and a health plan for the administration of infliximab for patients with Crohn's disease or ulcerative colitis.
- The program's cost-savings resulted from avoiding hospital-based infusion, and these savings outweighed the moderate increases in payments to providers.
- This example shows that solutions for delivering infused therapies through efficient sites of care can be achieved through good communication among all participants, aligned incentives, a comprehensive cost plan, and innovation.

ment of a healthcare professional in administering infused therapies, and the complexities of and variability in care delivery across patient types and sites of care, make cost-effective management of infused therapies a seemingly daunting challenge.

This article describes how one health plan collaborated with its network physicians and other stakeholders to develop a cost-effective approach for the administration of the infused therapy infliximab (Remicade).

Inflammatory Bowel Disease

A collaborative effort between gastroenterology office practices, a specialty pharmacy, and a health plan in southern Ohio provides an example of a successful, integrated approach that maintained continuity of care for patients with inflammatory bowel disease (IBD) at the site of care as preferred by the health plan and its network physicians, as well as by many patients, according to their physicians.

Crohn's disease and ulcerative colitis are chronic relapsing and remitting IBDs[3] afflicting an estimated 1.4 million Americans.[4,5] Treatments for patients with IBD may be administered by different means—orally with aminosalicylates, corticosteroids, azathioprine (Azasan, Imuran), or methotrexate (Trexall); injected intramuscularly with methotrexate or subcutaneously with adalimumab (Humira) or certolizumab (Cimzia); or administered by intravenous infusion with infliximab (Remicade) or natalizumab (Tysabri).[5,6]

Infliximab is an anti–tumor necrosis factor agent that has been approved for the treatment of Crohn's disease and ulcerative colitis.[7] Studies have demonstrated its effectiveness for the treatment of Crohn's disease and ulcerative colitis,[8-11] and infliximab has become a recognized therapeutic option for the management of moderate-to-severe active disease.[12]

To deliver infliximab to patients, gastroenterologists are faced with a choice of infusion delivery alternatives. Some office practices have infusion capacity to enable in-office delivery of infliximab; other office practices refer patients to a local hospital for infusion services; still others refer patients to ambulatory infusion suites in the community or to home infusion providers for infusion administration at home.[13]

Each of these distribution models has different implications for physician office operations, patient out-of-pocket (OOP) cost burden, third-party health plan costs, and patient experience. In-office infusions may require physicians to invest in additional infrastructure, including product acquisition processes, inventory management, infusion chair and nurse capacity, and infusion billing procedures.

From a payer perspective, specialty pharmaceutical products such as infliximab pose unique opportunities and challenges. It is critical that specialty products are distributed and administered efficiently to deliver quality patient care and control costs. However, because a variety of administration options may be available to physicians (eg, in-office infusion, hospital-based infusion, home infusion), health plans must ensure that physician incentives are aligned with payers' and patients' site-of-care preferences.

Ensuring that infusions are delivered in cost-effective sites of care requires a comprehensive and integrated solution to address the needs of different stakeholders—physicians, patients, payers, and intermediaries, such as distributors or third-party infusion therapy providers.

The purpose of this study was to investigate a program implemented by one health plan to encourage continued infliximab infusions in the low-cost physician office setting, identify the key determinants of its success, and describe the implications for health plans interested in managing the costs of infused therapies.

Methods

In October 2008, the authors interviewed individuals involved with an infusion management pilot program implemented in southern Ohio by one of the leading

regional health plans. Study participants were selected based on their direct involvement with developing and/or implementing the program and the relevance of their specific roles in assessing the program's results and impact. Individuals interviewed included:

- 6 practice managers from each of the 3 largest gastroenterology practices in the region. For one of these practices, members of the office staff were also interviewed, including the billing manager, the infusion nurse, and the precertification specialist. For the other 2 practices, the information provided by the practice manager was sufficient to understand the impact of the program on practice operations and decisions
- 2 health plan representatives who directly oversaw program development and assessment
- 2 specialty pharmacy representatives who were directly involved with program development and execution
- 1 infusion therapy nurse affiliated with the infusion therapy provider used by 2 of the 3 practices.

Interviews were generally conducted in person, at the respondent's place of business. In one case (the infusion therapy provider nurse), circumstances required that the interview be conducted by telephone. A structured discussion outline was developed before each interview, with adaptations made by the authors during the interviews, as appropriate. Interview content was structured around the following topics:

- Circumstances before implementation of the pilot program
- Motivation for the pilot program
- Logistic aspects of the program
- Results and outcomes from the program
- Program success factors and lessons learned.

Participants' responses were summarized based on the notes taken during the interviews. Cost and outcomes data before and after implementation of the program were not made available to the authors. The results summarized below are based exclusively on the interview findings.

Results

Since the introduction of infliximab in 1999, many gastroenterologists in southern Ohio had been infusing infliximab in their offices. Practice managers from all 3 participating practices noted that their physicians believed that in-office infusion provided the most comfortable and convenient patient experience and allowed for effective monitoring of patients' conditions. In-office infusion was also financially sustainable; the gastroenterologists were receiving sufficient payment from health plans to cover the costs of investing in infusion capacity, hiring and training infusion nurses, and developing business processes to support in-office infusion of infliximab.

Health Plan's Cost-Control Strategies

By early 2008, as part of a broader attempt to control costs, while still delivering quality care, a local health plan implemented several cost-management strategies that affected the in-office infusion model for infliximab. The health plan established prior authorization (PA) requirements to ensure that only appropriate patients received infliximab infusions, and changed its drug reimbursement strategy (for infliximab only) from being based on an average wholesale price to being based on an average sales price, resulting in a reduction in infliximab reimbursement rates. In addition, the plan began selling more high-deductible insurance policies to its employer and individual customers, effectively increasing the OOP cost burden for patients, as well as the collections burden for physicians. The plan believed that each of these activities would generate cost-savings, while continuing to provide quality care for patients.

The health plan did not anticipate that these changes would cause area gastroenterology practices to reconsider the sustainability of in-office infusions. With declining drug reimbursement levels and no payment increases for administrative services, sustaining in-office infusion services became a burden. The practice managers and billing personnel interviewed noted that the proliferation of medical coinsurance and high-deductible health plans led to increasing numbers of patients struggling to pay their share of infliximab costs, higher receivables for the gastroenterology practices, and more bad debt being written off by the physicians. In addition, the PA burden required more nurse and office staff administrative time.

Providers

Exacerbating the problem was a disruption to the infusion process at 2 of the 3 gastroenterology offices. These 2 practices had partnered with a third-party infusion therapy provider to assist with the operations associated with in-office infusions. The infusion therapy provider ostensibly provided a turnkey operation, handling all aspects of infusion provision. The infusion therapy provider's responsibilities included:

- Acquisition of product and management of inventory
- Provision of infusion supplies
- Provision of a trained infusion nurse
- Administering infusions to patients (within the walls of the physicians' offices)
- Securing PA
- Billing third-party insurers.

The 2 practices were satisfied with the arrangement. They referred patients to the infusion therapy provider, which specialized in addressing infusion-related issues and insurance coverage. In return, the gastroenterology

nurses and office staff were able to focus their attention on the other core aspects of patient care.

When the infusion therapy provider unexpectedly shut down its operations in the area, the infusion process at these 2 practices was disrupted. This disruption coincided with the health plan's implementation of the additional cost controls, contributing to the gastroenterology practices' decision to terminate in-office infusions and to send patients who required infusion to the hospital. If the infusion therapy provider had continued operating, the practices would have continued infusing the patients in their offices without interruption, possibly obviating the need for this specialty pharmacy pilot program. However, without an infusion partner, and facing higher infusion costs and lower revenues from the health plan, the practices reconsidered their provision of office-based infusions.

Taken together, these factors caused the 3 practices to conclude that providing in-office infusions of infliximab was no longer feasible. All 3 practices decided that their best choice was to send the health plan's patients to the hospital outpatient clinic for their infliximab infusions. "We could not continue to provide infusions in our offices when reimbursement for infliximab from this health plan barely covered our costs, let alone the nonclinical burden of managing inventory and collecting patient copayments," explained coauthor Edward Freeman, former chief operating officer for a 13-physician gastroenterology practice in the community, who was also one of the practice managers interviewed for this study.

Innovative Pilot Program

Before the complete transition to a hospital referral model was implemented, a new collaboration between these practices and the health plan led to an innovative solution that enabled continuity of care for the patients in the physicians' offices. The health plan, seeking to avoid the higher cost of hospital-based infusions and maintain access to in-office patient care, developed a pilot program that, it hoped, would enable the gastroenterologists to continue infusing infliximab in the office setting.

This pilot program consisted of 2 major components.

1. Specialty pharmacy distribution. Physicians would obtain infliximab vials from the Ohio-based specialty pharmacy, which was owned and operated by the health plan. The specialty pharmacy would verify patient benefits and collect the appropriate patient copayment before delivering the medication to the physician. In addition, office-friendly procedures, such as medication delivery scheduling and confirmation, were developed to meet the needs of the practices.

2. Infusion case rate. The health plan chose to provide an additional payment to compensate the gastroenterology offices for infusion-related costs, such as nursing time, office-staff time spent securing PA, and infusion-related supplies.

All 3 gastroenterology offices in the area chose to participate in the program, generating benefits for physicians, the health plan, and patients. Physicians were able to continue to provide consistent care in their offices, while reducing bad debts and receiving a fair payment for the infusion service.

The health plan avoided the transfer of patients to a more costly hospital outpatient clinic setting, continued to provide convenient access to infliximab, deepened its relationships with the provider network, and began capturing utilization data through its specialty pharmacy.

According to the gastroenterology practices interviewed, as well as representatives of the health plan, patients continued to receive high-quality infusion services in the office setting, their continuity of care was maintained, and many reduced their OOP costs by utilizing the more generous of their medical and pharmacy benefits with the help of the specialty pharmacy.

According to all participants interviewed, the program has been highly successful. As Mr Freeman described it, "We now have a win, win, win. Patients continue to receive their infusions in the more comfortable and convenient office setting. The practice is relieved of some of the burden associated with managing acquisition of the drug, along with improved reimbursement for nurse administration. And the health plan avoids the higher site-of-service costs incurred when patients are sent to the hospital."

Representatives of the health plan acknowledged the avoidance of higher hospital-based infusion costs, noting that the associated cost-savings far outweighed the increased case rate that enabled continued in-office infusions.

The authors do not have information on the specific cost-savings estimates associated with the implementation of the program. However, representatives of the health plan reported during the interviews that the program would be considered for expansion to other geographies, allowing its regional affiliates to adapt the program to fit the specific needs of their local markets. The health plan's willingness to expand this pilot program likely reflects its success at balancing appropriate access to care with the potential to reduce costs.

Discussion

Lessons Learned

This example highlights the impact of health plan policies on physician site-of-care choice for patients and

outlines one potential solution to encourage cost-effective infusion therapy. In particular, the combination of specialty pharmacy distribution and appropriate physician payment levels for in-office infusions can reduce costs and ensure continuity of care for patients. Implementation of such a program requires a level of integration between the payer and specialty pharmacy that may be more likely when the specialty pharmacy and health plan have common ownership.

Health plans and physician practices seeking collaborative solutions to deliver efficient and high-quality patient care may wish to consider the following factors, which were critical to achieving success in this program.

Communication. Early communication between the gastroenterology offices and the health plan enabled identification of the problem and development of a solution before physicians were forced to send patients to the hospital.

Aligned incentives. The plan's objective was to encourage infusions in the most efficient site of care (ie, the physicians' office), which also met with patient desires and provided continuity in patient care. The program enabled physicians and the health plan to align their objectives by assisting with the physicians' receivables and inventory concerns (through specialty pharmacy benefit checks and product distribution) and by providing a fair infusion case rate for in-office infusions.

Comprehensive perspective. The health plan took a comprehensive view of plan costs by understanding the linkages between physician payment rates and the flow of patients to the hospital. A more typical approach would have been separate efforts to minimize physician and hospital payment rates without appreciating the ways in which these payment schedules can become interrelated.

Innovation. Sometimes new tools need to be developed to address a problem; in this case, the adaptation of a patient-focused specialty pharmacy delivery mechanism into a system that addressed physicians' needs was the innovation that enabled a successful rollout of the pilot program. Other solutions can also be considered, such as the nurturing of infusion therapy providers or the development of alternative cost-effective infusion sites (eg, retail clinics or free-standing infusion centers).

Health plans should carefully consider whether their payment rates to these alternative sites of care are sufficient to enable ongoing financial viability for the infusion providers. Success of infusion therapy providers or other alternatives to hospital-based infusion could be an important step toward minimizing costs and ensuring quality and continuity of patient care.

Increasingly, health plans will need to pursue innovative and integrated solutions that meet the needs of different stakeholders and that can be customized toward addressing local market circumstances.

Implications for Payer-Owned versus Contracted Specialty Pharmacies

Close cooperation between the specialty pharmacy and the local health plan was a critical ingredient in the development of a solution that resolved concerns of the gastroenterology practices and prevented the costly transfer of patients to the hospital. In the Ohio situation, the health plan owned and operated the specialty pharmacy, but does that mean that business innovations like these are achievable only by plans that are vertically integrated?

It is true that there has been a trend toward health plans' ownership of specialty pharmacy capabilities, with several large health plans owning their own specialty pharmacies. Examples include Aetna Specialty Pharmacy, CIGNA's Tel-Drug Specialty Pharmacy, and a consortium of Blue Cross Blue Shield plans' joint ownership of PRIME Therapeutics and its Triessent subsidiary.[14-16] There are undoubtedly operational efficiencies that direct ownership can help unlock. However, although smaller health plans may never have the scale to justify vertical integration into specialty pharmacy distribution, in many cases it should be possible to develop innovative, locally driven initiatives through creative contractual relationships with partner specialty pharmacies.

Outlined below are 4 advantages afforded by specialty pharmacy ownership that likely contributed to the success of the program in Ohio, along with some steps that health plans without internal specialty pharmacy capabilities can take to facilitate appropriate cooperation for customized program development.

Communication. Extensive communication is required between a health plan and a specialty pharmacy to identify a business opportunity, agree on a clear objective, work through the operational aspects of a solution, and monitor the successes and failures of the program. That kind of communication is challenging even between operating units within a single company; common ownership of the health plan and specialty pharmacy formalizes the communication channels, and corporate leadership can ensure that communication is a priority. It is likely more difficult, albeit not impossible, to achieve similar levels of communication between 2 separate companies.

Aligned incentives. Specialty pharmacy ownership helps to ensure that incentives are aligned between the specialty pharmacy and the health plan, which at some level contribute to a single corporate profit and loss. Internal conflicts can be addressed through adequate

corporate leadership and internal incentive structures. Health plans that engage specialty pharmacies on a contracted basis would need to structure their contracts to encourage the desired behavior and/or explicitly compensate the specialty pharmacy for specific activities. In the present southern Ohio gastroenterologist example, if the specialty pharmacy had not been owned by the health plan, a contract that specified higher payments for each infliximab prescription or upfront payments to offset program development costs might have been required to align specialty pharmacy and health plan incentives.

Integrated health information systems. In some organizations, integrated health plan and specialty pharmacy information systems could simplify and expedite the extraction and analysis of relevant patient data required to inform treatment and coverage decisions.[17] Using our gastroenterologist example, a health plan with integrated systems may be able to access members' medical and pharmacy benefits or claims information to obtain a comprehensive view of the costs associated with infusions of infliximab in the physician's office compared with in a hospital outpatient setting.

Effective systems could also support more streamlined rollout and administration of the program, for example, through easier benefit verification and patient copayment collection processes, leading to greater member, physician, and plan satisfaction. This issue can be partially addressed with external specialty pharmacy vendors by defining data needs upfront, establishing a common format for all data input and output fields, and agreeing on the mode and frequency of data sharing; however, the level of investment required for more comprehensive systems integration is unlikely without common ownership.

Long-term commitment. Gains from innovative programs may only be fully realized over the long run. Therefore, a long-term relationship between health plans and the specialty pharmacies, and continued commitment to common goals, may be critical to program success.

In this present case, there were upfront investments in new infrastructure and business processes that could only be justified based on cost reductions that would occur over time. It is unlikely that the health plan would have funded the investment in additional specialty pharmacy capabilities if the partnership were to expire in just a few months. In addition, network gastroenterologists were more likely to support a program because of an expectation of efficiency improvements over time as a result of repeated dealings with the specialty pharmacy and a low likelihood of operational disruption from a possible future change in specialty pharmacy vendors.

However, there is opportunity for health plans without fully owned specialty pharmacies to enter into long-term strategic partnerships with contracted specialty pharmacies that share the plan's vision, values, and culture. For example, Medco had a 10-year partnership with Accredo[18] before it merged with that organization in 2005.[19] Such long-term relationships offer plans greater flexibility to test programs in which success is uncertain, and potentially benefit from joint investments.

Although in-house specialty pharmacies may offer plans greater flexibility to test and develop customized initiatives related to specialty products, in many cases it may be possible for health plans without such internal capabilities to pursue specialty pharmacy relationships to successfully execute customized programs. These efforts require detailed upfront planning that facilitates communication, aligns incentives, addresses systems differences, and enables the plan and specialty pharmacy to capture long-term program benefits.

Conclusion

To maintain high-quality, cost-effective patient care, health plans need to develop efficient infusion options that address the needs of local providers, patients, and healthcare delivery systems. Unlike traditional pharmaceuticals that are dispensed at a retail pharmacy, processes for treating patients with infused therapies must be carefully crafted, and sometimes innovative approaches must be developed, lest infusion costs increase as patients transfer to nonpreferred sites of care. Health plans can begin with focused pilot programs that address specific local market needs, perhaps for a specific product or specialty.

Appropriate expansion to other product categories, physician specialties, and geographies can be evaluated as payers gain experience, enabling the potential realization of more extensive cost-savings and quality improvements. Future research focusing on the cost-savings and patient outcomes associated with site-of-care programs may offer additional valuable insights for the payer community. ■

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STAKEHOLDER PERSPECTIVE

New Strategies Needed to Combat Increasing Costs and Optimize Use of Infused Therapies

PAYERS: Continued development of new strategies for infused pharmaceuticals is necessary to help combat the ever-increasing costs of such therapies, ensure appropriate use, and optimize clinical outcomes. The drug spending trend for specialty injectables is anticipated to grow by as much as 14% in 2011,[1] and by 2014, the value of specialty injectables in select key markets is anticipated to reach more than $90 billion.[2]

Current strategies used by payers to reduce the impact of the continuous rise in drug trends each year and support appropriate drug use may include a variety of benefit modifications, including benefit design wherein drug coverage is shifted to or shared with the pharmacy benefit; revised product distribution, such as required use of specialty pharmacy providers (SPPs); expanded utilization management techniques, such as prior authorization, step therapy, or clinical guidelines and preferred products; remodeling provider reimbursement, such as matching SPP average wholesale price discounts or average selling price, plus pricing; and widening patients' share in the cost of treatment, with or without a maximum out-of-pocket limit.[3]

In this article, the authors outline a successful collaboration in an attempt to deal with the increasing costs of infused therapies. The authors describe a model that supports the strategy of cooperation between providers' use of physician office–administered injectables and pharmacies for self-injectables and for distribution of specialty infused therapies to the physicians' offices.

Such a delivery model may already exist within an organization as part of their focus to address claim issues and incorrect J-code unit billings. For plans where such a program is not currently available, the authors point out a multitude of barriers that may affect their ability to roll out such a program within an organization and its partners. Barriers that may be grappled with include setting infusion case and drug reimbursement rate assignments.

Continued

STAKEHOLDER PERSPECTIVE *(Continued)*

The alignment of financial incentives may be difficult between the physician practices, SPPs, and the health plan. The use of internal or external subject matter experts may be necessary to ensure a fair balance is reached between all parties involved.

PATIENTS: The authors note that an increased number of patients are struggling to pay their portion of the cost-sharing arrangement for their therapy. Because overall treatment costs show no signs of stabilizing, patients should consider discussing with their providers opportunities to maximize first- and second-line noninjectable treatments before the use of injectable therapy, when appropriate, to assist in reducing the cost burden.

Of note, the authors in this case elected not to interview patients involved with the pilot program. However, patients who offer constructive feedback to their health plan or purchasing organization (eg, employer) regarding a pilot program can assist in refining the program to best address the needs of the specific population.

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