

New Challenges to the IDN Infusion Center Business

And How Drug Manufacturers Can Respond

Look inside to answer:

- How does the Hospital Outpatient Department (HOPD) infusion center business work? How is it changing?
- What are IDNs' major challenges and opportunities in the infusion center business?
- What are the implications for drug manufacturers?
- How can manufacturers respond?

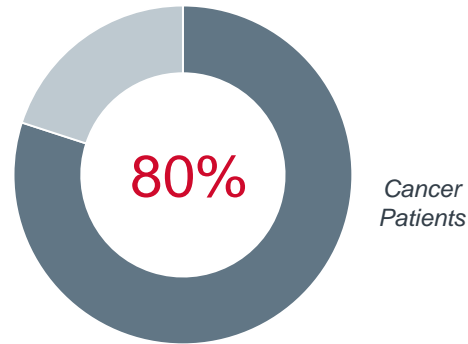
How Infusion Centers Fit into IDNs' Larger Strategy

Patient and Treatment Mix

Infusion centers administer infused and injectable treatments. While most infusion patients are undergoing cancer treatment, infusion centers also treat other types of complex and chronic disease, such as rheumatoid arthritis, multiple sclerosis, and Crohn's disease. Given the prevalence of these diseases, infusion centers are critical to meeting community needs.

Infusion Center Patient Mix

n=234 cancer centers

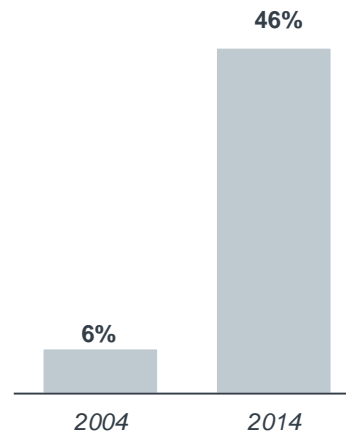


Site of Care Shift

Prior to 2005, the majority of infused and injectable treatments were administered in the physician office setting. But after Medicare changed its reimbursement policy for Part B drugs¹, many physicians began shifting their infusion patients to the HOPD setting, or selling their practices to hospitals and IDNs. As a result, most infusion patients are now treated in the HOPD setting.

Percentage of Chemotherapy Infusions Delivered in HOPD Setting

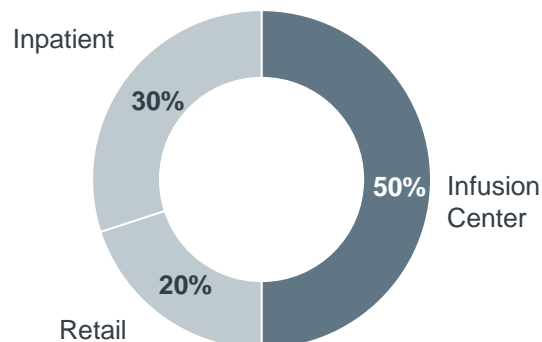
Private Payers



Impact on IDN Drug Spend

As a result of growing patient volumes and rapid drug price inflation, the typical IDN now spends approximately half of its drug budget on infused and injectable drugs. Because outpatient drugs are separately reimbursed, they represent a large and growing revenue stream; however, rising drug prices also come with increased financial risk for the infusion center under the "buy and bill" model.

Typical IDN Drug Spend



1) Part B drugs are drugs covered under Medicare's outpatient medical benefits.

How Does the Infusion Center Business Work?

Key Challenges to HOPD Infusion Centers' Financial Performance

Infusion centers are able to bill for two types of services: drug administration and separately payable drugs. 2018 Medicare reimbursement for drug administration in the HOPD setting ranges from \$37 to \$298, depending on the length and complexity of the treatment. Reimbursement for separately payable drugs is typically based on the average sales price (ASP) of the drug plus a fixed percentage mark-up. Medicare currently pays ASP + 4.3%, and private insurers may pay much higher rates. Consequently, infusion center revenues increase in correlation with patient volumes, treatment complexity, and drug prices.

Although reimbursement rates are generally favorable, most HOPD infusion centers struggle financially. In fact, without 340B drug pricing, the best managed HOPD infusion centers typically just break even due to their operational complexity and high costs. Key challenges include:

Lack of visibility into and accountability for financial performance



Responsibility for drug purchasing, inventory management, utilization, administration, and billing are typically distributed across multiple hospital departments and stakeholders. At the same time, financial reporting is very limited; few IDNs are able to produce a profit and loss statement for their infusion centers. As a result, no one has visibility into—or accountability for—the totality of the infusion center business.

Patient complexity



Infusion center patients tend to be acutely ill or frail, and the treatments are often highly toxic, so complications and delays are routine; thus it is very difficult to operate the infusion center efficiently.

Payer mix



As reimbursement rates have declined, private practice physicians have increasingly shifted unprofitable patients, including the uninsured, Medicaid, and Medicare patients without supplemental coverage, to hospitals for care, resulting in a less favorable payer mix for HOPD infusion centers.

High operating costs



Operating costs tend to be high because infusion centers must employ highly trained nurses and pharmacists, maintain an inventory of high-cost drugs, and adhere to stringent regulatory requirements.

Challenging revenue cycle operations



As drug prices have increased, health plans have increased their efforts to manage drug spending. Their tactics include increasing prior authorizations, expanding the documentation required to demonstrate medical necessity, and scrutinizing claims for high-cost drugs. As a result, hospitals and IDNs report increases in denials and underpayments. Yet few are tracking denials for outpatient drugs, appealing denials, or investigating their causes.

Source: Advisory Board interviews and analysis.

Why Is the Infusion Center Business Imperiled?

With the increasing incidence of cancer and autoimmune diseases, IDNs must ensure that their communities have access to high-quality affordable outpatient infusion services. That said, numerous reimbursement and policy changes are threatening infusion center's financial sustainability.

What reimbursement and policy changes are impacting infusion centers' business performance?

1

Rising drug prices

For example, the total cost of oncology drugs in the US increased 88% from 2011 to 2016. It is now routine for even a single dose of these medications to cost thousands of dollars. As a result, even a single denial or patient defaulting on his or her bill can have a significant impact on revenues.

2

Changes to 340B program

Starting January 1, 2018, Medicare cut reimbursement for Part B drugs purchased at 340B prices from ASP + 6% to ASP-22.5%. As a result, infusion centers that have typically relied on 340B drug margins must now find new efficiencies and improvements in revenue capture.

3

Medicare's site neutrality policies

As of January 1, 2017, Medicare cut reimbursement for non-excepted HOPD sites. In 2018, non-excepted reimbursement rates are 40% of HOPPS rates. Non-excepted sites include new satellite facilities opened after November 2, 2015 as well as physician practices acquired after November 2, 2015.

4

Medicare's conditional packaging¹ of drug administration fees

Starting in 2018, Medicare began packaging reimbursement for certain drug administration codes. While the changes have been relatively small to date, they are indicative of a larger trend and likely portend more packaging in the future.

5

Commercial payers' policies

Commercial payers are trying to combat rising drug costs by requiring certain patients to receive their injections and infusions in the lower-cost, freestanding or physician office setting. So far, they have targeted patients with less acute diagnoses, but they may expand site-of-care policies to other patient populations, including cancer patients.

6

Growth in white bagging²

In an effort to better manage drug spend, many commercial payers are shifting infused and injectable drugs from the medical to pharmacy benefit. Under this approach, the drug is dispensed by a specialty pharmacy but administered by an infusion center. The infusion center is no longer able to bill for the drug; however it continues to bear the costs of acquiring, storing, and preparing the drug for administration.

1) "Conditional packaging" means that Medicare will no longer reimburse for the service when it is provided on the same date as certain other services.

2) "White bagging" consists of payers purchasing drugs through a specialty pharmacy, and then shipping them to a provider (e.g., physician clinic or hospital) for administration.

Source: "CY 2018 Hospital Outpatient Prospective Payment System Final Rule," CMS, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Claims-Accounting.pdf>; Oncology Roundtable interviews and analysis.

How Can IDNs Protect Their Infusion Business?

As part of its 2018 national meeting research, Advisory Board's Oncology Roundtable developed a set of strategic recommendations and best practices to help HOPD infusion centers ensure the sustainability of their business.



Aligning drug spending and revenue accountability

As drug prices continue to rise, managing drug spending and revenues will only become more important. Progressive IDNs have begun to consolidate oversight and accountability for outpatient drugs, including revenue cycle operations, under a single service line, such as pharmacy or oncology. As a result, they are able to capture efficiencies, increase revenue capture, and gain insight into outpatient drug profitability.



Improving revenue cycle operations to ensure capture of every dollar owed

Progressive IDNs are investing in dedicated prior authorization (PA) staff who can develop expertise and experience in securing PAs for infused and injectable drugs. In addition, they are producing monthly or quarterly reports on outpatient drug denials and underpayments so that staff can appeal them and avoid future billing errors.



Expanding patient financial counseling

Patients' out-of-pocket costs are also rising in proportion to drug prices, but most IDNs lack experience and expertise in collecting patients' contribution. Best practice organizations are investing in dedicated financial counseling resources to help uninsured patients enroll in coverage, underinsured patients tap into external sources of financial assistance, and well-insured patients understand and plan for their out-of-pocket costs.



Instituting multi-stakeholder group to assess drug value and profitability

Best-in-class IDNs are convening physician leaders, as well as representatives from revenue cycle, pharmacy, and administration, to discuss the relative value of new high-cost drugs. These committees have a range of names: value analysis committees, ambulatory P&T¹ committees, revenue integrity committees, and chemotherapy councils. Their goal is to promote adherence to evidence-based practice and, when appropriate, select lower-cost therapies. The intention is not to restrict access to high-cost drugs, but rather to develop a holistic understanding of the associated patient outcomes, including toxicities, and the financial ramifications for the patient and IDN.



Reviewing pricing of infusion center services

IDNs affected by site of care management policies may consider changing their billing status or lowering their reimbursement rates to maintain their status in payer networks. The right strategy for any one IDN depends on multiple variables including: payer mix, adoption of risk-based contracts, competitive landscape, and 340B status.

1) Pharmacy and Therapeutics.

Source: Oncology Roundtable interviews and analysis.

The Implications for Drug Manufacturers

The growing financial stresses on HOPD infusion centers have multiple ramifications for drug manufacturers.



Multidisciplinary value-analysis committees introduce new stakeholders

Whereas in the past, manufacturers primarily marketed to physicians and pharmacy leaders, the advent of multidisciplinary value-analysis committees means that new stakeholders are now taking interest in the choice of drug therapy. In particular, manufacturers need to understand revenue cycle leaders' priorities and educate them about their resources for assisting with billing and patient access.



More robust data required to earn a place on oncology clinical pathways

Oncology providers, especially dedicated cancer hospitals and independent oncology practices, continue to adopt clinical pathways to increase adherence to evidence-based protocols and the likelihood of being reimbursed. Thus manufacturers will face greater urgency to prove their drugs' value in order to earn a place on clinical pathways. Specifically, they need to demonstrate increased efficacy, lower toxicity, and lower costs.



Encourage commercial payers' to cover biosimilars

IDN leaders and physicians are interested in adopting biosimilars to lower total costs of care while preserving patient outcomes; however, a key barrier is that many commercial payers do not cover them and instead only reimburse for the reference product. Manufacturers must continue to work with payers to ensure access to biosimilars and the long-term viability of the biosimilar market.



Infusion centers experimenting with pricing and billing status

To combat site of care management policies and preserve their in-network status with commercial payers, some HOPD infusion centers are lowering their reimbursement rates or changing their billing status from HOPD to non-excepted HOPD or freestanding. Although this strategy generally results in lower revenues, the goal is to maintain patient volumes and preserve continuity of care for patients undergoing treatment at the hospital. Switching billing status from HOPD to freestanding may also have implications for the class of trade under which IDNs purchase certain infused and injectable drugs.

Source: Advisory Board interviews and analysis.

How Can Manufacturers Partner with IDNs?



Support research on dose right-sizing and rapid infusion protocols

Increasingly providers have grown distrustful of manufacturers. To rebuild trust with IDN leaders, manufacturers should consider investing in mutually beneficial research initiatives. For example, manufacturers might partner with providers on clinical trials that inform opportunities to reduce dosages without compromising outcomes. Another possibility is studying opportunities to use rapid infusion protocols. These kinds of studies will not only assist providers in improving patient experience, but also help them reduce patient toxicities, increase operational efficiencies, and increase infusion center capacity.



Lend providers revenue cycle management support

When making prescribing decisions, providers increasingly consider not just patient outcomes, but also the probability that they will be reimbursed for the drug. In addition to assisting providers with PAs, manufacturers should seek to learn about the most common reasons that commercial payers deny payment for their drugs and proactively work with providers to help them avoid common pitfalls.



Work in partnership with IDN-owned specialty pharmacies

White bagging¹ and brown bagging² reduces infusion centers revenues and adds complexity to drug inventory management and patient care. To counter these pressures, many IDNs have invested in in-house specialty pharmacies to diversify revenues and preserve care continuity. Manufacturers can improve partnerships with IDNs by giving them access to limited distribution drug (LDD) networks. In addition, progressive IDNs are eager to partner to develop consensus-based pharmacy outcomes metrics to measure their performance.



Simplify and enhance patients' financial assistance programs

As drugs grow increasingly expensive and commercial payers shift coverage of more drugs from the medical to pharmacy benefit, patients' out of pocket expenses continue to increase. Simplifying the application process and broadening the eligibility criteria are straightforward ways manufacturers can support IDNs. Additionally, with so many different sources of patient financial assistance, financial counselors struggle to even identify optimal programs for any one patient. Manufacturers should consider how they can help providers navigate the maze of patient financial assistance programs to build a portfolio of financial aid that fits patient needs.

1) "White bagging" consists of payers purchasing drugs through a specialty pharmacy, and then shipping them to a provider (e.g., physician clinic or hospital) for administration.
2) "Brown bagging" takes place when drugs are purchased through a specialty pharmacy but shipped directly to the patient, who is then responsible for transporting the drug to the provider (e.g., physician clinic) where it is administered.



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