Safety Impacts and Considerations for Emerging Payor Coverage Policies

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Faculty Disclosure

• Aaron Poe and Audrea Szabatura declare no existence of a financial interest in any amount related to the content of this activity.

• Advisory Board members and other individuals, not previously disclosed, who may review, propose recommendations, and/or edit the content of PharmCon CE activities declare no existence of a financial interest in any amount related to the content of this activity.
Learning Objectives

At the conclusion of this activity, participants should be better able to:

1. Identify site of care and preferred product guidelines
2. Recognize the impact of payor coverage policies on healthcare institutions and the medication use process
3. Identify the safety implications of payor policy changes on healthcare institutions and patient care

Traditional Drug Supply Chain

[Diagram showing the traditional drug supply chain with Supplier(s), Manufacturer, Wholesale distributor (primary), Hospital, Repacker, Wholesale distributor (secondary), and Patient(s).]
Impact of Payor Coverage Policy Changes on Healthcare Systems

I. Drug Supply Chain

II. Clinical Care Chain

III. Formulary Management
I. Drug Supply Chain

Shift to Specialty Pharmaceuticals

- Specialty Drugs
  - High-cost medications used to treat rare, complex and chronic conditions such as cancer, HIV, and organ transplant patients
    - Primarily outpatient; may be self-administered, injected, or infused
    - High cost: usually > 1,000$/month
    - Treat rare, complex, and/or chronic conditions
    - May require special storage and/or handling
    - Require ongoing patient monitoring for safety and efficacy

- Specialty Drug spending has increased by > 60% since 2010

- 60% of the 508 new drugs awaiting approval from the U.S. Food and Drug Administration (FDA) between June 2019 and 2021 are specialty drugs

* 2016 Advisory Board. The current Specialty Pharmacy Landscape

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Definitions

- Brown bagging: dispensing of a medication from a specialty pharmacy directly to a patient, who then transports the medication to the hospital or clinic for administration
- White bagging: Distribution of patient-specific medication from a specialty pharmacy to the hospital or clinic for administration
- Clear bagging: Health system's specialty pharmacy delivers medication to the clinic for administration
Incentives for Specialty Pharmacy Services

- Reimbursement assistance
- Patient care coordination
- Pharmacists engage in a more active role in providing patient education, therapeutic assessments, and ensuring drug adherence
- Reduced provider costs associated with purchasing and stocking expensive medications
- Eliminate administrative process of billing payers for reimbursement
Impacts of Payer Coverage Policies on Health Systems: White Bagging

- Online Survey to health system pharmacy and infusion services across the United States
- Survey time: May 21, 2020 until July 7, 2020
- Responses: 43 individuals representing 35 health systems

How did the frequency of payer white bagging requirements change in the last year? (n=36)

- 84% Stayed the same
- 14% Increased
- 3% Decreased

Percentage of patients required to use white bagging by their payor (n=37)

- 84%
- 14%
- 3%

Advantages
- Beneficial for small providers to minimize costs/time associated with reimbursement assistance, stocking, inventory management, and billing

Disadvantages
- Patient-specific medications that require special handling
- Can pose safety, operational, and financial burdens

Safety Concerns

**Communication/Coordination of Care**
- Therapeutic Modification
- Dose Changes
- Delays in drug acquisition
- Lack of access to the electronic health record

**Consequences**
- Treatment delays
- Patient Confusion
- Patient burden

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Safety Concerns

**Drug Distribution/Dispensing**
- Incorrect handling
- Incorrect storage
- Damaged product
- Excess of supply

**Consequences**
- Compromised product integrity Reduced potency or efficacy
- Increased risk of adverse reactions
- Increased storage burden on receiving institution
- Dosing/drug errors
Safety Concerns

<table>
<thead>
<tr>
<th>Waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage or drug changes</td>
</tr>
<tr>
<td>Patient specific medication</td>
</tr>
<tr>
<td>3 month supply</td>
</tr>
<tr>
<td>Criteria to treat not met</td>
</tr>
</tbody>
</table>

Consequences

| Drug waste | Costly disposal | Additional state and federal requirements |

II. Clinical Care Chain
Payer Policy Example - Aetna

Effective July 1, 2020 Aetna requires patients to receive certain specialty medications *(when administered as monotherapy for maintenance)* at a non-HOPD site, including:

- nivolumab, pembrolizumab, ipilimumab, durvalumab, cemiplimab, avelumab and atezolizumab

Alternatively, per the policy, Aetna can coordinate with the facility to deliver patient-specific medication from a specialty pharmacy.

This white bagging scenario would create a payer specific inventory within an institution’s pharmacy and require a number of exceptions to standard, established workflows.


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Payer Policy Example - Cigna

Per Cigna’s Specialty Medical Injectables with Reimbursement Restriction list, “For new prior authorizations obtained on or after September 1, 2020, we will expand the Specialty Medical Injectables with Reimbursement Restriction list to include additional specialty medical injectables. Cigna may grant approval for coverage of an initial dose to a facility when medical necessity for the medication is met. This allows the customer to receive needed care before arrangements can be made to obtain subsequent doses of the drug from a Cigna-contracted specialty pharmacy, unless otherwise authorized by Cigna.

What this means to you: Cigna will no longer reimburse facilities directly for the drugs that are included in the Specialty Medical Injectables with Reimbursement Restriction list. Please note that facilities cannot bill patients with Cigna-administered coverage for the cost of these injectables when they are not obtained from a specialty pharmacy in the Cigna network. The restriction does not apply to physicians who bill Cigna using their own physician fee schedules. The Specialty Medical Injectables with Reimbursement Restriction list only applies to facilities and physicians that bill Cigna using a hospital fee schedule. This is typically associated with the hospital outpatient setting.”

Source: CignaforHCP.com > Resources > Reimbursement Policies and Payment Policies > Precertification Policies > Specialty Medical Injectables with Reimbursement Restriction
Payer Policy Example - Cigna

Cigna’s Medication Administration Site of Care Policy states, "If a prior authorization request includes an outpatient hospital setting for administration of the drug, a Cigna Medical Director or Pharmacist may contact the provider to discuss administration at a less intensive site of care. Following that clinical discussion, a case manager may help transition the patient to a Cigna-contracted specialty pharmacy for home administration or to an alternative infusion provider. Please note that a medical director may deny continued authorization of coverage if the outpatient hospital setting is determined to not be medically necessary for the patient."

This treatment scenario may break many hospital practices put in place for safe drug administration and quality care.

Source: Medication Administration Site of Care – 1605

Examples of Medical Necessity Criteria for Drug Administration in an HOPD

- Patient receiving an initial infusion or re-initiation
- Medically unstable patient
- Presence of a comorbidity that may cause an increased risk of severe ADR or unstable renal function that may result in inability to safely tolerate IV volume loads
- Physically or cognitively impaired
- Difficulty establishing/maintaining vascular access
- Patient experienced past episodes of severe ADR with drug administration that cannot be managed through premedication
- Past episodes of acute mental status changes with drug administration
- Home care or infusion provider has deemed home an unstable environment
- Drug prescribed has limited distribution and is not available for non-hospital outpatient facilities or for home infusion.

Transition to Site of Care Programs

- Between 2013 and 2017, there was a 135% increase in commercial health plans use of Site of Care (SOC) programs
- 2018: 60% of commercial payors used SOC programs
  - Autoimmune disorders
  - Oncology
  - Oncology immunotherapy
- Direct patients from hospitals to community offices, ambulatory infusion suites, or home-based settings
- 85% of programs direct patients to the home-infusion setting
- More than two-thirds (67%) of commercial payors experienced significant savings—an average of 61% reduction in cost.


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### Safety Concerns

#### Transitions of Care

<table>
<thead>
<tr>
<th>Communication Breakdown</th>
<th>Patient Education Breakdown</th>
<th>Accountability Breakdown</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Medication orders for external sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Therapeutic regimen changes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Drug dosing changes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Conflicting recommendations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Confusing regimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Product confusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Responsibility to assure coordination across various settings and among different providers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Multiple entities involved: Clinician, specialty pharmacy infusion, nurse administering the medication</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### Patient Perspective of Non-HOPD Drug Administration

**REVIEW OF THIRD-PARTY SPECIALTY PHARMACY USE FOR CLINICIAN-ADMINISTERED DRUGS**

Section 130 of Chapter 47 of the Acts of 2017

Report to the Massachusetts Legislature JULY 2019

*“It only took my first visit to realize this option wasn’t for me. ... They sent me an incorrect itemization list, the incorrect amount of sodium chloride and bag sizes which goes hand-in-hand with the mixing dilution process, no IV pole and a number of miscellaneous items I overheard the assigned nurse mention while at my home. ... The nurse appeared to be very uncomfortable and unconfident with herself in this procedure, as I noticed her hands shaking and appeared also to be sweating. This made me feel very vulnerable because I knew my care was in her hands. Due to the lack of supplies, the nurse began making due with what she had... personally I felt like I wasn’t given my Remicade infusion correctly which has caused me a very painful and depressing flare-up. I was forced to make an emergency call to [a hospital] infusion center to request an immediate early infusion that required a newly written prescription order from my gastroenterologist for authorization. ... This home infusion requirement was thrown at me... This is something I should have been informed of in detail which I wasn’t.”*
Clinician Perspectives of Non-HOPD Drug Administration

“The NCCN clinical practice guidelines in Oncology® (NCCN Guidelines) Management of Immunotherapy-Related Toxicities outline monitoring of the following clinical pre-therapy assessments at each clinical exam visit. The recommendations include a physical examination; comprehensive patient history of any autoimmune/organ-specific disease, endocrinopathy, or infectious disease; Neurologic examination; Bowel habits; and Infectious disease screening, as indicated. By moving subsequent patient infusions out of the primary cancer care setting, xxxx is implementing a policy that strips providers of their ability to be adherent to the NCCN Guidelines®”

Robert W. Carlson, MD (National Comprehensive Cancer Network®) Letter to: Dr. Brito (Divisional Head-Enterprise Oncology CVS/Aetna). August 3, 2020

Clinician Perspectives of Non-HOPD Drug Administration

“There is limited data from other countries demonstrating that, under certain circumstances and for specific agents, home infusion can be safe, well-tolerated, and may be preferred by some patients. However, multiple criteria in ASCO’s existing safety standards may be difficult to satisfy in the home infusion context. For example, safety principles emphasize using more than one practitioner to verify and document patient name, drug name, dosage, infusion volume, route/rate of administration, etc., to minimize errors and prevent patient harm. Within a health care setting additional trained staff are available for such verification. In the home infusion setting, these verifications need to be performed virtually and with multiple forms of identification, as sending multiple health workers to supervise home infusions may not be practical or feasible. Most importantly, certain adverse events that may quickly escalate and become life-threatening emergencies may not be able to be safely resolved in the patient’s home. This risk could be minimized by initiating treatment with any new agents within an outpatient setting, but life-threatening adverse events remain an ongoing concern for routine home infusion of chemotherapy. Ensuring the satisfactory cleaning of hazardous spills (to prevent subsequent exposure of people in the household) is also more difficult in the home setting”

Recommendations Based on Safety Impact of Payor Policy Practice Changes

RECOMMENDATION 1: Providers should not require brown bagging for any drug. Providers should not require direct dispensing to a patient of any specialty drug that must be administered by a clinician. There is strong clinical consensus that requiring patients to properly store and then transport a drug to their clinician for administration jeopardizes patient safety.

RECOMMENDATION 2: Providers should offer home infusion as an optional benefit, not as a requirement. Use of home infusion should be an individual decision by the provider and patient in cases where a provider and patient determine that drugs can be safely shipped, stored, and administered in the patient’s home. While home infusion may increase the risk of adverse safety outcomes in some cases, it may also result in positive benefits for patients in other cases. This range of possible consequences underscores the need for home infusion to be an optional benefit, rather than a mandatory one, based on patient preference and clinician judgment that drugs can be safely shipped, stored, and administered in the patient’s home. While home infusion should remain available for cases in which patients and providers conclude that it is the best option for the patient, it is important that patients and providers, rather than payers, are able to make this determination. Policies that allow exceptions only for demonstrated medical necessity may result in treatment delays and place an unnecessary burden on the patient.

RECOMMENDATION 3: Payers that require white bagging should use best practices in policies and ensure minimum safety standards and capabilities in the third-party specialty pharmacies with which they contract. While some providers voiced concern regarding safety and access, other providers supported the use of white bagging in their practices in some cases. White bagging may also offer particular advantages for some small providers. This range of practices and perspectives suggests that white bagging can be used safely in some cases.

RECOMMENDATION 4: Payers that require white bagging should offer site neutral payments for those drugs that are subject to white bagging requirements, allowing providers the option to use the buy and bill method with reimbursement for the drug set at the third-party specialty pharmacy rate. The site neutral payment option would only need to apply to the drugs for which a payer specified white bagging. This policy lowers drug prices, reduces provider administrative expenses associated with compliance with multiple different policies, and addresses concerns about safety and access.

RECOMMENDATION 5: Lawmakers should take action to increase public transparency and public oversight for the full distribution chain. Increased transparency, including regarding rebates, would enable a more precise accounting of payer incentives in white and brown bagging. Consistent with previous HPC recommendations, lawmakers should enable increased public transparency over the distribution chain to provide pharmacists, pharmacy benefit managers, and others with a greater understanding of the rebates paid by payers to pharmacies, consistent with existing requirements on payers and providers, including through mandated participation in the HPCs annual cost trends. 

RECOMMENDATION 6: The Group Insurance Commission, the Massachusetts Health Connector, MassHealth, and all other state payers should consider requiring all plans with which they contract to adopt best practice provisions, which should include prohibiting requirements for brown bagging and home infusion, implementing safety standards, and providing a site neutral payment option. The Commonwealth should use its power as a major health care purchaser to set expectations for the market. By implementing best practices in its plan contracts, the Commonwealth would support alignment in the market while also providing the highest quality care to its health plan members.

III. Formulary Management

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Biosimilars

- Biosimilars will reduce direct spending on biologic drugs by $54 billion from 2017 to 2026, or about 3 percent of total estimated biologic spending over the same period, ($24 to $150 billion).

- Potential out-of-pocket cost savings for patients

- A prominent issue is the practice of payers increasingly dictating which biosimilars are administered to outpatients in the clinic and hospital settings

Payer Policy Example – UHC

Effective Oct 1, 2019 United Healthcare announced new coverage criteria requiring providers to use specific biosimilar products when treating patients with bevacizumab or trastuzumab. This policy does not allow for parity among the other commercially available biosimilars.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Effective Date</th>
<th>Treatment Uses</th>
<th>Summary of Changes</th>
</tr>
</thead>
</table>
| Oncology Medication Clinical Coverage | Oct. 1, 2019 | Used to treat oncology conditions as per the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). | Includes preferred product coverage criteria for Avastin® (bevacizumab) and Herceptin® (trastuzumab). Preferred product language was added:  
  - Use of Mvasi® (bevacizumab-awwb) prior to the use of Avastin® and other bevacizumab biosimilar products.  
  - Use of Kapi® (trastuzumab-anns) prior to the use of Herceptin® and other trastuzumab biosimilar products. |


Payer Policy Example – UHC (cont.)

In addition to the innovator bevacizumab and trastuzumab the UHC coverage policy restricts the use of five other commercially available biosimilars:

<table>
<thead>
<tr>
<th>Bevacizumab</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mvasi® (bevacizumab-awwb)</td>
<td>GS107</td>
</tr>
<tr>
<td>Zirabev® (bevacizumab-bkyb)</td>
<td>GS198</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trastuzumab</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herizumab (trastuzumab-pkhr)</td>
<td>GS131</td>
</tr>
<tr>
<td>Kanikanti® (trastuzumab-arns)</td>
<td>GS177</td>
</tr>
<tr>
<td>Ogivre® (trastuzumab-dsit)</td>
<td>GS144</td>
</tr>
<tr>
<td>Ontuzax® (trastuzumab-dftb)</td>
<td>GS192</td>
</tr>
<tr>
<td>Tesamore® (trastuzumab-qggp)</td>
<td>GS156</td>
</tr>
</tbody>
</table>
Formulary Management

ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System

- American Society of Health-System Pharmacists (ASHP) believes that health systems should develop, organize, and administer a formulary system that follows key principles in order to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective medications

  - Establish and assist in programs and procedures that ensure safe and effective medication therapy
  - Participate in performance improvement activities related to procurement, prescribing, dispensing, administering, monitoring, and overall use of medications
  - Take actions to prevent, monitor, and evaluate adverse drug reactions and medication errors in the health care setting, including those occurring with biological products and vaccines.

- https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx

Formulary Management

- When planning for formulary additions and changes, the medication’s integration into technology should be carefully coordinated:
  - Dosage forms, concentrations, and ordering options should be limited and standardized.
  - Required monitoring for efficacy and toxicity should be built into computerized prescriber order entry (CPOE) panels or sets whenever possible.
  - If a drug is infused through a smart pump, it should be programmed with a standardized concentration and volume and the appropriate limits
  - In addition to cost savings, patient safety is enhanced by minimizing look-alike sound-alike medications through streamlined inventory and the medication reconciliation process. Minimizing the number of agents available on a formulary also improves staff competency and knowledge about specific medications.
  - Packaging of the pharmaceuticals is also important to take into consideration, especially with increased usage of barcode medication administration (BCMA).
Safety Impacts

Providers
- Drug dictionary
- Template build
- Product selection

Pharmacists
- Storage
- Labeling
- Drug selection

Nurses
- Smart pump/guardrail selection
- Patient Education
- Side-effect monitoring

Safety Impacts

• Order Verification

• Lengthy product selection lists

• Look-alike-sound-alike risks due to naming convention

Safety Impacts

• Storage

• Look-alike packaging

https://mms.mckesson.com/product/462543/Amgen-Inc-55513020910
https://www.empr.com/drug/granix/
https://www.google.com/search?q=prolia+and+udenyca
Safety Impacts

- Administration
  - Product Selection
    - Smart pump guardrail selection risks
  - Patient education

- Indirect impacts due to resource intensive product management
  - Informatics specialists
  - Chemotherapy Template Builders
  - Materials management

Payer Policy Example - Cigna

Cigna Drug and Biologic Coverage Policy for Oncology Medications specifies sequence of medications that must be given prior to another therapy: "Where coverage requires the use of preferred products, the following criteria apply:"

<table>
<thead>
<tr>
<th>Medication</th>
<th>Effective Date</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herceptin® (trastuzumab)</td>
<td>7/1/2020</td>
<td>EITHER of the following are met:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- History of beneficial clinical response with trastuzumab (Herceptin)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Documented intolerance to Ogivri (trastuzumab-dkx) AND Trastuzumab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(trastuzumab-dkx)</td>
</tr>
<tr>
<td>Herceptin Hylecta® (trastuzumab and hyaluronidase-cysk)</td>
<td>7/1/2020</td>
<td>EITHER of the following are met:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- History of beneficial clinical response with trastuzumab and hyaluronidase-cysk (Herceptin Hylecta)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Documented intolerance for Ogivri (trastuzumab-dkx) AND Trastuzumab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(trastuzumab-dkx)</td>
</tr>
<tr>
<td>Kankri® (trastuzumab-ann)</td>
<td>7/1/2020</td>
<td>EITHER of the following are met:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- History of beneficial clinical response with trastuzumab-anns (Kankri)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Documented intolerance to Ogivri (trastuzumab-dkx) AND Trastuzumab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(trastuzumab-dkx)</td>
</tr>
</tbody>
</table>

For this scenario, the payer guidelines may overrule a therapy deemed most appropriate by the clinician, such as a hyaluronidase treatment in the example above.

Source:
Mitigation Strategies for HOPDs and Payers

• Maintain an open dialogue regarding patient safety and quality of care implications as they relate to emerging payer policy guidelines

• Educate third party payers on hospital workflows and regulations implemented to maximize patient safety

• Collaborate with payers to identify acceptable payment rates for certain high cost medications

Key Takeaways

• Payer policy changes demonstrate a desire by insurers to minimize expenses for certain specialty medications

• Definite impact on healthcare institutions and the medication use process with significant safety implications

• Plan to collaborate with payers in order to highlight the concerns to patient safety and the mechanisms established to promote safe medication use practices and prevent errors
Thank You