

White-Brown-Clear Bagging Policies Disrupting the Buy-and-Bill Model

Published June 2021

- Over the past several years, the nation's largest insurers have vertically integrated by acquiring pharmacy benefit managers (PBMs) and specialty pharmacies.
- As these organizations have merged, priorities and opportunities for increased revenue and decreased costs have emerged as well.
- Payers have begun to mandate the use of a specialty pharmacy for drugs administered in outpatient hospital and physician office settings (i.e. mandating that providers accept white bagging and brown bagging of medications).
- Hospitals and health systems are lobbying regulatory officials to prohibit payers and PBMs from mandating white bagging or steering patients away from health systems that refuse to accept white-bagged drugs.

Background

Most patients obtain their medication by going to a brick-and-mortar retail pharmacy or receiving it via a mail-order pharmacy. However, for patients with serious health conditions that require complex therapies, they acquire their medications via specialty pharmacies.

With specialty products filling the drug pipeline and specialty drug approvals outpacing traditional medication approvals, specialty pharmacy became a booming opportunity around a decade ago, with the number of specialty pharmacies multiplying exponentially in 2014, according to Utilization Review Accreditation Commission (URAC) accreditation numbers from [Drug Channels](#). As of the end of 2020, Drug Channels identified [1207](#) unique pharmacy locations with URAC and/or Accreditation Commission for Health Care (ACHC) accreditation. At the same time, the number of expensive specialty drugs also increased at a similar rate along with the utilization of these specialty drugs, thus increasing interest in this space even more.

Because of the high expense of specialty medications, there is an opportunity for a significant profit, even if the margins are smaller. A 20%–25% profit margin on drugs that cost \$50,000 per prescription makes dispensing specialty pharmacy drugs desirable.

In another [RxBrief](#), we discuss how payers and health plans have experienced significant cost savings by establishing site-of-care optimization policies. An example of such a strategy is how payers have begun to mandate the use of a specialty pharmacy for drugs administered in outpatient hospital and physician office settings.

Table 1 provides descriptions for practices involved in specialty pharmacy drug administration known as “white bagging,” “brown bagging,” and “clear bagging.”

Table 1. Medication Bagging Policies and Descriptions

Term	Description	Concerns
White Bagging	An external specialty pharmacy ships the drug directly to the provider (e.g. hospital, clinic, physician office). The provider holds the drug until the patient arrives for administration. This does not allow providers to buy and bill, but still reimburses them for drug administration.	Providers have to keep track of medication for a specific patient upon delivery. This leads to inventory management issues.
Brown Bagging	The patient picks up the drug at a pharmacy or has it delivered to their home, then takes the medication to the provider (e.g. hospital, clinic, physician office) for administration.	Patient is responsible for storing and bringing the drug to the provider for administration, so providers are unable to determine whether the drug was stored correctly.
Clear Bagging	Similar to white bagging, except the provider’s internal specialty pharmacy dispenses and delivers the drug to the location of administration. This practice has emerged as hospitals expand into the specialty pharmacy business, with health system-owned specialty pharmacies supplying drugs for their affiliated clinics.	The drug does not leave custody/control of a single entity (integrated health system), but the provider still needs to keep track of what medication is for which patient.

Drugs that were previously purchased by hospital facilities or physician offices through “buy and bill”—when providers purchase and administer drugs and then are reimbursed by payers under the medical benefit—are now required to be filled through specialty pharmacies, particularly payer/PBM-owned specialty pharmacies. Because these drugs are often intravenous (IV) specialty drugs, they cannot be self-administered by the patient and still require healthcare provider administration. Essentially, payers and PBMs are requiring that hospital-based infusion clinics and/or physician practices accept “white-bagged” and “brown-bagged” medications and administer them to their patients, thus removing the healthcare providers from drug procurement.

Hospitals and health systems are pushing back against these policies, uniting through the American Society of Health-System Pharmacists ([ASHP](#)) to advocate that the FDA and regulatory agencies prohibit insurers and PBMs from mandating white bagging or from steering patients away from health systems that refuse to accept potentially dangerous white-bagged drugs.

Payer Policies

As mandatory white-bagging and brown-bagging policies have been on the rise among payers in recent years, hospital-based infusion centers and physician practices have been negatively impacted by these policies through lost revenue and increased legal and administrative concerns. In Table 2, we will address specific payer actions regarding white bagging and brown bagging as well as the impact of these actions on providers and patients.

Table 2. Specific Payer Bagging Activity

Payer	Action
UnitedHealthcare	<ul style="list-style-type: none"> • White-bagging program: Requirement to use a specialty pharmacy provider for certain medications (originally started April 1, 2020) • Expanding its medication sourcing requirement to apply to additional drugs that are administered in an outpatient hospital setting • To meet the requirements, outpatient hospital providers must order the medications listed from their approved specialty pharmacies, unless otherwise authorized by UnitedHealthcare. • Applies to Commercial members • American Hospital Association (AHA) Rebuttal (February 2021)
Anthem	<ul style="list-style-type: none"> • Requiring providers to use CVS Specialty Pharmacy to obtain specialty medications administered in the office or outpatient hospital setting (effective July 1, 2020) • Policy applies to all listed specialty drugs covered for Commercial and Medicaid members under the medical benefit where Anthem has financial risk for the cost of specialty medications • Physician/provider group will continue to be responsible for the utilization management and prior authorization of specialty medications • Drugs can be delivered to any destination of the patient’s choice, potentially explicitly authorizing brown bagging • The new policy impacts both hospital-based infusion centers and physician practices (e.g. oncology, hematology, or ophthalmology practices) that routinely administer medication to patients in-office
Cigna	<ul style="list-style-type: none"> • Per the Specialty Medical Injectables with Reimbursement Restriction requirement, certain specialty medical injectables must be dispensed and their claims must be submitted by a specialty pharmacy with which Cigna has a reimbursement arrangement, unless otherwise authorized by Cigna • The Reimbursement Restriction list: <ul style="list-style-type: none"> ○ Applies when the specialty medical injectable is administered in an outpatient hospital setting ○ Applies to specialty medical injectables covered under the medical benefit; coverage is determined by the customer’s benefit plan ○ Only applies to hospital outpatient; does not apply when the specialty medical injectable is administered in a provider’s office, non-hospital affiliated ambulatory infusion suite, or home setting • Cigna will not reimburse facilities that purchase these injectables directly from specialty pharmacies, manufacturers, or wholesalers
BCBS Tennessee	<ul style="list-style-type: none"> • White-bagging requirement pilot program started on January 1, 2020, with self-funded employer groups • Requires HCPs to obtain provider-administered drugs from specialty pharmacies; does not allow buy and bill of drug, but still reimburses for administration • Implemented with a 6-month transition period

Abbreviations: HCP, healthcare provider; PBM, pharmacy benefit manager

Hospital/Health System Impact

Clinical Challenges

- Inability to adjust dosages in response to emergent laboratory or clinical findings
 - Diseases and conditions that require drug infusions (e.g. cancer, solid organ transplant) require same day treatment decisions due to the critical condition of patients
 - Health systems and doctors' offices have medications readily available to support timely, safe treatment
 - Delays can be life-threatening (e.g. transplant organ rejection, chemotherapy progression, or hospitalization)
 - Drugs and doses may be modified due to changes in patient-specific conditions (e.g. weight gain, renal function, bone marrow function, other labs, or imaging studies)
 - Unavailable drugs and doses result in treatment delays
 - Increased drug waste since white-bagged drugs are designated for specific patients and theoretically cannot be used for others
- Risks at discharge
 - Patients remain in hospital due to delays in arranging for post-discharge dose, which increases the risk of hospital-acquired infection
 - Patient readmissions due to delay in mail-order delivery, resulting in exacerbation/life-threatening symptoms requiring hospital admission

Operational Challenges

- Bypasses health system formularies, safety checks, and care planning processes
- Threatens practices that healthcare organizations have established to keep patients safe; hinders the ability of pharmacists to ensure medication and supply chain safety
 - Disrupts the ordering process, introducing the risk of errors:
 - Complete evidence-based drug therapy plans are built in electronic health records (EHRs) to support patient safety by having all the necessary medications, supportive treatment, labs, etc.
 - Drug therapy plans are not available for e-prescribing of infusion therapy; duplicate ordering in 2 different systems creates potential for errors
 - EHR systems typically cannot be used for white-bagged medications; EHR contains detailed information on the patient that may alert the pharmacy of various patient-specific warnings or precautions (e.g. allergies, drug interactions, etc.) to consider prior to dispensing
- Patient disruption
 - Patients often change their scheduled appointments; patients may arrive, but their drugs may not be available
- Safety and operational concerns
 - Requires separate patient-specific inventory tracking for white-bagged medications; most chemotherapy regimens are 2–3 medications, complicating tracking further
 - Drug integrity safeguards are bypassed (more of a concern with brown bagging)
 - Unable to verify the source of medications

- Unable to ensure proper temperature storage

Physician/Provider Impact

- Large financial impact by no longer being able to seek reimbursement for medications administered within the office or facility
 - For many specialty providers (i.e. oncologists), revenues from drug administration can constitute 50% or more of their practices' overall income, even though they can still bill for a Current Procedural Terminology (CPT) code
 - Cannot take advantage of institutional 340B pricing
- Difficulty tracking different policies for patients

Patient Impact

- May be more or less expensive for patients for specialty medications (based on benefit design)
- Potential inability for the patient to pay upfront for co-pay or co-insurance, which could interrupt treatment
- Brown bagging requires the patient to properly handle and store the drug
- May require the patient to change their appointment or return to the facility/doctor's office if the drug is not available or if lab tests require a dosage change

Opposition to White-Bagging and Brown-Bagging Practice

- [Louisiana](#) has banned payers from white bagging
- The [Massachusetts](#) Health Policy Commission formally recommended that:
 - Payers should not require brown bagging for any drug due to concerns of potential patient mishandling of products acquired via brown bagging
 - Payers that require white bagging should ensure minimum safety standards and capabilities from their contracted third-party specialty pharmacies
- [AHA](#) urges regulators to prohibit brown bagging and certain white bagging
- [ASHP](#) is urging the FDA to prohibit [white bagging](#)
- The National Association of Boards of Pharmacy ([NABP](#)) recommends that specialty pharmacies be accountable for brown-bagging protocols to ensure patient protection, similar to the role of retail pharmacies

Recommendations for Health Systems

- Have conversations with payers, and possibly negotiate to accept the same reimbursement rate as the payer's specialty pharmacy
- Own and operate an in-house specialty pharmacy for clear bagging; become an in-network specialty pharmacy for payers
- Obtain accreditation to compete as a specialty pharmacy: URAC, ACHC, Joint Commission, etc.
- Work with drug manufacturers to gain access to limited-distribution drugs (if possible)
- Become clinical experts for a patient-centered continuum of care

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- Become efficient and proficient in reimbursement and inventory management, even if it includes white bagging inventory management
- Integrate specialty pharmacy-delivered drugs into an inventory system and electronic medical record (EMR) system (if possible)

Payer White-Bagging Lists

Brand Name/ Drug Class	Generic Name	J-code	<u>United</u>	<u>Anthem</u>	<u>Cigna</u>	<u>BCBST</u>
Abraxane	paclitaxel	J9264				✓
Actemra	tocilizumab	J3262	✓	✓		✓
Acthar	corticotropin	J0800				✓
Adakveo	crizanlizumab-tmca	J0791	✓			✓
Adcetris	brentuximab vedotin	J9042		✓		✓
Aliqopa	copanlisib	J9057				✓
Amondys 45	casimersen	J3590, C9399	✓		✓	✓
Aldurazyme	laronidase	J1931	✓	✓		✓
Alimta	pemetrexed	J9305		✓		
Alpha1-Proteinase Inhibitors	multiple	J0256 J0257	✓	✓		
Arranon	nelarabine	J9261				✓
Arzerra	ofatumumab	J9302				✓
Asparlas	calaspargase pegol-mknl	J9118				✓
Avastin	bevacizumab	J9035				✓
Bavencio	avelumab	J9023		✓		✓
Beleodaq	belinostat	J9032				✓
Bendamustine	multiple	J9034, J9036				✓
Benlysta	belimumab	J0490	✓	✓		✓
Beovu	brovacizumab-dbll	J0179		✓		✓
Besponsa	inotuzumab ozogamicin	J9229				✓
Bevacizumab Biosimilars	multiple	Q5107, Q5118				✓
Blenrep	belantamab mafodotin-blmf	J9037				✓
Blinicyto	blinatumomab	J9039		✓		✓
Botulinum Toxins	multiple	multiple	✓	✓		✓
Breyanzi	lisocabtagene maraleucel	C9399, J9999				✓
Brineura	cerliponase alfa	J0567	✓		✓	✓
C1 Esterase Inhibitors	multiple	J0596, J0597, J0598, J0599		✓		✓

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Brand Name/ Drug Class	Generic Name	J-code	<u>United</u>	<u>Anthem</u>	<u>Cigna</u>	<u>BCBST</u>
Cerezyme	imiglucerase	J1786	✓			✓
Cimzia	certolizumab pegol	J0717	✓			✓
Cinqair	reslizumab	J2786	✓	✓		✓
Colony-Stimulating Factors	multiple	multiple	✓			✓
Cosela	trilaciclib	C9399, J3490				✓
Crysvita	burosumab-twza	J0584	✓	✓		✓
Cyramza	ramucirumab	J9308		✓		✓
Danyelza	naxitamab-gqgk	J9348				✓
Darzalex	daratumumab	J9144, J9145		✓		✓
Elaprase	idursulfase	J1743	✓	✓		✓
Ellelyso	taliglucerase alfa	J3060	✓	✓		✓
Elzonris	tagraxofusp-erzs	J9269				✓
Empliciti	elotuzumab	J9176		✓		✓
Enhertu	fam-trastuzumab deruxtecan-nxki	J9358			✓	✓
Entyvio	vedolizumab	J3380	✓	✓		✓
Erbitux	cetuximab	J9055		✓		✓
Erwinaze	asparaginase Erwinia chrysanthemii	J9019				✓
Erythropoietin- Stimulating Agents	multiple	multiple		✓		✓
Evenity	romosozumab-aqqg	J3111		✓		✓
Evkeeza	evinacumab-dgnb	J3590, C9399			✓	✓
Exondys 51	eteplirsen	J1428	✓			✓
Eylea	aflibercept	J0178				✓
Fabrazyme	agalsidase beta	J0180	✓	✓	✓	✓
Fasenra	benralizumab	J0517	✓	✓		✓
Faslodex	fulvestrant	J9395		✓		
Firazyr	icatibant	J1744				✓
Firmagon	degarelix	J9155				✓
Flolan/Veletri	epoprostenol	J1325		✓		✓
Folotyng	pralatrexate	J9307				✓
Gamifant	emapalumab-lzsg	J9210	✓			✓
Gazyva	obinutuzumab	J9301		✓		✓
Givlaari	givosiran	J0223	✓		✓	✓

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Halaven	eribulin mesylate	J9179				✓
Hemlibra	emicizumab-kxwh	J7170		✓		
Hemophilia Factors	multiple	multiple		✓		
Herceptin/Hylecta	trastuzumab	J9355, J9356		✓		✓
Hyaluronate	multiple	multiple				✓
Immune Globulins	multiple	multiple	✓			✓
Ilaris	canakinumab	J0638	✓	✓		✓
Ilumya	tildrakizumab-asmn	J3245	✓	✓		✓
Iluvien	fluocinolone acetonide	J7313		✓		✓
Imfinzi	durvalumab	J9173		✓		✓
Imlygic	talimogene laherparepvec	J9325				✓
Infliximab Biosimilars	infliximab	Q5103, Q5104, Q5121	✓	✓		✓
Infugem	gemcitabine	J9198				✓
Istodax	romidepsin	J9315				✓
Ixempra	ixabepilone	J9207				✓
Jelmyto	mitomycin	J9281				✓
Jevtana	cabazitaxel	J9043				✓
Kadcyla	ado-trastuzumab emtansine	J9354		✓		✓
Kalbitor	ecallantide	J1290		✓		✓
Kanuma	sebelipase alfa	J2840	✓		✓	✓
Keytruda	pembrolizumab	J9271		✓		✓
Krystexxa	pegloticase	J2507	✓	✓		✓
Kymriah	tisagenlecleucel	Q2042				✓
Kyprolis	carfilzomib	J9047				✓
Lartruvo	olaratumab	J9285				✓
Lemtrada	alemtuzumab	J0202	✓	✓	✓	✓
Leukine	sargramostim	J2820				✓
Leuprolide Acetate	multiple	multiple		✓		✓
Levoleucovorin	multiple	J0641				✓
Libtayo	cemiplimab-rwlc	J9119				✓
Lucentis	ranibizumab	J2778		✓		✓
Lumizyme	alglucosidase alfa	J0221	✓	✓	✓	✓
Lumoxiti	moxetumomab pasudotox-tdfk	J9313				✓
Luxturna	voretigene neparvovec	J3398	✓		✓	✓

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Brand Name/ Drug Class	Generic Name	J-code	<u>United</u>	<u>Anthem</u>	<u>Cigna</u>	<u>BCBST</u>
Macugen	pegaptanib	J2503		✓		✓
Margenza	margetuximab-cmkb	J9353				✓
Marqibo	vincristine liposomal	J9371				✓
Mepsevii	vestronidase alfa	J3397	✓			✓
Monjuvi	tafasitamab-cxix	J9349				✓
Mylotarg	gemtuzumab ozogamicin	J9203				✓
Naglazyme	galsulfase	J1458	✓	✓		✓
Nplate	romiplostim	J2796		✓		✓
Nucala	mepolizumab	J2182	✓	✓		✓
Nulibry	fosdenopterin	J3490				✓
Nulojix	belatacept	J0485		✓		
Ocrevus	ocrelizumab	J2350	✓	✓		✓
Oncaspar	pegaspargase	J9266		✓		✓
Onivyde	irinotecan liposomal					✓
Onpattro	patisiran	J0222	✓	✓	✓	✓
Opdivo	nivolumab	J9299		✓	✓	✓
Orencia	abatacept	J0129	✓	✓		✓
Oxlumo	lumasiran	C9074	✓			✓
Ozurdex	dexamethasone	J7312		✓		✓
Padcev	enfortumab vedotin-efjv	J9177				✓
Pepaxto	melphalan flufenamide	C9080				✓
Perjeta	pertuzumab	J9306		✓		✓
Phesgo	pertuzumab, trastuzumab, and hyaluronidase-zzxf	J9316				✓
Polivy	polatuzumab vedotin-piiq	J9309				✓
Portrazza	necitumumab	J9295				✓
Poteligeo	mogamulizumab-kpkc	J9204				✓
Prolia/Xgeva	denosumab	J0897	✓	✓		✓
Proleukin	aldesleukin	J9015				✓
Provenge	sipuleucel-T	Q2043				✓
Radicava	edaravone	J1301	✓			✓
Reblozyl	luspatercept-aamt	J0896	✓			✓
Reclast	zoledronic acid	J3489				✓
Remicade	infliximab	J1745	✓	✓		✓
Remodulin	treprostinil	J3285				✓
Retisert	fluocinolone acetonide	J7311		✓		✓

Rx BRIEF: DRUG MANAGEMENT

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Revcovi	elapegademase-lvlr	J3590, C9399	✓			✓
Rituxan/Hycela	rituximab	J9311, J9312		✓		✓
Rituximab Biosimilars	multiple	Q5115, Q5119		✓		✓
Sandostatin/LAR	ocreotide	J2353, J2354		✓		✓
Sarclisa	isatuximab-irfc	J9227				✓
Signifor/LAR	pasireotide	J2502, C9454				✓
Simponi Aria	golimumab	J1602	✓	✓		✓
Soliris	eculizumab	J1300	✓	✓	✓	✓
Somatuline Depot	lanreotide	J1930				✓
Spinraza	nusinersen	J2326	✓		✓	✓
Stelara	ustekinumab	J3357, J3358	✓	✓		✓
Supprelin LA/Vantas	histrelin acetate	J9225, J9226		✓		✓
Sylvant	siltuximab	J2860				✓
Synagis	palivizumab	90378	✓			✓
Synribo	omacetaxine mepesuccinate	J9262				✓
Takhzyro	lanadelumab-flyo	J0593		✓		✓
Tecartus	brexucabtagene autoleucel	Q2053				✓
Tecentriq	atezolizumab	J9022		✓		✓
Tegsedi	inotersen	C9399, J3490				✓
Temodar	temozolomide	J9328				✓
Tepezza	teprotumumab-trbw	J3241	✓		✓	✓
Testopel	testosterone	S0189				✓
Thyrogen	thyrotropin alfa	J3240				✓
Torisel	temsirolimus	J9330				✓
Trastuzumab Biosimilars	multiple	Q5112, Q5113, Q5114, Q5116		✓		✓
Trelstar/Triptodur	triptorelin pamoate	J3315, J3316		✓		✓
Trodelyv	sacituzumab govitecan-hziy	J9317				✓
Trogarzo	ibalizumab-uiyk	J1746	✓			✓
Tysabri	natalizumab	J2323	✓	✓		✓
Ultomiris	ravulizumab-cwvz	J1303	✓	✓	✓	✓
Uplizna	inebilizumab-cdon	J1823	✓			✓
Vectibix	panitumumab	J9303		✓		✓
Velcade	bortezomib	J9041, J9044				✓
Vidaza	azacitidine	J9025				✓

Rx BRIEF: DRUG MANAGEMENT

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Vilteproso	viltolarsen	J1427	✓			✓
Vimizim	elosulfase alfa	J1322	✓	✓		✓
Visudyne	verteporfin	J3396				✓
Vpriv	velaglucerase alfa	J3385	✓	✓		✓
Vyepti	eptinezumab-jjmr	J3032	✓			✓
Vyondys 53	golodirsen	J1429	✓		✓	✓
Vyxeos	daunorubicin/ cytarabine	J9153				✓
Xiaflex	collagenase clostridium histolyticum	J0775	✓			✓
Xolair	omalizumab	J2357	✓	✓		✓
Yervoy	ipilimumab	J9228		✓	✓	✓
Yescarta	axicabtagene ciloleucel	Q2041				✓
Zoladex	goserelin acetate	J9202				✓
Zolgensma	onasemnogene abeparvovec-xioi	J3399	✓		✓	✓
Zometa	zoledronic acid	J3489				✓

Sources: [United Healthcare List April 2021](#); [Anthem Drug List May 2021](#); [Cigna List March 2021](#); [BCBS Tennessee List June 2021](#)

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