White Paper

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White bagging, brown bagging and site of service policies: best practices in addressing provider markup in the commercial insurance market

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New Institute for Clinical and Economic Review (ICER) analysis evaluates potential risks and advantages of reforms to current policies related to white bagging, brown bagging, and site of service policies that aim to address provider markup in the commercial insurance market.

Plain language summary: The high cost of specialty pharmaceuticals is driving change across the healthcare system, including consequences for life science research and development investments, employer benefit designs, payer approaches to prior authorization and step therapy, and provider priorities for consolidation and expansion. Markups on prescription drugs refer to providers being reimbursed for products at higher amounts than product acquisition costs. Payers have been actively working to reduce prescription drug markups, but such efforts should balance possible savings with the need for thoughtful consumer protections and transparency. Policies must also be structured to promote health equity by keeping the risks to patients with lower incomes and fewer social supports front and center as they may have the greatest challenges navigating these policies.

Tweetable abstract: New ICER policy analysis evaluates potential risks and advantages of reforms of current policies related to white bagging, brown bagging and site of service policies that aim to address provider markup in the commercial insurance market.

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For people with conditions like autoimmune disease, cancer and multiple sclerosis, clinician-administered specialty drugs represent positive, sometimes lifesaving, innovation. Payers and policymakers recognize these advances but also see these products as leading drivers of increased drug spending. While use of specialty drugs is concentrated in less than 5% of the population, they now account for about half of total drug spend [1].

In response to these pressures, employers, other plan sponsors and the commercial health plans and pharmacy benefit managers (PBMs) who manage health benefits and create formularies, have all deployed strategies intended to control drug spending while maintaining appropriate access for patients. To complement formulary tiering and prior authorization, payers have recently moved to aggressively manage the 'markup' over drug acquisition costs that is charged by providers through the traditional 'buy and bill' reimbursement mechanism for clinician-administered drugs. Policies that address markup by providing the drug through a separate entity can take different forms that are often called white bagging, brown bagging or clear bagging. In addition, payers are increasing their use of policies requiring patients to receive drugs from a site with lower or no markup in comparison to more expensive hospital-affiliated locations, an approach known as site-of-service policies.

Large payers report significant cost savings with bagging policies and with site of service policies [2]. Internal data and independent reports also have shown stable or improved patient satisfaction with the care process [3]. However, the data to perform independent evaluations of these policies are not publicly available, and while payers have touted their positive effects, hospitals and provider groups have argued that there are important risks and underappreciated negative consequences for both patients and providers [4].

The goal of this paper is to summarize the arguments and scant data for and against different bagging policies and site-of-service policies. We then present an analysis of potential policy reform options that may help improve the design and implementation of these policies and other efforts to control costs for clinician-administered drugs. Of note, publicly available evidence on the impact of white bagging, brown bagging and site of service policies is very limited. Many of the purported benefits and drawbacks of these policies are supported solely by anecdote or internal analyses not subject to public examination or peer review. We therefore acknowledge the potential for bias within the views of different stakeholders whose experience and views are reported in this paper and are sensible that our own analyses and conclusions are vulnerable to the selective information provided to us by sources with varying conflicts of interest.

Methods

To inform this work, we performed a literature review and stakeholder interviews focusing on the challenges around the shifts in drug delivery and site of service for clinician-administered drugs. The literature review was also used to understand the impact of changes that drug delivery and site of service has on patients, providers and payers. We interviewed 19 experts from large and small pharmaceutical manufacturers, health plans, PBMs, specialty pharmacies, comprehensive care centers and physicians. We also tracked current legislation regarding these issues that were introduced to inform our understanding of how legislation may impact the drug delivery and site of service models used to date.

From this background work, we developed a set of potential policy reforms reflecting different themes and challenges discovered throughout our research. These potential policy reforms were the basis of formal discussion and further revision during a 2-day policy summit in December 2022 with representatives from 33 payers, life science companies and provider groups. A final white paper based on this work was posted in April 2023.

Background

Traditional management of drug spending by health plans and PBMs has emphasized price negotiation linked to formulary placement and evidence-based utilization management, including prior authorization and step therapy when equivalent or more effective treatment options are available at lower cost. However, 45% of specialty spend is on drugs that are clinician-administered and reimbursed through the medical benefit. For these specialty drugs, formulary tiering is not usually feasible and payers often have more limited data with which to track and manage utilization in real time through prior authorization and step therapy [5].

Given the high costs of specialty drugs and the limitations of traditional utilization management, many commercial payers are increasing efforts to reduce the markup on specialty drug acquisition and administration that is charged by providers who buy drugs directly from drug wholesalers and then bill payers for the drug at a higher price. The intent of markup is to cover the operational and infrastructure costs to the provider associated with storing and managing a large number of specialty drugs so that the right drug at the right dose can be selected at the time the patient is seen by the provider. Under this buy and bill approach, however, markups can be more than the price of the drug itself. For example, markups charged to payers by hospitals when clinicians administer drugs in the hospital setting have been found to be as high as 200–300% of the base price of the drug [6]. These added costs create real pressure on insurance premiums and are viewed by payers and plan sponsors as an outgrowth of an outdated contracting approach that was more suited to an environment when very few patients required specialty drugs and the cost of specialty drugs was far lower. The goal of reducing these substantial costs, without adversely affecting patient access to appropriate treatment, has spurred many payers to make important changes in their coverage policies in recent years.

Payers have developed two primary strategies for managing drug markups. The first involves bypassing the buy and bill approach by providing the drug to the clinician directly through a payer-affiliated specialty pharmacy. With this approach, payers avoid provider markup while also leveraging the negotiation power of specialty pharmacies, which can often obtain a lower price for the drug from drug wholesalers. This practice is widely known as 'white bagging' since the drug is envisioned as being delivered in a white bag to the provider. Another approach used to

supersede the buy and bill model is 'brown bagging,' in which the payer's specialty pharmacy delivers the drug directly to the patient, either to take to the provider at the time of administration or for use at home through a home infusion program. There is a third concept, referred to as 'clear bagging,' when a hospital uses its internal specialty pharmacy to fulfill a patient's specialty drug prescription and transports it to the site of administration. The payment for the drug flows through the provider-owned specialty pharmacy, as opposed to the provider themselves (i.e., buy-and-bill).

The common theme across all bagging policies is that the traditional buy and bill approach is replaced by providing the drug to the clinician through another entity and reimbursing the clinician only for drug administration without any markup on the cost of the drug itself.

Claims of the positive impact of bagging policies emphasize the substantial cost reduction that has been realized without negative feedback from patients or plan sponsors. Anecdotes suggest that many employers have asked for more services to be provided at home in an attempt to meet employee requests for greater flexibility in care options, particularly during the years of the COVID-19 pandemic. Payers also argue that white and brown bagging allows them to leverage the expertise of specialty pharmacies to treat complex and rare conditions and that white bagging can improve continuity of care in the face of supply chain shortages and disruptions.

Clinicians and provider organizations tell a different story. They argue that real-world experience has shown the shifting away from buy and bill reimbursement has caused negative outcomes for patient safety, access, clinician burden and drug wastage. Brown bagging has raised the most notable safety concerns from provider groups because not all individuals live in a setting where they can receive private mail deliveries or have someone responsible to receive drug deliveries and store them appropriately. Providers worry that packages containing temperature-sensitive drugs could be left outside in the heat or unpacked and left at room temperature.

White bagging is generally viewed as a safer practice than brown bagging because drugs are delivered by a specialty pharmacy to clinicians. Still, clinicians point to challenges when a change in a patient's condition noted at the office visit means that the patient needs a different dose or an entirely different medication than the one previously delivered. White bagging can make clinicians feel like their hands are tied, leading to unnecessary and potentially dangerous delays before a new dose/medication can be approved and delivered.

Providers also note that white bagging and brown bagging can make patients subject to far higher cost sharing amounts, that white bagging adds multiple new resource-intensive requirements to provider processes and disrupts safety mechanisms already in place for their current care flow, and that white and brown bagging policies may also increase drug wastage for high-priced products [7]. Payers counter each of these points with examples demonstrating that patients can have reduced out-of-pocket spending, that white bagging is implemented in a way that should not create significant new burdens for providers, and that any drug wastage does not undercut the broader picture of lower overall costs.

The second main approach payers are using to avoid the markups associated with buy and bill reimbursement is to require patients to receive treatment at a lower-cost site of care, either at a clinician's office outside of a hospital-based system, a stand-alone infusion center, or home. Requirements for patients to have their drug administered in specific locations are called 'site of service' policies. The most significant concern regarding site of service policies voiced by providers is that these policies can create a disconnect between the treating clinician and the patient, potentially resulting in substantial logistical burdens for patients and increasing the risk that their treatment will be incorrectly dosed or delivered. Just the hassle of sorting out additional time and transportation can lead to missing or delaying of treatment. Interviewed providers suggest that patients with lower financial and social resources are at higher risk for this negative outcome, adding to the disparities of care experienced by many patients from communities of color. Conversely, home infusion may reduce the burden on patients, but not all patients live in settings conducive to home infusion, with the same patients with lower financial and social resources being less likely to be able to benefit.

Providers also suggest that site of service policies result in considerable unpaid administrative burden for individual physician offices, since patients often call their clinicians to ask questions about medication administration. Patients may also call clinicians' offices to ask questions about the scheduling of home infusions. While most payers have case managers to assist with logistical issues, there have been reports from providers that monitoring patient treatment at home can be difficult.

In the sections below we explore potential best practices among the different variants of bagging and site of service policies currently in the marketplace. We also analyze the potential advantages and disadvantages of broader policy options that could support the right balance between controlling unnecessary costs and maintaining adequate

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Table 1. Summary of best practices and broader policy options.

White and brown bagging	
Promote patient-centered care and health equity	• Prohibit brown bagging outside of selected treatments suitable for home infusion • Establish criteria for clinical appropriateness • Facilitate rapid exceptions inclusive of clinical and social factors • Share cost savings with patients
Address same-day medication changes	• Devise emergency reimbursement mechanisms for same-day treatment changes
Increase specialty pharmacy oversite	• Increase transparency of the chain of custody for white-bagged drugs
Create balance with existing physician incentives under buy-and-bill	• Require payment parity between specialty pharmacy and buy-and-bill • Replace white bagging with a fee schedule, eliminating buy-and-bill incentives • Target white bagging to high-cost settings • Cap markup through legislation
Improve transparency for providers and patients	• Provide advance notice of new coverage policies
Site of service policies	
Promote patient-centered care and health equity	• Measure patient experience and clinical outcomes • Establish criteria for clinical appropriateness • Facilitate rapid exceptions inclusive of clinical and social factors • Measure rates of exceptions • Share cost savings with patients
Improve transparency for providers and patients	• Provide advance notice of new coverage policies • Communicate effectively with patients about site of service shifts

flexibility in coverage to ensure that patients and clinicians can make appropriate, patient-centered care decisions. A summary of these best practices and broader policy options are shown in Table 1. For white and brown bagging and site of service policies, we suggest a broad goal in the first column with specific potential policy options to accomplish each goal in the second column.

Policy reforms for white bagging & brown bagging

Promote patient-centered care & health equity

Policy option: Prohibit brown bagging outside of selected treatments suitable for home infusion

Given the complex requirements for safely storing drugs, many stakeholders suggest that brown bagging presents serious patient safety and quality assurance concerns. Though many payers report that they no longer use brown bagging, the limited data that exists suggest that approximately 9% of patients receiving care in HOPDs are subject to brown bagging policies [8].

The only negative consequence of eliminating brown bagging would be the loss of its potential to reduce markup costs, but it is unclear that brown bagging reduces costs more than a comparable white bagging policy. Therefore, actions by payers or legislators to eliminate existing brown bagging policies would be welcomed by patients and providers while being unlikely to jeopardize broader initiatives to reduce markup costs. It is important to note, however, that prohibitions on brown bagging should be designed to allow its use in appropriate home infusion situations, where brown bagging may be the most convenient and cost-effective approach to delivery of the medication.

Policy option: establish criteria for clinical appropriateness

Payers interviewed suggested that they implement white bagging or brown bagging only after a first successful treatment is provided by the clinician, thereby avoiding the disruption of necessitating a separate appointment to receive the initial dose. This approach may already be nearly universal and should be considered a required feature of white or brown bagging policies. Currently, however, most payers assign treatments to white or brown bagging on a product-by-product basis without any additional qualifying clinical criteria through which the appropriateness of either approach could be determined for an individual patient. It is likely that clinical considerations guide which drugs are selected for white bagging or brown bagging (but these criteria are not transparent).

Therefore, payers could establish explicit and transparent clinical criteria by which to determine whether white and/or brown bagging would be acceptable, allowing some patients to be exempt from either approach without having to go through an exceptions process. For white bagging, payers could confirm appropriateness by asking clinicians to confirm one single clinical criterion at the outset of treatment: treatment selection and dosing is not subject to same-day variation during the course of treatment.

For brown bagging, two additional clinical criterion could be added to assure clinical appropriateness: the patient has adequate social supports to ensure safe receipt and timely transport of the treatment to the clinician's office; and the patient has appropriate equipment at home to safely store the medication.

The potential downside of establishing clinical criteria is that it may leave so much discretion in the hands of clinicians that the financial incentives embedded in buy-and-bill could lead them to exempt many patients from white bagging, undermining the goals of reducing markup. However, this risk should be balanced against the possible advantages of adding a more nuanced approach to patient selection that would reduce the burden of an exceptions process and enable care to be tailored more effectively for individual patient needs.

Policy option: facilitate rapid exceptions inclusive of clinical & social factors

While payers have existing channels for clinicians to seek an exemption to white and brown bagging for individual patients, interviews suggested that these procedures can be opaque and cumbersome to navigate. If payers do not create clinical criteria by which clinicians would confirm the appropriateness for each patient at the initiation of treatment, payers could improve the process on the back end by creating a real-time electronic portal to support an efficient exemptions process. Exemptions could be based on explicit criteria or could be left broadly to the clinician's judgment that clinical or social factors (e.g., transportation challenges, housing instability and or difficulty storing medications safely) make white or brown bagging inappropriate.

A rapid exceptions process would improve clinician buy-in to white and brown bagging policies and would reduce the risk that the burden of seeking exceptions would inhibit clinicians from taking the time and effort necessary to affirm the approach that would be in patients' best interest. These benefits are likely to accrue particularly to patients with lower financial and social resources, thereby improving health equity and perhaps reducing disparities in outcomes across diverse communities. However, as with upfront clinical appropriateness criteria, there is some risk that the most efficient exceptions process would make it 'too easy' for clinicians to blunt the cost-saving potential of white and brown bagging.

Policy option: share cost savings with patients

Payers have seen savings as a result of white and brown bagging policies. A potential best practice would be for payers to structure benefit designs so that the cost savings associated with white or brown bagging are shared in a meaningful way with patients, or that, at the very least, these approaches do not lead to increased patient out-of-pocket requirements.

The key reason to consider this reform is that patients can end up paying more out of pocket when their treatment is subject to white or brown bagging due to the shift in coverage from the medical to the pharmacy benefit. Some payers have moved to address this by structuring their benefit designs to ensure that patient cost-sharing is lower in the pharmacy benefit. However, such broad benefit design changes may create unintended consequences and may impair the cost-saving potential of white and brown bagging policies. One way to link lower cost-sharing only to those drugs provided under white or brown bagging is to place these drugs in the pharmacy benefit at the lowest formulary tier, a tier that frequently requires relatively small cost-sharing.

Address same-day medication changes

Policy option: Devise emergency reimbursement mechanisms for same-day treatment changes

Physicians who obtain medication via brown or white bagging face challenges if the drug delivered for a patient is incorrect or no longer the appropriate treatment or the right dose based on changes in the patient's condition. Such scenarios are particularly common for seriously ill patients with cancer, who may have disease progression or side effects at any time that necessitate an immediate, even same-day, shift in treatment.

When this occurs in the setting of white or brown bagging, patients may need to return for another visit to receive the newly updated drug or dosage. However, in some instances, the new drug or dosage may be in stock within the clinician's office. To reduce the risk of imposing a disruption in care, payers could adopt as a best practice an emergency buy-and-bill reimbursement mechanism for such situations. However, if a payer uses widespread white or brown bagging policies in their commercial business, they may not have a negotiated buy-and-bill rate with many providers. In this instance, providers would likely default to billing the payer based on their chargemaster (assuming the payer and provider are not contracted), which is typically much higher than the negotiated rate for payers. Such a scenario could result in surprise bills to patients if providers balance bill them for the difference between the chargemaster and paid amount. Recent federal policies prohibiting surprise billing to patients have

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revealed the complexity of finding an appropriate reimbursement rate for non-contracted services, but these policies may also provide a roadmap for how the amount of such an emergency payment could be established. Alternatively, the policy could stipulate that commercial payer payments for an emergency buy-and-bill drug would be set at the Medicare reimbursement rate of Average Sales Price (ASP) + 6%.

The major potential pitfall of this payment mechanism would be that it creates a backdoor through which clinicians could face financial incentives to find minor dosing changes or other reasons to shift from the dosage sent via white or brown bagging over to their buy-and-bill stock. This risk could be minimized by devising a specific contracted rate for drugs within an emergency reimbursement system that does not pay clinicians a much higher amount than they receive under their normal negotiated rate for drugs delivered through white or brown bagging.

Increase specialty pharmacy oversight

Policy option: increase transparency of the chain of custody for white bagged drugs

With little insight into how drugs are handled and stored, clinicians harbor important concerns about the safety of the drugs delivered for their use via outside specialty pharmacies. One way to address this concern would be to require specialty pharmacies to include scannable barcodes on white bagged products, as they do on drugs delivered to hospital pharmacies [9]. Such bar codes enable clinicians to better track the chain of custody for a given product.

While such a change would be relatively easy to implement when shipping to hospital outpatient departments, individual physician offices and infusion centers may not have the technology and interoperable systems required to access the information. And, although addressing the concerns of clinicians and improving their acceptance of white and brown bagging is an important goal, payers believe that requiring measures to augment specialty pharmacy oversight would add significant administrative burden and costs with limited tangible benefits to patient safety.

Create balance with existing physician incentives under buy-&-bill

Policy option: Require payment parity between specialty pharmacy & buy-&-bill

A payment policy that reimbursed the same amount for specialty pharmacy and buy-and-bill would address the concerns held by clinicians about revenue loss that results from shifting payment from buy-and-bill practices to specialty pharmacies. An example of a payer that has implemented this policy is Blue Cross and Blue Shield of Massachusetts (BCBSMA). This health plan allows any specialty pharmacy that meets its qualifications (e.g., a hospital's specialty pharmacy) to join its specialty pharmacy network for any drugs subject to white bagging. If a clinician does not have access to a pharmacy that meets those qualifications, they are eligible for an exception that allows them to buy-and-bill for the drugs that require white bagging while being reimbursed at the third-party specialty pharmacy rate.

Such a payment policy would help mitigate safety and access concerns for patients, as many of those concerns stem from the practice of using a third-party specialty pharmacy that is not overseen by the prescribing provider. Payers would also benefit from having lower costs compared with traditional buy-and-bill reimbursement. Payers that own specialty pharmacies or other specialty pharmacies may have their own concerns that this approach diminishes their involvement in the supply chain, thus reducing their revenue. This policy could also pose challenges for contract arrangements in place between specialty pharmacies and payers, particularly if exclusivity is a required element of the contract [10].

Payment parity would dramatically reduce hospital revenue by eliminating drug markups. However, relative to mandatory white bagging, this policy would effectively require that payers let hospitals clear bag and fulfill drugs through their own specialty pharmacies. This would enable 340B covered entities to maintain access to 340B discounts. Independent physicians and non-340B providers would be hurt most by this policy. Those providers may not be able to acquire clinician-administered drugs for less than the site-neutral payment, so they would likely be willing to accept white bagging arrangements rather than take a loss on buy-and-bill.

Policy option: replace white bagging with a fee schedule, eliminating buy-&-bill incentives

Rather than paying negotiated rates for clinician-administered drugs, payers could establish a fee schedule for some, or all, of these products. The fee schedule would specify provider reimbursement rates on a per product basis to reduce or eliminate markup. Providers who want to buy-and-bill a product would need to accept the fee schedule reimbursement rate. The fee schedule could set payment rates at any level, meaning reimbursement could

remain higher than it would be through specialty pharmacy but lower than the markup charged by the highest-paid providers.

Policy option: cap markup through legislation

Another option would be for state or federal policymakers to cap maximum provider markup at a certain percentage and/or absolute dollar amount (e.g., 200% markup or not more than $10,000). While this would limit markup by providers, it also risks setting a new psychological ceiling for payer-provider negotiations that could result in higher markup for some drugs than would be negotiated otherwise.

Policy option: target white bagging to the settings with highest costs

In many cases, payer white bagging policies are set by product and do not vary by setting, meaning that they apply equally to products whether they are administered in more expensive HOPD settings or in independent physician offices. White bagging policies could be designed to target only the highest-cost settings while allowing physician offices to continue to buy-and-bill. This more nuanced approach could mitigate some of the physician concerns about the impact of white bagging policies on smaller physician offices, which generally are more reliant on the revenue from drug markups and are most challenged by the operational burden associated with white bagging.

Improve transparency for providers & patients

Policy option: provide advance notice of new coverage policies

Payers are able to change the required administration channel of a drug at any time, even in the middle of a course of treatment, which can create confusion for providers (and patients) and requires provider staff to change processes and come quickly into compliance with payer policies. A potential best practice would be for payers to provide notification of any coverage policy changes that impose white or brown bagging to providers and patients at least 60 days in advance of any changes being implemented. This timeframe would ensure that clinicians and their staff have sufficient time to come into compliance with the policy without significant administrative burden or impact to patients. Clinicians also may need this much time to develop new processes, ensure proper storage capabilities and develop proper communication practices to ensure patient education.

Policy reforms related to site of service policies

Promote patient-centered care & health equity

Policy option: measure patient experience & clinical outcomes

To ensure that patients are not negatively affected by site of service policies, payers should capture data measuring the patient experience and clinical outcomes of patients who had their site of care shifted. Capturing information such as the number of skipped doses, time between treatments, and clinical outcomes would provide data that payers could use in determining future site-of-service policies.

Policy option: establish criteria for clinical appropriateness

Most payers specify site of service requirements on a product-by-product basis without any additional qualifying clinical criteria through which the appropriateness is determined for an individual patient. Payers could establish specific criteria regarding the maximum distance or time of travel for a patient to be considered eligible for a site of service policy. In addition, payers could consider adding criteria that must receive clinician attestation before implementing a site of service policy. For example, three criteria could serve to confirm appropriateness: whether the patient's clinical condition is sufficiently stable to allow a change in site of service for this treatment without undue risk; whether the patient has had no immediate side effects from this treatment that necessitate close monitoring by the current treating clinician and staff; and whether the patient has adequate social support to ensure safe travel to the intended new site of service.

Any set of appropriateness criteria might have the potential of adding administrative burden without providing a true benefit for patients or clinicians. In addition, opt-in clinical criteria might lead clinicians to block site-of-service policies more than necessary, undermining the goal of reducing costs. The potential benefit, however, would be a reduction in the risk that individual patients would face unusual risks or burdens in a shift in the site of care, while it could also lead to enhanced clinician (and patient) trust.

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Policy option: facilitate rapid exceptions inclusive of clinical & social factors

Providers contend that existing procedures to seek exceptions to site-of-service shifts are insufficient. In particular, they advocate for exceptions that can be requested during the course of treatment if patients report that they are struggling with site of service policies, such as home infusion, and feel they need to return to a physician's office, infusion center or hospital outpatient department.

A more robust exceptions process could also address concerns regarding the impact of these policies on health equity and timeliness of care. As a best practice, payers should consider the delineation of specific exceptions related to housing, health literacy and availability/access to a caregiver. Patients with lower income, or those with low health literacy, may have difficulty accessing alternative sites of service. For example, if home infusion is required, some patients may not have a safe and comfortable location at home to receive treatment.

Policy option: measure rates of exceptions

No matter how good the intentions are behind a site of service policy, it may result in high rates of exceptions that call into question whether the policy is clinically appropriate. Measuring rates – and reasons – for exceptions would therefore provide payers and other stakeholders critical insight about where policies may not be working as intended and may help drive change in the content or application of policies so that they are a better fit for different clinical or practice situations.

Policy option: share cost savings with patients

Patients should benefit from their successful participation in shifting the site of care to a lower-cost setting. One approach would be to design their cost sharing so that it is lower in the site of care required by their insurance policy than it would have been otherwise. This may be difficult to administer for practical reasons, however, and so it may be reasonable only to ensure that patients do not have to pay more out of pocket than previously. As with white and brown bagging, one potential approach to accomplish this goal is to place a drug on the lowest relevant tier of the pharmacy benefit's formulary so that patients pay less than they would under the medical benefit.

Improve transparency for providers & patients

Policy option: provide advance notice of new coverage policies

Payers can change the site of service requirements for a drug at any time, even in the middle of a course of treatment, which can create confusion for providers (and patients). A potential best practice would be for payers to provide notification of any coverage policy changes that impose a site of service requirement to providers and patients at least 60 days in advance of any changes being implemented.

Policy option: communicate effectively with patients about site-of-service shifts

While payers do provide a notice of policy change to providers and patients, a best practice would be to develop a standardized form explaining to patients why the change is occurring. Providing this information to patients may reduce patient hesitation to receiving care at a different location as well as allow them to understand who is making the decision. The form should communicate any impact on accessing providers, any change in costs and the rationale for the policy. However, there are administrative challenges to this approach. It may be time intensive for payers to develop a standard form and then distribute unique notices to every patient each time they trigger a site of service policy. The forms themselves would be difficult to develop in an easily understandable way to all patients given that in addition to ensuring accurate patient information on each letter, forms would need to distill complex policy decisions into a clear and easy to understand reading level. Rather than each payer developing its own standardized form, one option is for an industry or stakeholder organization (e.g., America's Health Insurance Plans, the Pharmaceutical Care Management Association, or the National Patient Council) to take the lead in this effort.

Conclusion

The high cost of specialty pharmaceuticals are driving change across the healthcare system, with provider markups being just one component of those costs. But payers have both a business interest and a stewardship responsibility to try to wring out unnecessary costs in the healthcare system. Therefore, it is not surprising that they have been increasing their efforts to reduce provider markup embedded in the buy-and-bill system that has been the bedrock of reimbursement for many specialty drugs.

White and brown bagging policies, along with site-of-service policies, are neither inherently good nor bad. But there are approaches to the design and implementation of these policies that seem more likely to reduce markup while being mindful of the risk for patient harm. We have presented analyses of many policy options that seem best suited to achieve the right balance, although data are extremely limited on the effects of certain approaches to date, and in that vacuum have arisen strongly held and contrasting opinions of whether these policies serve the best interests of patients.

Drawing from the ideas in this paper, we believe a balance can be achieved. We also highlight that any approach to white bagging, brown bagging and site-of-service policies must be structured to promote health equity by keeping front and center the risks to patients with less income and social support who may have the greatest challenges navigating these policies. We hope that the information and perspectives in this paper will help all stakeholders reach this important common goal.

Summary points

- Given the high costs of specialty drugs and the limitations of traditional utilization management, many commercial payers are increasing efforts to reduce the 'markup' on specialty drug acquisition and administration that is charged by providers who buy drugs directly from drug wholesalers and then bill payers for the drug at a higher price.
- In both white and brown bagging, the traditional buy and bill approach is replaced with some approach through which the drug is provided to the clinician by another entity and reimbursed with a drug administration fee but without any markup on the cost of the drug itself.
- Despite the potential for reducing costs without adversely affecting access, some observers express concerns about the impact of white bagging and brown bagging on patient safety, access, clinician burden and drug waste.
- Site of service policies require patients to receive treatment at a lower-cost site of care, either at a clinician's office outside of a hospital-based system, at a stand-alone infusion center, or at home.
- The most significant concern regarding site of service policies voiced by providers is that these policies can create a disconnect between the treating clinician and the patient, potentially resulting in substantial logistical burdens for patients and increasing the risk that their treatment will be incorrectly dosed or delivered. Other concerns with site of service policies are related to patient out of pocket spending and provider impact.
- Publicly available evidence on the impact of white bagging, brown bagging and site of service policies is very limited.
- The authors categorize the white and brown bagging policy goals and best practices into 5 categories, including: promote patient-centered care and health equity; address same-day medication changes; increase specialty pharmacy oversite; create balance with existing physician incentives under buy-and-bill; and Improve transparency for providers and patients.
- The authors categorize site of service policy goals and best practices in the following two categories: promote patient-centered care and health equity and improve transparency for providers and patients.
- Drawing from these ideas, sound business practice and policymaking should aim to balance possible savings from reducing markup while implementing thoughtful consumer protections and transparency that recognize the challenges that these policies create for seriously ill patients.
- Policies should be structured to promote health equity by keeping front and center the risks to patients with less income and social support who may have the greatest challenges navigating these policies.

Author contributions

All authors were responsible for the conception and design of this project. All authors participated in the drafting and review, and are responsible for its contents.

Acknowledgments

The full ICER White Paper, which includes an examination of payer policies to address markup, criticisms of white bagging, brown bagging, and site of service policies, as well as recent legislation introduced to restrict and/or prohibit the use of these practices, is available on ICER's website at https://icer.org/assessment/markup-policies-2023/.

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