

Navigating and Optimizing Infusion Services when Hospital-based Care is Not an Option

Introduction

Site of care issues impact hundreds of thousands of patients daily. In this paper, we will examine the critical steps that need to be considered while facing these issues and will address:

- Location considerations
- Clinical considerations
- Drug access and purchase costs
- Patient out-of-pocket costs
- Managing patient handoffs
- Other business considerations

This paper will consider two patient care cases and how we can use these steps to navigate two patients' site of care issues.

1. Patient one is Ms. James. Ms. James is a 59 year-old female with rheumatoid arthritis. She has tried NSAIDs, oral methotrexate, and other oral disease-modifying antirheumatic drugs with little relief of her symptoms. Her rheumatologist would like to start her on a course of infliximab with one dose at 0, 2 and 6 weeks, followed by doses every 8 weeks thereafter. Ms. James works full-time, has commercial insurance, and would like to use the closest infusion center to her place of employment. Luckily, there is a hospital-based infusion center affiliated with the health system where her rheumatologist practices less than a mile away.
2. Patient two is Mr. Nguyen. Mr. Nguyen is a 67 year-old male with stage III non-small cell lung cancer. His oncologist would like to start him on pembrolizumab 200 mg every three weeks. He has difficulty ambulating and is insured by Medicare. He prefers not to receive treatment on the campus of the academic medical center where his oncologist practices due to traffic and parking difficulties.

Background

Site of care issues are challenging for both patients and healthcare providers. Patients and healthcare providers often feel like they are caught in the middle of a game over which they have little control or input. Navigating and understanding the financial decision of using one site of care over another, convenience, familiarity, and continuity of care all weigh heavily for everyone involved. Devastating diagnosis and prognosis news is challenging enough, and adding on site of care issues can contribute to significant stress, longer lengths of time before treatment, and a lack of clarity about the treatment plan.

Pharmacists are an integral part of the healthcare team that will be tasked with managing site of care issues. One example many pharmacists have experienced is when a medication that can be given in an outpatient setting is instead given while the patient is admitted as an inpatient. In some of these cases, the cost of the medication may be higher and the reimbursement may be lower or in some cases there may be no reimbursement.

Another site of care issue that pharmacists may have less experience with are the current challenges in the outpatient infusion setting. Patients have recently been receiving letters from payers regarding policies that infusion payments will only be reimbursable in non-hospital-based site of care settings or a specific drug needs to be administered in order to receive reimbursement (e.g. brand vs biosimilar, oral vs injectable drug based on formulary). This particular site of care issue will be the focus on the discussion in this paper.

Given these new challenges, pharmacists have the opportunity to intervene and optimize site of care coverage with their clinical and operational knowledge. Clinical and operational knowledge encompasses several facets. As good stewards of care, pharmacists have the ability to and should understand payer coverage and how to navigate settings that would be most appropriate for drug administration – whether that be an infusion center or home care. Pharmacists can fill in the gaps where other providers may not be aware of; they can understand and explain the economics of pharmaceutical reimbursement as well as understand the most clinically effective and safest place for care delivery.

Furthermore, pharmacists can address patient safety concerns, such as potential adverse drug events, expected side effects or abnormal lab values. To this point, pharmacists can help assess whether an outpatient or acute care setting is more appropriate for each patients' individual situation. All this leads to better patient-centered care and improved patient satisfaction.

Finally, as pharmacy leaders we must provide knowledgeable fiscal stewardship on the alternatives our organization should consider in managing these complex patients, ranging from evaluation of which site of care whether it be a non-health system owned provider to guiding decisions on establishing non-hospital based but health system owned infusion services. Maintaining patient centeredness care planning is of course paramount, but ensuring a viable and sustainable patient care model is critical.

Critical Steps

If you have the opportunity to work with a patient who is facing site of care challenges in the outpatient infusion space, it will be important to evaluate each individual from a holistic perspective as opposed to a one-time infusion. For example, a patient with rheumatoid arthritis is experiencing a chronic disease state that may require long term therapy with high cost infusions or injectables. Conversely, a patient diagnosed with cancer may receive episodic care of high intensity therapies. These patients are also likely to be suffering from comorbid diseases that may put them at higher risk of hospital admissions.

Outlined in the following sections are critical steps that should be considering when navigating site of care challenges. These steps include location considerations, which may be determined by the payer, clinical considerations, drug access and purchase costs, patient out-of-pocket costs, other business issues, and managing patient handoffs. The goal of presenting these critical steps is to provide discussion points, but an organization should evaluate their financial situation prior to making any final decisions for each patient or disease state. Please note that these critical steps do not address any joint ventures or contractual arrangements that could be considered.

Locations

One of the first critical steps to consider is the multiple locations where infusions can be administered. Based on payer restrictions and patient characteristics, one of these locations may be a better option, either financially or clinically. The four locations to be discussed are hospital outpatient departments (HOD), free standing infusion clinics (physician or payer), home infusion, and specialty pharmacy.

Hospital Outpatient Departments

HOD otherwise known as provider based (PB) departments, are the traditional clinic where patients receive infusion therapy. In this setting, drug charges are reflective of hospital mark-ups, making them less attractive for commercial payers, especially those reimbursing on a

percent of charge. These clinics remain a good option for a more complex patient as they are located close to the hospital (some exceptions with off-campus PB departments) and are equipped to handle emergency situations. Clinic workflows traditionally are more established, pharmacies are equipped to handle hazardous preparations, prepare drugs using USP 797/800, coordinate care and medication safety with members of the patient care team, and electronic medical records (EMRs) have been designed to handle the multi-drug therapy orders, as well as labs. Hospital based clinics are also included in the evaluation of the hospitals compliance by the Centers for Medicare and Medicaid Services (CMS) and must abide by the hospitals Conditions of Participation in addition to the The Joint Commission, DNV and State Boards of Pharmacy.^{1,2} Physician offices and other non-hospital based outpatient locations are held to different, less stringent standards.³ The HOD are an ideal site of care for a wide array of services and the complex patient with multiple comorbidities or an infusion with a high propensity for adverse reactions.

Free-Standing Infusion Clinics

Free-standing or professional/physician infusion clinics typically have a lower charge structure, and the majority of the payers reimburse utilizing a fee schedule that is near or at the Medicare allowable rate (ASP+6%). This serves as the main driving force for commercial payers mandating alternative options to HOD or PB departments. The number of free-standing infusion clinics have been growing at a relatively fast pace and some organizations have created their own free standing clinic to circumvent the site of care limitations and may contract directly with payers. One disadvantage of free-standing clinics is that there may be a lack of well-designed workflows or pharmacy clean rooms to prepare sterile and/or hazardous medications. Physical location may be further from emergency room or hospital services in the event of adverse reactions. Some states may not require direct physician oversight leaving these clinics a risky alternative for the highly complex patient. Further described below, there is no access to 340B drug pricing at these locations, shrinking margins even further for these organizations.

Home Infusion

Home infusion provides a unique alternative option. Patients may be treated in the comfort of their home and may present them a lower cost alternative.^{4,5} Similarly, commercial payers have included this as an alternative option to HOD. Organizations must consider all the logistical components or work with a trusted company prior to pursuing this location. Additionally, home infusion is not an appropriate location for all types of medication infusions. Medicare does not cover infusion services within the home setting; thus, limiting the ability to

have a one size fits all solution. However, private payers are recommending home infusion for certain drugs and it is necessary to be knowledgeable of this treatment setting, in case an adverse event occurs and the patient needs to be admitted.

Specialty Pharmacy

An organization may want to continue to service patients within their clinic and employ a white or clear-bagging operation. This option allows the patient to continue to be served within an organization's clinic and bill for the infusion administration procedure. This option is limited by the inability to purchase and bill for the drug under the patient's pharmacy benefits. Proceed with caution as many commercial payers have contracted with a specialty pharmacy network which may require the prescription to be filled by a specific pharmacy excluding an organization's own pharmacy from retaining the prescription fill. The organization will lose out on the drug margin and have an additional layer of complexity managing the prescription fill. However, in comparison to building an infusion center or coordinating home infusion, it is a relatively simple alternative to ensure continuity of infusion administration within an established clinic operation. Doing a prior authorization for all patients, new and current, will allow you to determine where the patient's drug will be sourced. The organization should consider separate storage for patient supplied drugs and ensure the drug's integrity during shipping.

Clinical Considerations

Another critical step that needs to be considered when deciding on site of care issues is the clinical and logistical characteristics of administering the medication. For clinical characteristics, the risk of severe or potentially life-threatening events needs to be assessed. If there is a history of such adverse events, it may be medically necessary to administer the medication at a HOD so that the patient can be properly managed. Insurances may allow this reimbursement exemption for a HOD if there are plans to reassess the patient after a certain number of months. For patients who are being administered the first dose of an infusion with no knowledge of expected adverse events, the first dose may also be exempt from the site of care limitations. Besides adverse events, the patient will also need to be assessed for medical status and comorbidities. If the patient has a complex medical history that requires potential interventions beyond the capabilities of an alternate site of care, the infusion may also be exempted from the site of care limitations.

Drug Access and Purchase Cost

Drug access is another critical step to consider when considering site of care challenges. Certain medications may be restricted in how they can be accessed or purchased. For example, with Soliris (eculizumab), prescribers must enroll in the Risk Evaluation and Mitigation Strategies (REMS) program before an order for the medication can be placed and shipped. Certain infusion practices may not have any registered providers who could prescribe and order the medication. Other medications may be restricted by limited distribution networks as previously described. In these situations, the patient can only receive the medication from authorized specialty pharmacies. Especially in the case of external infusion vendors, it will be important to ensure treatment can be continued without interruption due to supply chain issues before transferring a patient to their care.

Drug purchase costs can also vary among the different site of care locations. Group purchasing organizations and individual contracts may result in lower purchase costs to non-hospital based sites of care, but this should be carefully validated with the entire drug and utilization portfolio on an ongoing basis. Free standing clinics are not eligible for 340B priced drugs which presents a greater financial divide for these 340B organizations.

Patient Out-of-Pocket Cost

Except for home infusion, CMS reimburses all outpatient therapy under Part B. Patients are responsible for the \$185 deductible, followed by a 20% coinsurance of the Medicare allowable. There are additional facility-based evaluation and management (E&M) charges that result in higher out-of-pocket cost (and reimbursement) when infused within a HOD.

Patients with commercial insurance can customize and tailor their plan designs to meet their needs. However, high deductible plan designs are becoming more common. In such situations, a patient with a complex disease state and multiple comorbidities may benefit by keeping all their care in a HOD. These patients quickly reach their maximum out-of-pocket cost. Transitioning care to an alternative site may incur additional copays on top of their high deductible plan. Commercial insurance companies are passing on higher co-pays/out-of-pocket costs if a patient does not comply with the health plans model for providing care.

Managing Handoff Communication

Regardless of the infusion location and whether a patient will be managed internally or externally to your health system, there is an advantage to both the patient and the health system to have a plan in place for managing the handoff communication and maintaining a strong relationship with the patient. In an ideal state, there should be a coordinator to help the

patient navigate through this process and ensure the following key steps are completed: educate the provider, educate the patient, transfer the information, establish follow-up visits, and ensure other internal care is not disrupted.

Educating the provider is an important first step in managing the handoff. Many providers are not familiar with these new site of care restrictions. As such, if a decision is made to transfer care, it will be important to ensure they understand why that is occurring and how they can continue to support the process.

For patients who are navigating the ever-growing complexity of healthcare, they need to be supported to be advocates for their own healthcare. Educate the patient on upcoming treatments and make sure they understand when, what, and where they should receive their medications. Advise them to ask questions to ensure all their care providers understand the treatment plan.

Once providers and patients are educated, the next important step is to understand what information has to be sent to the alternative site of care. High quality of care can only be achieved if all pertinent information is shared from one provider to the next. EMRs that are not shared lead to lengthy processes and manual workflow. Thus, pertinent labs, adverse events, and current and past medication lists should be extracted and sent to the alternative site of care.

Following the transfer of care, establish a follow-up visit or phone call with the patient after each infusion. Assess patient compliance and ensure appropriate care was received. Use this follow-up encounter as an opportunity to determine if the patient experienced any adverse events. At the same time, ensure that all other healthcare services involving the patient are still occurring internally. Services such as prescription refills through retail or specialty prescriptions are a large business opportunity for health systems. Health systems will be financially advantaged by optimizing this capture and improve coordination of patient care.

Other Business Considerations

Certain organizations may have a mix of both hospital and non-hospital sites of care. When site of care issues arise, these organizations are faced with complex decisions regarding the ability to maintain consistent levels of care while minimizing financial impact to the organization. As previously mentioned, medication costs are generally higher and reimbursement is lower in the non-hospital based clinic environment. As patients are shifted

away from HODs, site of care changes may begin to influence formulary choices and medication availability across sites of care. Additionally, organizations that only have hospital based care sites may begin to explore the ability to retain patients through reclassification from HODs to non-HODs. This can be a lengthy process and requires moving from a UB-04 billing model to a CMS 1500. As described above, this reclassification may also impact the purchase cost of drugs and may gain access to specialty GPOs offering special discounts but may lose access to 340B pricing; thus, careful consideration of financial implications to the organization must be considered.

Additional consideration should be taken to track site of care changes at an organizational level to validate reimbursement and minimize exposure to denials by payers. It is possible that a patient's therapy could have previously been financially authorized, but a site of care change would impact the status of the authorization. As site of care changes are communicated, a valuable exercise for the organization is to review all patients who are currently receiving impacted therapy and seek accommodations to allow for continued therapy at the HOD or facilitate transition to a non-HOD care site. Unfortunately, many situations resulting in lack of reimbursement are unidentified until the point a denial is received. There are various reasons denials could exist including a lack of prior authorization, change in payer contracts, or inaccurate/incomplete claim generation. If an organization's proactive methods for ensuring payment fail, a process for timely review and processing of denied claims should be used to identify potential issues caused by site of care changes.

Applying Concepts

A review of the two cases below demonstrate how the critical concepts are applied and the resulting cause and effect of decisions made. The most important application of the critical steps provided is to assess your organizations payer mix, common patient care challenges, and general care location preferences by your managed care and finance team. Through this assessment, develop agreed upon care plans that leverage the organization's resources, optimizes financial outcomes, and ensures optimal therapy for the patient.

1. Ms. James was referred to the hospital based infusion center affiliated with the health system for her infliximab infusion. A prior authorization was completed prior to her first visit. The coordinator relays from Ms. James to you a letter stating, "Ms. James has been approved for the first dose of infliximab. Any subsequent doses must be administered in a non-hospital based location." Confused and frustrated Ms. James demands an explanation.
 - a. What is a way to explain this situation to Ms. James?
 - i. Ms. James' commercial insurance is driving a policy change through the prior authorization process. They have approved you for the first dose, but the insurance company wants to see the infusion given at a lower cost setting provided there are no complications with the first infusion.
 - b. What are Ms. James options?
 - i. Ms. James continues to work full time and is not at home during business hours, and home infusions do not appeal to her. There is a free standing infusion center not affiliated with the health system approximately 3.5 miles from her work. Her insurance will accept the infusion at this location.
 - c. How will the cost for Ms. James change?
 - i. Other than her rheumatoid arthritis, Ms. James maintains relatively good health and does not require additional medical services. After some investigation, you determine she has a high deductible plan for all hospital based services, but only pays 10% of the allowed plus a \$50 copay for each infusion in the non-hospital based locations. Assuming she does not require any additional medical care, her out-of-pocket cost is less in the non-hospital based setting as she is not likely to reach her high deductible (note: patient's benefits are uniquely designed and would need to assess on a case-by-case basis).

- d. What are some additional considerations for the original health system?
 - i. To provide optimal care to the patient, the health system should ensure all pertinent notes, labs and medication history is transferred along with the orders to the non-hospital based clinic.
 - ii. Providing a post follow-up phone call to Ms. James may enable her to maintain her care for all other services within your health system. Additionally, it may allow you to intervene after the trial of infliximab and the patient requests to move to a self-administered injectable like adalimumab. This would allow you to regain the drug margin within your outpatient pharmacy.

2. Mr. Nguyen sees an advertisement for a new home infusion company that states they can save money and provide the infusion in the comfort of his home. He calls his oncologist and request that he receive his pembrolizumab infusion at home. The oncologist is unfamiliar with any home infusion and asks you for advice?
 - a. Is home infusion appropriate for Mr. Nguyen?
 - i. This is the first infusion that Mr. Nguyen will be receiving and it is unknown if he will experience an infusion related reaction. Pembrolizumab is a hazardous medication requiring dilution prior to administration and is only stable for 24 hours under refrigeration ruling out the home infusion possibility.
 - ii. Lastly, Mr. Nguyen has Medicare with no supplemental coverage. Medicare does not cover infusions at home and he will be responsible for the full charge out-of-pocket.

Mr. Nguyen follows asking about the newly built free standing infusion center affiliated with your hospital. You know your organization is eligible for 340B drug pricing.

- a. What do you explain to Mr. Nguyen?
 - i. Mr. Nguyen is still not a candidate for the free standing infusion center. This location is not equipped to handle hazardous preparations, and in the event of an adverse reaction this location is several miles from the nearest hospital emergency room.
- b. How does the change in location impact your organizations reimbursement?
 - i. From a financial standpoint, it is advantageous for you to continue to infuse Mr. Nguyen in the hospital outpatient department. The organization is eligible for 340B drug pricing which is only accessible in the HOD, not the free standing infusion even though it is affiliated with your health system.

Conclusion

Determining the proper site of care for medication therapy is a growing challenge, and there are multiple avenues available making decisions complex. The clinical and financial pros and cons should be evaluated for each patient with the understanding that the decisions may vary based on patient characteristics and insurance. Pharmacy teams are in a pivotal position to become the experts in this area. Pharmacists have the knowledge and understanding of the patient and the patient's drug therapy to make recommendations that are safe for the patient. Additionally, the pharmacy team can help determine and drive the site of care based on the financial outcome and clinical information as part of coordinating care with the patients insurance.

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