



Site of Care Issue Brief

Background

Site of care is a program where insurance mandates that specific medication infusions and injections occur at alternative locations, which could include a stand-alone infusion center, physician provider practice, or home infusion. This is sometimes referred to as site of care optimization or site of care steering. There is a current shift in insurance payor policies restricting certain locations where infusions can occur. Navigating and understanding the financial decision of using one site of care over another, convenience, familiarity, safety, and continuity of care can be a difficult and stressful process.

Benefits of Choices in Site of Care Outside the Hospital Setting

The intent of site of care optimization policies is to direct patients to sites that have a lower overall cost of care for specialty biologic medications. Having the choice of different sites of care purportedly decreases the care providers' expenses and cuts down on indirect costs for institutions. There are four locations that a patient can receive specialty pharmaceuticals: Hospital Outpatient Infusion, Physician Based Infusion, Free Standing Infusion centers and Home Care Infusion. Patients may prefer the home infusion model, or local ambulatory infusion centers, because it may be more convenient. Alternate sites may increase flexibility with work and home schedules, and it may reduce long traveling distances to receive treatments.

Drawbacks of Choices in Site of Care Outside the Hospital Setting

Patient safety is a major concern about having different site of care choices. Variations in the setting introduce risks that impact the patient's health and outcome for care. For home infusion, the patient may not have appropriate safety checks in place around equipment and patient assessment. Cases have been reported where a patient has had immunotherapy toxicity resulting on the medication to be placed on hold by the provider, but the home infusion company infused the drug to the patient anyway. Furthermore, at home the patient does not have the equipment to handle adverse events and is reliant on 911 emergency services. Devices used to administer products in the home have less accuracy, which can lead to inadvertent rapid infusion causing harm to the patient. Safety of the patient also extends to the transition of the patient from a hospital setting to another site of care.

Concerns regarding safety of the drug, its compounding and handling also can arise with alternate site of care locations. At provider-based or ambulatory infusion centers, the staff who are checking the drugs may not be pharmacists, so errors in mixing and preparation of medications may be overlooked. Not all ambulatory infusion centers may not have USP <800> compliant rooms for compounding hazardous drugs, limiting which therapies can be offered. Inexperienced staff at infusion centers may also be less familiar with unique drug properties and compounding requirements. Storage and handling are also major issues, since temperature excursions when being delivered for home infusion could compromise drug stability or potency.

Providers may not be comfortable giving patients care through alternative infusion sites since it introduces so many nuances to the care delivery model that are outside of their control. Not all patients are ideal candidates for a change in their site of care, such as patient that may exhibit one of the following: Stage IV disease, multiple comorbidities, patient anxiety about re-direction of care, risk and complexity of infusion, brain metastases, advanced patient age, complex patient, and complicated treatment regimen. Site of care can also create an administrative burden for providers, with increased staff time needed to follow up on restrictions. In rural areas, it is very challenging to set up home infusion and home health. Often an extender of the oncologist is coordinating care, adding to the administrative burden.

Finally, there are concerns that an insurance mandate to receive care at sites outside of the hospital setting will eliminate patient choice. There are some policies that allow patients to receive the first dose in hospital-based clinics, but some payers mandate that even first doses must be given in a home setting. If the initial dose is completed at the prescriber's preferred location, the prior authorization will have to be canceled and resubmitted with the new Tax ID number, which introduces administrative waste and potential for error. If providing initial doses at the prescriber's preferred clinic is prohibited, there is an increased risk for infusion reactions to occur at the other site of care, where support may not be as robust.

Impact on Cancer Patients

Cancer patients have very serious medical conditions and require close monitoring by their cancer providers. By pushing care out of the hospital-based clinic, it is more difficult to continuously monitor patients. Pharmacists and providers may not be able to follow-up on toxicities. As more expensive chemotherapy medications come to the market the impact of value-based care models, capitated markets, and global payment initiatives will become even more confusing with the shuffling of costs to different sites of care.

Mandating sites of care outside the hospital setting can cause a number of detrimental impacts on cancer patients and their caregivers, including:

- Confusion over how supportive care medications, such as anti-emetics, anti-anxiety, and pain management medications, are provided, how they will be billed, and where will the patient pick them up. If it is at a retail pharmacy, these medications may not always be in stock or may need to be delivered from a pharmacy hundreds of miles away from the patient's home.
- Delays in administration of time sensitive medications. E.g. delivery of peg-filgrastim, a medication used to stimulate the production of white cells within a narrow time window following chemotherapy may require a patient to coordinate with a specialty pharmacy hundreds of miles away, and a delayed dose or missed dose
- Fragmentation of care for patients receiving multi-drug regimens.
- Barriers to participation in clinical trials if policies require a patient to seek alternate sites for different elements of care.
- Need for additional visits because patients would be unable to receive toxicity checks, radiation therapy, palliative care visits, nutrition visits, social work, nursing care navigators, and other services on the same day as their treatment administration.
- Loss of patient education as many practices counsel patients both during the clinic visit and during infusion, and this critical layered learning would be absent if patient is sent to an alternative site of care.

Recommendations

HOPA believes that patients with cancer deserve to receive treatment at sites with the acumen to deliver optimal outcomes, and HOPA's vision is that all individuals affected by cancer have a hematology/oncology pharmacist as an integral member of their care team. Thus, HOPA opposes mandated requirements on site of care and believes that the choice should be made with shared decision-making between the patient and providers. The choice of site of care should consider the individual circumstances of the patient, including drug characteristics, safety risks, and financial impacts. It is crucial that the patient be the first consideration in any decision. If home infusion is provided, there needs to be adequate safety policies and procedures in place.