Home Infusion's Expanding Role in OptimizingSite of Care

By Jeannie Counce

PHARMACISTS AND PHARMACY TECHNICIANS

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Learning Objectives

- 1. Identify three key drivers in the site of care optimization trend.
- 2. Explain three strategies used by payers to move patients to more optimal sites of care.
- 3. List five common IV/injectable therapeutic areas that are targeted by site of care programs.
- 4. Understand the clinical and operational challenges that can limit patient movement to the home site of care.

Author Bio

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As health care evolves, more and more patient care is delivered outside the hospital walls. But even in the midst of this post-acute migration, outsized service models are still the norm, which drives up costs and contributes to the country's standing as the largest spender on health care per capita of any developed country.¹ Truly efficient care pathways can achieve the triple aim: provide the best care for the patient at the lowest cost to the system and, by doing so, improve overall population health.

This notion has given rise to a more granular evaluation of the specific settings and ways in which care is delivered. Looking to reduce costs and promote positive clinical outcomes, commercial payers are leading the charge in "site of care optimization." As they analyze mountains of claims and outcomes data, health plans are concluding that when it comes to infusion therapy, not all sites of care are equal. And, rather than simply offer coverage of IV therapies and services in cost-effective settings, they are actively driving care to these optimal sites.

Also referred to as site-of-care management, siteof-care (SOC) optimization is already proving to be a boon to some home infusion providers. As these programs grow and permeate commercial health plan benefits structure, it behooves all providers to understand their origins and how they work.

What and Why

SOC optimization is a utilization management strategy that seeks to lower costs associated with certain infused or injected drugs, including expensive specialty drugs and biologics, by encouraging the use of clinically appropriate, convenient, lower-cost care settings. Take, for instance, infliximab (Remicade®, Janssen). While it's no longer typical for an otherwise healthy Crohn's disease patient to be admitted to the hospital to receive his or her infusion, that same patient may be treated in a hospital outpatient department (HOPD), a physician's office, an ambulatory infusion suite (AIS), or even in the comfort of home. But payments for the same drug and service can vary significantly with HOPD rates two to three times higher than rates in alternate treatment sites.²⁻⁴ Infliximab was one of the first drugs that appeared in payer studies and is often used to illustrate the dramatic difference in cost between sites of care (see Exhibit 1).

Exhibit 1

Infliximab Cost Differential by Site of Care

Code	Drug	Alternate Treatment Site Rate	Outpatient Hospital Rate	Per-unit difference
J1745	Infliximab injection	\$63.4/unit	\$129.04/unit	103.27%
		\$3,134/claim	\$5,790/claim	
		\$2,424/claim	\$3,748/claim	

Source: Einodshofer M and Duren L. Cost management through care management, Part 2: The importance of managing specialty drug utilization in the medical benefit. American Health & Drug Benefits. 2012 Sep-Oct; 5(6):359-364.

*ATS = Patient's home, physician office, or infusion suite

Findings are similar across a variety of therapies. In a 2018 report, the cost of administering antihemophilic drugs was reported to be three to four times higher in the HOPD, with the most expensive drug, Factor VIII (recombinant), costing 3.7 times more in the HOPD.⁵ Despite the relatively small patient population receiving these therapies, the cost per claim is one of the highest in the medical benefit category with the highest category trend, which makes it an area of focus for payers wanting to optimize SOC. For this reason, nearly half (42%) of commercial plans surveyed in 2018 utilized an SOC preferred network strategy to manage their hemophilia cost center⁵

The substantial savings associated with these programs is driving their popularity. In 2014, when SOC optimization initiatives were beginning, they were estimated to save payers 12-34%, or approximately \$1.7 billion, per year.⁶ In addition to the end goal of reducing total costs, SOC programs seek to optimize clinical outcomes achieved through improved compliance and slowed disease progression. The flexibility of alternate sites also contributes to a higher quality of life by improving patient access to care, reducing time away from work or school, and offering a degree of independence to patients living under otherwise rigid medical parameters.

Not surprisingly, SOC programs for infused and specialty drugs are becoming more prevalent. Between 2013 and 2017 there was a 135% increase in commercial health plans that reported using SOC programs to direct patients from hospitals to community offices, ambulatory infusion suites, or home-based settings. Of those without a program in place, more than half planned to implement one within a year.⁷ By 2018, a strong majority (60%) of commercial payers used SOC programs, most commonly for biologic drugs for autoimmune disorders (BDAIDs), oncology, and oncology immunotherapy categories.⁸ Of the commercial payers that utilized SOC strategies, more than two-thirds (67%) experienced significant savings—an average of 61% reduction in cost.⁵

Target Areas

For infused and injectable drugs, the most significant potential savings can be found in the medical benefit. Drug coverage—medical versus pharmacy—varies widely by therapy class. Typically, injectable drugs are much more likely to be covered under the pharmacy benefit and IV-administered drugs under the medical benefit. However, there is a large area of overlap with payers offering plans with both pharmacy and medical benefit coverage (see Exhibit 2).⁸

Interestingly, high-priced specialty drugs fall into both categories fairly equally with drug spend under the medical benefit representing 45% of total specialty spend and the pharmacy benefit representing 55%. Industry trends suggest that as overall specialty spend grows from about one-third of total drug spend in 2016 to more than half by 2020, this ratio will remain about the same.⁹

Some therapies and/or disease states require higher-touch clinical services and aren't well suited for the dispense-only model of the pharmacy benefit. Although coverage under the medical benefit is appropriate, specific characteristics of this payment model limit payer "visibility" into spending. Delayed claims adjudication, bundled billing, and tracking and consolidation with pharmacy benefits make it more difficult for payers to analyze their costs. Nevertheless, the potential savings are prompting an increasing number of payers to identify areas of the medical benefit that can be managed more efficiently.

Exhibit 2

Medical vs. Pharmacy Benefit Coverage

	Pharmacy only	Medical only	Both
Inflammatory (IV)	8%	51%	41%
Inflammatory (injectable)	59%	10%	31%
Asthma	32%	44%	24%
Erythropoiesis-stimulating agents	22%	19%	59%
Granulocyte colony-stimulating factor	20%	19%	61%
Hemophilia Factor	20%	19%	61%
Hereditary angioedema	19%	42%	36%
Macular degeneration	15%	59%	25%
Multiple sclerosis (IV)	15%	59%	25%
Multiple sclerosis (injectable)	76%	5%	19%
Osteoporosis (injectable)	20%	51%	29%
Pulmonary arterial hypertension	14%	59%	27%
Respiratory syncytial virus	25%	56%	19%

Source: EMD Serono Specialty Digest, 14th edition



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Throughout the rise of specialty and infused drugs, insurance plans have controlled drug spending through mechanisms such as prior authorization, utilization management, and formulary management. More recently, cost variation between sites of care has emerged as an area of focus. After identifying the high costs of the HOPD—often double the cost compared to other settings—commercial health plans are increasingly shifting care out of the HOPD when clinically appropriate.¹⁰

Mechanisms

Early strategies began with redirecting patients to less expensive sites of care voluntarily. Working in concert with a pharmacy benefits manager (PBM), provider partner—or both—commercial payers

Exhibit 3

Examples of Medical Necessity Criteria for Drug Administration in an HOPD

Commercial insurers usually require that IV and injectable drugs be administered in non-hospital outpatient settings, unless:

- The patient is receiving an initial infusion or re-initiation of therapy
- The patient is medically unstable
- There is presence of a comorbidity, such as clinical history of cardiopulmonary conditions that may cause an increased risk of severe adverse reactions or unstable renal function that result in an inability to safely tolerate intravenous volume loads, including from unstable renal function
- The patient is physically or cognitively impaired
- There is difficulty to establishing or maintaining vascular access
- The patient has experienced past episodes of severe or potentially life-threatening adverse events with drug administration that cannot be managed through pre-medication in the home or office setting
- The patient has experienced past episodes of acute mental status changes with drug administration
- A home care or infusion provider has deemed the home an unsuitable setting
- The drug requested is subject to limited distribution and is not available for administration at non-hospital outpatient facilities or for home infusion

began educating targeted patients regarding their treatment options, highlighting the affordability and convenience associated with different sites of care. In one example, Express Scripts and Accredo Convenient Care contacted 27 patients receiving high-cost infusions at outpatient facilities. By converting 15 of them to in-home care, the plan saved \$787,680 per year.¹¹

Insurance plans also configure benefits and plan packages so that financial incentives, such as lower copays or out-of-pocket expenses, encourage patients to choose a lower-cost setting. For these efforts to be successful, however, payers must ensure that there is a provider network in place to serve patients moving to alternative sites of care. If alignment of incentives between the payer and the provider cannot be obtained, it's likely that patients will default to the higher-cost outpatient department.⁴

In a 2018 report, 25% of commercial payers reported using benefit design as an SOC strategy.⁵ That same year, average co-pays for services in an HOPD were \$155 compared with \$80 for home infusion and the average maximum out of pocket expense was \$2,721 compared with \$2,331 for home infusion.⁸

Employers, who purchase insurance, are also interested in SOC initiatives. In addition to reducing skyrocketing benefit costs, they are motivated to keep their employees as healthy and productive as possible, and sites of care that are convenient allow patients to continue with regular activities and promote compliance. By 2017, 84% of employer groups offered an incentive to their employees for utilizing lower cost sites of service, including shared cost savings (53%) and benefit structures that included higher co-pays for higher cost sites of service (44%). In addition, more than half (55%) were providing education to encourage the use of lower cost sites of service for infusion drug treatment.¹⁰

As SOC programs evolve, it is increasingly common for payers to structure medical coverage guidelines to move care to lower-cost settings, including the home. By 2018, 88% of commercial plans with SOC programs utilized clinical policy criteria as a means of implementation.⁵ Standard SOC policies allow treatment in an HOPD for the initiation or re-initiation of certain therapies in order to assess a patient's ability to receive therapy in an alternative site of care. Otherwise, plans require that IV and injectable drugs be administered in non-hospital outpatient settings unless the patient meets narrowly defined medical necessity criteria (see Exhibit 3 for examples). Clinical rationale and documentation are needed for the payer to review requests for medical necessity exceptions.¹²⁻¹⁴

Sources: United, Aetna, BCBS Anthem Medical Criteria

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Of course, given the number of payers and variety of plans on the market, it's normal to see a variety of SOC mechanisms being used—often in combination with one another (see Exhibit 4).

Bring Therapies Home

Most SOC programs employ a strong focus on home infusion with an overwhelming 85% directing patients to this site of care.¹⁵ When it is clinically appropriate, home infusion is often the lowest cost SOC. According to a Walgreen's industry analysis of more than 5.3 million commercial managed care lives from January 2008 through December 2010, the potential savings of transferring patients from complex sites without changing a drug and its dosage was 20-60% per infusion.¹⁶ Home infusion also offers the convenience of care in the home without the hassle of traveling to a care center and remaining there throughout treatment. Additionally, it eliminates exposure to infectious agents by keeping patients out of institutional settings, which is especially critical for those with compromised immune function.

Current SOC programs for IV and injectable therapies typically target the following therapeutic areas: immune globulin, Crohn's disease, rheumatoid arthritis, psoriasis, oncology and supportive care, hepatitis C, and multiple sclerosis.¹⁵ These therapies represent large portions of business for payers because they are used to treat many diagnoses which impact a large swath of their members. Data from 2017 shows commercial plans primarily focused on immune globulin and rheumatoid arthritis with large increases in programs targeting multiple sclerosis and oncology (see Exhibit 5).⁸

Overall, commercial insurance payments for medical pharmacy in the home rose 40% from 2016 to 2017, indicating the rate of migration to the home setting is accelerating.⁵ When it comes to specialty drugs, commercial payers consider the home a highly economical site of care. In a 2018 report, 53% of plans considered it competitive; the HOPD was considered the least competitive with less than one-fifth (19%) of plans rating it as competitive.⁸

Utilization of the home SOC for the administration of specialty drugs has more than doubled in the past 15 years or so—from 10% in 2011 to 21% in 2017.^{4,8} Even with its competitive advantages, a 2018 report shows that specialty claims billed through the medical benefit are serviced in the home less often than in a physician's office or HOPD (see Exhibit 6).⁸

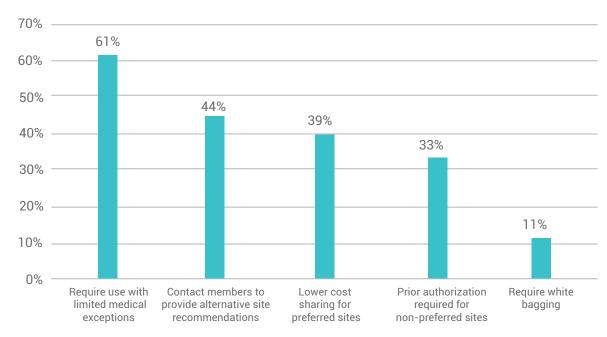
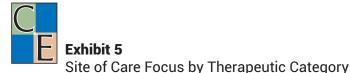
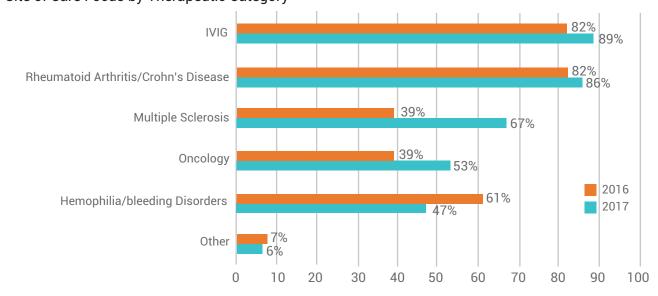


Exhibit 4 Site of Care Mechanisms

Source: EMD Serono Managed Care Strategies for Specialty Pharmaceuticals, $14^{\mbox{\tiny th}}$ edition





Source: EMD Serono Managed Care Strategies for Specialty Pharmaceuticals, 14th edition

Specialty Drug Administration by Site of Care

Not every therapy is appropriate for administration in the home, but many suitable therapies are not fully optimized. Exhibit 7 shows a breakdown of site of care market share for the top 25 commercial drugs ranked by home infusion penetration. Hemophilia factor and immune globulins are most commonly provided in the home site of care with a handful of others, including Remicade[®], also staking out respectable market positions.⁵

As market share increases, it appears that providers of all sizes stand to benefit from SOC programs. Nearly half (46%) of plans use multiple national and regional home infusion therapy vendors. Medium and large plans are more likely to use a mix than smaller plans. About one-third (32%) of plans use no national vendor, opting for more regional and local vendors.⁸

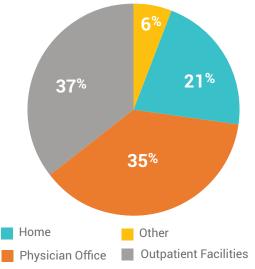
Strategies for Providers

As SOC programs continue to proliferate and payers refine their mechanisms, the influx of patients to the home setting stands to surge dramatically. Home infusion providers could take advantage of growth opportunities in a variety of ways.

Health system-based providers are well positioned to capture patients directed away from their system's HOPDs. There are numerous benefits for both the provider and the system, including more efficient use of the HOPD and preventing "leakage" from the system. Patients are likely to appreciate the continuity of care,

Exhibit 6

Specialty Drug Administration by Site of Care



Source: EMD Serono Managed Care Strategies for Specialty Pharmaceuticals, 14th edition

enabled by access to electronic health records, which can improve patient satisfaction. Providers of all types can partner on a local level with health systems lacking their own home infusion organization to take referrals or continue care for patients whose therapy was initiated in the HOPD.

For providers with large geographical coverage capabilities, there may be opportunities to partner with drug manufacturers. These arrangements are typically product specific and could require special clinical knowledge and/or competencies for certain therapies or disease states. In these arrangements, it would be beneficial to understand how rebates and patient assistance programs factor into calculating patient financial responsibility.

Providers of all sizes can benefit from forging partnerships with commercial payers. Many insurers employ an SOC vendor to comb through patient records and convert them to more optimal sites of care when appropriate. There is opportunity for home infusion providers with positive payer relationships to assist in developing SOC policies and work with payerbased health navigators or case managers to direct patients to lower-cost settings. Other provider-payer partnership models include participating in vertical networks to receive referrals directly from the plan. In these arrangements, it's important to have intake processes ready and provide adequate geographical coverage—along with clinical competencies.

The growing demand for the cost-effective home SOC affords providers an opportunity to dialog with payers about the value of the services they provide. These discussions may be an ideal opportunity to address any pain points and help make SOC optimization programs a win-win-win for the payer, patient, and provider of services.

Exhibit 7

Home Infusion SOC Market Share for Top 25 Commercial Drugs

Drug	J-Code	Rank		Market Share		
			Home Infusion	Physician	HOPD	
Factor VIII Recombinant)	J7192	11	77%	13%	10%	
Xolair®	J2357	16	43%	50%	8%	
Gamunex [®] -C/Gammaked [®]	J1561	6	36%	17%	47%	
Gammagard® Liquid	J1569	10	35%	35%	30%	
Stelara®	J3357	17	30%	53%	17%	
Privigen®	J1459	24	30%	16%	53%	
Botox®	J0585	19	19%	72%	9%	
Soliris®	J1300	13	17%	26%	57%	
Remicade®	J1745	1	10%	53%	37%	
Orencia®	J0129	23	7%	69%	24%	
Tysabri®	J2323	7	6%	42%	52%	
Xgeva [®] /Prolia [®]	J0897	15	5%	66%	28%	
Rituxan®	J9310	3	2%	42%	56%	
Keytruda [®]	J9271	14	1%	39%	60%	
Neualsta®	J2505	2		50%	50%	
Herceptin®	J9355	4		48%	52%	
Avastin [®]	J9035	5		77%	23%	
Opidivo®	J9299	8		43%	57%	
Perjeta®	J9306	12		44%	56%	
Yervoy®	J9228	18		38%	62%	
Eylea®	J0178	21		98%	2%	
Alimta®	J9305	22		32%	58%	
Abraxane®	J9264	25		45%	55%	

Source: Magellan Rx Management. Medical Pharmacy Trend Report, 2018



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