

Buy and Bill Drugs 101

Module 1: Introduction

PUBLISHED BY

Health Care Industry Committee

Health Care Industry Committee

Project Director

Lindsay Conway
ConwayL@advisory.com

Research Team

Viggy Hampton, MPH

LEGAL CAVEAT

Advisory Board has made efforts to verify the accuracy of the information it provides to members. This report relies on data obtained from many sources, however, and Advisory Board cannot guarantee the accuracy of the information provided or any analysis based thereon. In addition, Advisory Board is not in the business of giving legal, medical, accounting, or other professional advice, and its reports should not be construed as professional advice. In particular, members should not rely on any legal commentary in this report as a basis for action, or assume that any tactics described herein would be permitted by applicable law or appropriate for a given member's situation. Members are advised to consult with appropriate professionals concerning legal, medical, tax, or accounting issues, before implementing any of these tactics. Neither Advisory Board nor its officers, directors, trustees employees, and agents shall be liable for any claims, liabilities, or expenses relating to (a) any errors or omissions in this report, whether caused by Advisory Board or any of its employees or agents, or sources or other third parties, (b) any recommendation or graded ranking by Advisory Board, or (c) failure of member and its employees and agents to abide by the terms set forth herein

Advisory Board and the "A" logo are registered trademarks of The Advisory Board Company in the United States and other countries. Members are not permitted to use these trademarks, or any other trademark, product name, service name, trade name, and logo of Advisory Board without prior written consent of Advisory Board without prior written consent of Advisory Board. All other trademarks, product names, service names, trade names, and logos used within these pages are the property of their respective holders. Use of other company trademarks, product names, service names, trade names, and logos or images of the same does not necessarily constitute (a) an endorsement by such company of Advisory Board and its products and services, or (b) an endorsement of the company or its products or services by Advisory Board. Advisory Board is not affiliated with any such company.

IMPORTANT: Please read the following.

Advisory Board has prepared this report for the exclusive use of its members. Each member acknowledges and agrees that this report and the information contained herein (collectively, the "Report") are confidential and proprietary to Advisory Board. By accepting delivery of this Report, each member agrees to abide by the terms as stated herein, including the following:

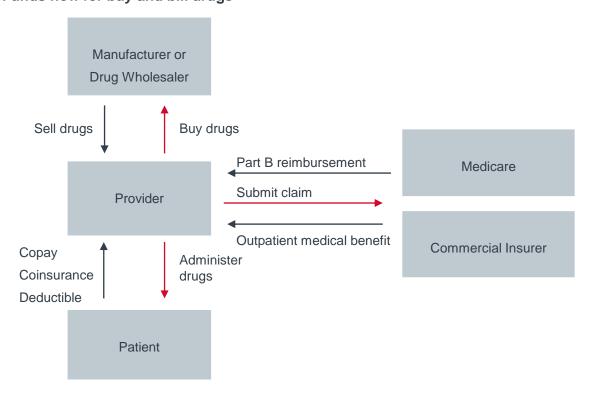
- Advisory Board owns all right, title, and interest in and to this Report. Except as stated herein, no right, license, permission, or interest of any kind in this Report is intended to be given, transferred to, or acquired by a member. Each member is authorized to use this Report only to the extent expressly authorized herein.
- Each member shall not sell, license, republish, or post online or otherwise this Report, in part or in whole. Each member shall not disseminate or permit the use of, and shall take reasonable precautions to prevent such dissemination or use of, this Report by (a) any of its employees and agents (except as stated below), or (b) any third party.
- 3. Each member may make this Report available solely to those of its employees and agents who (a) are registered for the workshop or membership program of which this Report is a part, (b) require access to this Report in order to learn from the information described herein, and (c) agree not to disclose this Report to other employees or agents or any third party. Each member shall use, and shall ensure that its employees and agents use, this Report for its internal use only. Each member may make a limited number of copies, solely as adequate for use by its employees and agents in accordance with the terms herein.
- Each member shall not remove from this Report any confidential markings, copyright notices, and/or other similar indicia herein.
- Each member is responsible for any breach of its obligations as stated herein by any of its employees or agents.
- If a member is unwilling to abide by any of the foregoing obligations, then such member shall promptly return this Report and all copies thereof to Advisory Board.

What is "buy and bill"?

"Buy and bill" is the term used to describe how infused and injectable outpatient drugs are typically reimbursed. Under this model, providers buy the drugs, administer them to patients, and then submit a claim to the patient's insurance for the drug and collect any money owed (e.g. copay, coinsurance, or deductible) by the patient.

Drugs reimbursed through buy and bill are paid for under the outpatient medical benefit. That is, the patient's health plan (e.g. United Healthcare, Aetna, BCBS) reimburses the provider for the drug. Medicare calls the outpatient medical benefit Medicare Part B. Consequently buy and bill drugs are often referred to as "Part B Drugs." Generally speaking, they are medications that must be injected or infused by a health care provider. Usually they are administered by an RN in a physician office or outpatient infusion center. They tend to be high-cost medications that are used to treat complex and rare conditions, such as cancer and autoimmune diseases. Often they are categorized as specialty medications.

Funds flow for buy and bill drugs



Top five Medicare Part B drugs by spending, 2016

Drug (generic name)	Total Spending (in millions)	Total Volume (dosage units, in millions)	Therapeutic Area
Aflibercept	\$2.2	2.3	Colorectal cancer
Rituximab	\$1.7	2.2	Rheumatoid arthritis
Pegfilgrastim	\$1.4	0.4	Cancer
Infliximab	\$1.3	16.7	Autoimmune diseases
Bevacizumab	\$1.1	15.9	Cancer

How is buy and bill different from reimbursement for other types of prescription drugs?

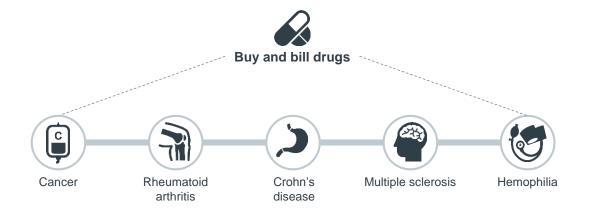
Usually, when a patient gets a new prescription, he or she takes it to a pharmacy. The pharmacy dispenses the drug to the patient, sends a claim to the patient's insurance, and collects any money owed by the patient.

Most prescription drugs are covered by the patient's pharmacy benefit, which is typically managed by a Pharmacy Benefits Manager (PBM), such as ExpressScripts or OptumRx. In Medicare terms, the pharmacy benefit is called Part D and so these drugs are often referred to as "Part D drugs."

How buy and bill drugs compare to other types of prescription drugs

	Buy and Bill Drugs	Other Prescription Drugs
Which types of drugs are typically included in this category?	infused or injectable drugs administered in a physician office or infusion center ¹	Self-administered drugs, including oral drugs, inhalers, and certain injections
Which part of the patient's insurance benefit covers the drug?	Outpatient medical benefit, known as Part B for Medicare beneficiaries	Pharmacy benefit, known at Part D for Medicare beneficiaries
Who prescribes the drug?	Providers	Providers ²
Who dispenses the drug?	Providers	Pharmacy
Who bills the patient's insurance?	Provider	Pharmacy
Who collects the patient's payment?	Providers	Pharmacy

Conditions commonly treated using buy and bill drugs



There are exceptions. For example, Medicare covers certain oral oncolytics under Part B, instead of Part D

²⁾ In some states, pharmacists are allowed to substitute generic for brand name drugs without a new prescription from the provider.

Why does buy and bill matter?

Implication #1: Buy and bill gives providers an economic incentive to prescribe more expensive drugs

Medicare and most commercial health plans reimburse providers for the average sales price (ASP) of the drug plus a fixed percentage mark-up. Currently Medicare pays ASP + 6% for most Part B drugs¹. Commercial payer reimbursement ranges widely and may be as high as ASP + 200%. Consequently providers can increase their revenues and profits by prescribing a drug with a higher ASP.

Examples of how profit differs in relation to choice of drug

Average Sales Price (ASP)	Medicare Mark-up	Medicare Reimbursement	Provider's Gross Profit
\$100	+6%	\$106	\$6
\$1,000	+6%	\$1,060	\$60

Implication #2: Buy and bill forces providers to take on financial risk for drugs

Providers' risk for buy and bill drugs falls into three categories:

<u>Inventory risk</u>: Providers administering buy and bill drugs routinely spend millions of dollars each year on drug inventory, some of which may need to be discarded due to damage or expiration. This inventory "shrinkage" is an expense to the practice.

Reimbursement risk: There is no guarantee that providers will be reimbursed for the drugs they administer to patients, and it is not unusual for insurance companies to deny payment. Meanwhile, patients are increasingly struggling to cover their out of pocket expenses, and so providers may never collect the patient's portion of the bill.

\$3.6 million
Average drug spend in 2014 per full-time oncologist



Many providers have decided that they no longer want to carry this financial risk, and it is one of the reasons that many independent physicians have sold their practices to hospitals or IDNs.

<u>Pricing risk</u>: As noted above, reimbursement rates are generally calculated based on the ASP. However, the ASP is a national average, and the actual price paid by any one practice for a given drug may be higher or lower. In some cases, practices' drug acquisition costs may exceed their reimbursement. Generally speaking, providers are able to secure lower prices when they purchase a higher volume of drugs. Thus, many providers have merged with or acquired other practices in order to gain larger scale.

Hospital-owned physician practices on the rise

Number of hospital-owned practices (in thousands)



There are exceptions. For example, newer drugs for which ASP data are not yet available are often reimbursed based on their wholesale acquisition cost (WAC).

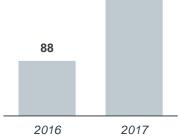
Source: Carla Balch, John D. Ogle, and James L. Senese, "The National Practice Benchmark for Oncology: 2015 Report for 2014 Data," available at: http://ascopubs.org/doi/full/10.1200/JOP.2015.008458; Physician Advocacy Institute, "Updated Physician Practice Acquisition Study," 2018, available at: http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/2016-PAI-Physician-Employment-Study-Final.pdf; Advisory Board research and analysis.

Implication #3: Providers may have an economic incentive to prescribe buy and bill drugs instead of oral drugs.

Providers that administer infused and injectable drugs earn revenue from the drugs under the buy and bill model. However, oral drugs are supplied by a pharmacy, even when Medicare covers them under Part B. As a result, unless the provider owns the pharmacy, prescribing oral (instead of injectable or infused) therapies requires the provider to forgo revenues. In other words, providers have an economic incentive to prescribe infused or injectable drugs over their oral equivalents.

The impact of these financial incentives on prescribing patterns has not been rigorously studied. But it's notable that in recent years, IDNs and large physician practices have been starting specialty pharmacies to handle expensive outpatient drugs that typically require special handling and additional patient support. One reason is that owning a specialty pharmacy enables providers to capture revenue from oral therapies.

Number of accredited provider- owned specialty pharmacies 186



Implication #4: Health plans want to minimize growth in buy and bill spending

Health plans are very concerned about their spending on buy and bill drugs. In response, they have deployed a number of tactics to try to ensure that their beneficiaries receive evidence-based, cost-effective care.



Medicare Part B spending on outpatient drugs increased between 2005 and 2015

+268%

+143%

Increase in spending at hospital outpatient departments

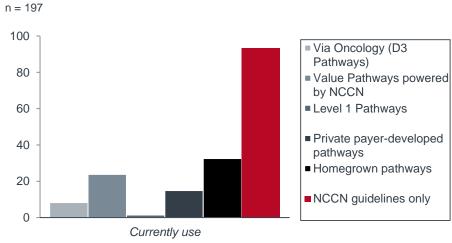
Increase in spending at physician offices and other suppliers

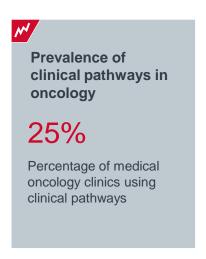
The most common approach is increasing prior authorization (PA) requirements.¹ Health plans are increasing both the number of drugs requiring PAs and the amount of information physicians must provide to secure a PA. According to a 2016 AMA survey, physician office staff spend 20 hours each week working on PAs, and 90% of physicians report that PAs sometimes, often, or always delay patient care.

In oncology, where the clinical evidence may not clearly support the choice of one drug over another, health plans are increasingly turning to clinical pathways. Clinical pathways are developed by first starting with evidence-based guidelines, and then whittling down the possible treatment options based on efficacy and toxicity. If more than one drug yields equivalent patient outcomes, then pathways recommend the less expensive option. Health plans may pay physicians a bonus for treating patients "on pathway;" alternatively they may refuse treatment for regimens that are "off pathway."

Medical oncologists use a variety of clinical pathways²

Percentages of cancer programs using specific pathways





Source: Oncology Roundtable, "Infusion Center Business Strategy," 2018; Drug Channels, "New Part B Buy-and-Bill Data: Physician Offices Are Losing to Hospital Outpatient Sites," 2017, available at: https://www.drugchannels.net/2017/08/new-part-b-buy-and-bill-data-physician-Infusion (noclogy Roundtable, "Prior Authorization for Physician-Administered Ortugs," available at: https://www.advisory.com/research/orcology-roundtable/studies/2017/prior-authorization-for-physician-Administered-drugs, 'Advisory Board, "Stop losing drug revenue to prior authorization denials," available at: https://www.advisory.com/research/care-transformation-center/care-transformation-ce

See Module 5 (glossary) for a definition of prior authorization.
 We asked oncology providers, "Which of the following clinical pathways do your medical oncologists use?"

Implication #5: Patients' out-of-pocket costs differ when the drug is reimbursed under the medical benefit

For example, Medicare FFS beneficiaries are responsible for a 20% coinsurance on all Part B (buy and bill) drugs. In contrast, Medicare beneficiaries' out-of-pocket costs for drugs covered under their prescription benefit varies depending on their choice of Part D plan. The patient's costs could be higher or lower depending on the plan's cost sharing structure and how much the patient has already paid toward their deductible.

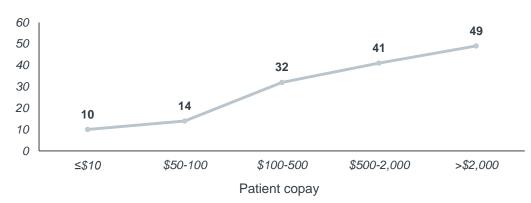


Average annual cost to patient of non-retail outpatient oncology drugs

Generally speaking, patients' out-of-pocket costs are rising in correlation with drug prices. This is concerning because patients' adherence to their treatment regimen—and ultimately their outcomes—is inversely correlated to costs. For example, a recent study found that medication abandonment rates for oncology drugs increased as patient copays rose.

Medication abandonment¹ rate for novel anti-cancer drugs rises with increasing copay n = 38,111

Abandonment rate, %



Implication #6: Infused and injectable drug regimens create more touch points with patients, increasing opportunities for care management

Because buy and bill drugs must be administered in an outpatient facility and treatments usually extend over a period of weeks or months, patients usually have regular in-person appointments with their care teams. These appointments create more opportunities for the team to provide care management, including symptom management, psychosocial support, and education for patients and families. These additional touch points can be helpful as this patient population tends to have serious illnesses and an elevated risk for complications.

Buy and bill drugs 101: roadmap

Next up in the buy and bill drugs 101 series

1 Introduction

Overview of buy and bill basics

2 Health plan perspective

Health plans' top priorities and strategies for managing buy and bill drugs

Physician practice perspective

Physician practices' top priorities and strategies for managing buy and bill drugs

4 HOPD infusion center perspective

HOPD infusion centers' top priorities and strategies for managing buy and bill drugs

Glossary

Buy and bill glossary of key terms

The best practices are the ones that work for **you.**SM

