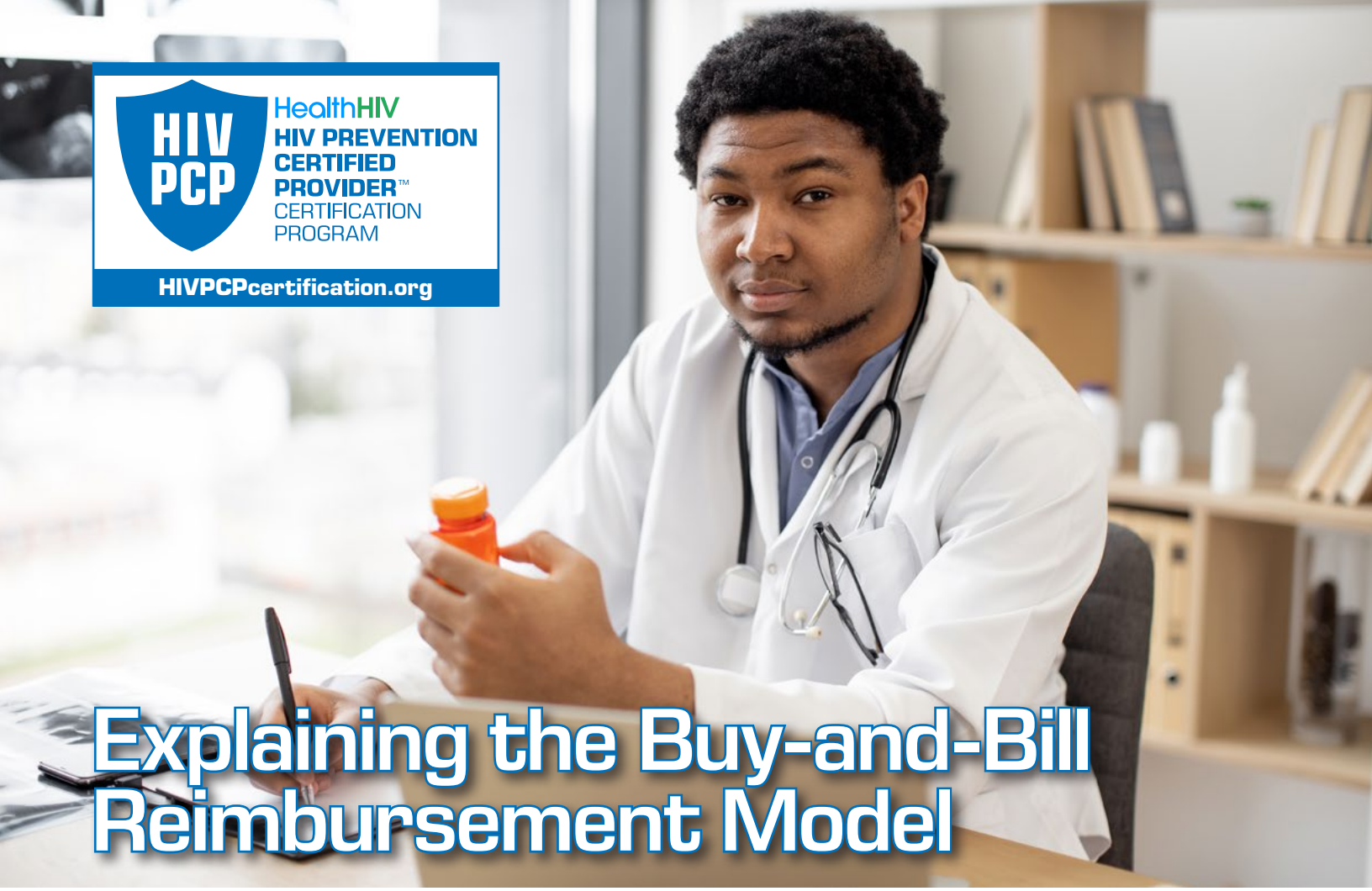


Explaining the Buy-and-Bill Reimbursement Model

If your practice purchases medications for patients, you may be familiar with the term "buy-and-bill". This reimbursement model is a key component of specialty drug distribution.

The buy-and-bill practice is gaining attention from policy makers, physicians, and patient advocacy groups, so it is important for you to stay informed on how healthcare systems may be impacted.

What Providers Need to Know

Long-acting cabotegravir and rilpivirine are covered typically through the patient's medical benefit rather than their pharmacy benefit.

When it comes to physician-administered medications, providers interested in the buy-and-bill model should be aware of reimbursement rates, inventory management, and billing practices.

The most common way for a physician to acquire and administer these medications is through a buy-and-bill model. This means that the physician buys the medication and then bills a third-party payer for the purchase price plus an administration fee.

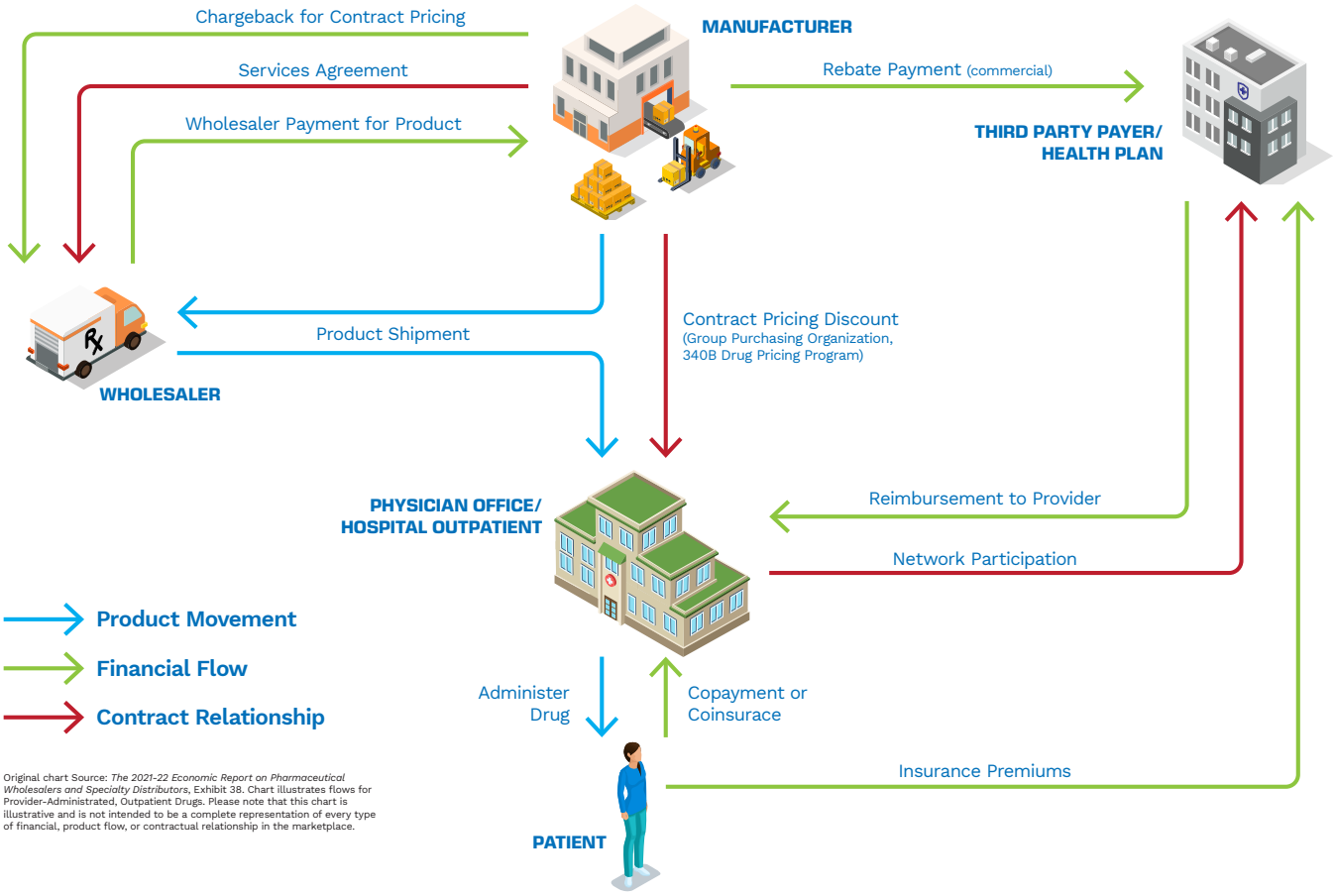
A healthcare provider will buy, store, and then administer the medication to a patient as part of the buy-and–bill process. The provider submits a claim to third-party payers for reimbursement once the patient has received both the medication and any other care.

The provider is ultimately responsible in the buy-and–bill system for:

- Ordering and purchasing the medication
- Managing medication inventories
- Dispensing the medication to a person
- Submitting reimbursement claims for a medication as well as any related professional services
- Recovering copayments or coinsurance from patients for all services.
  - A copay is a fixed amount of money required to be paid by the patient, attached to covered services. It is different from a deductible in that a deductible is the set amount of money you pay out-of-pocket for covered services per plan year before your insurance plan starts to pay.

Financial Flow Chart For Buy-and-Bill Model

The financial flow chart below outlines the distribution and reimbursement process for provider-administered outpatient medications via the buy-and-bill model.



Types of Distributors

A specialty distributor is typically used by community-based physician practices to purchase medications. Specialty drug or medication distributors primarily carry specialty pharmaceutical medications. These distributors' customer base includes independent specialist physician offices, physician-owned clinics, hospital-owned clinics, specialty pharmacies, home healthcare providers, and to a lesser extent, hospital pharmacies.

For example, a hospital pharmacy buys medications from a full-line pharmaceutical wholesaler. This is how outpatient hospitals and hospital-based practices get their products.

What Distributors are Responsible for

- Getting the products directly from the manufacturer
- Negotiating the price of the medication to the provider
- Delivering the specialty medication to the provider
- Recovering payment from the provider

Reimbursement Rates

Medicare Part B, the medical component of Medicare, reimburses physician-administered medications based on the medication's average sales price plus a 6% rebate payment from the manufacturer. The reimbursement formula is mandated by Congress and works to optimize effective price competition for branded products and innovator biologics.

Benefits of Buy-and-Bill

Many Federally Qualified Health Centers do not (yet) have the option of buying and billing. Often seen as a speciality medication, and more expensive to advance stock it without a guarantee of reimbursement, many providers and their offices may prefer a more convenient location for administration. Others simply lack systems-level inventory control for a myriad of other reasons, logistics alone. While providers can Buy-and Bill, it may be difficult for them to increase staffing, clinical services and fridge space to give monthly injections to the patients they may see only once or twice a year prior to prescription of injectables. Pharmacy or other vendor staff are used to managing stock and inventory costs, and can also administer the injection.

The supply chain is one of the most important benefits for clinical practices who choose to buy-and-bill. A buy-and-bill system offers the opportunity to increase revenue while ensuring proper onsite treatment for patients through control of the supply chain.

By allowing providers control of the supply chain of pharmaceuticals, it can simplify care coordination and ensure that your patients receive the medications they need when necessary *and* as prescribed by you or your practice.

Potential Challenges of Buy-and-Bill

It is likely that your staff and practice operations will need to change to accommodate this new way of purchasing specialty drugs.

While the buy-and-bill system is effective for many specialty medications, it also can create issues that the provider needs to be aware of.

Cash Flow

Small healthcare organizations that utilize a buy-and-bill model may have challenges with cash flow when trying to ensure that they have the right medication for patients on-hand. The model can tie up cash, which creates an up-front risk if medications aren't delivered on time or patient compliance doesn't happen. If this is not administratively monitored, it also can affect scheduling and patient access.

Inventory Management & Logistics

Healthcare organizations also may have challenges with procurement and inventory when trying to ensure that they have the right medication for patients on-hand.

Patients' excitement to injectable treatment options is noticeable, especially with the realization that there are no more pills to take or refills to manage. There is no more pill burden, the stigma associated with HIV may be lessened by not having daily reminders, and privacy is enhanced. Providers also are excited as they anticipate improved patient satisfaction and increased medication therapy adherence.

Inventory management is a complex process that requires procedures, controls, and tools tailored to your practice's needs. Whether you stock your goods in-house, work with fulfillment centers or utilize dropship suppliers, keeping track of inventory data is crucial for ensuring accuracy.

A critical aspect of inventory control is determining how much product you need on-hand at any given time to meet demand. This requires accurate sales projections. You also should regularly perform inventory audits to ensure that stock quantity matches financial records. These audits can be performed monthly or annually.

Billing and Reimbursement

Another challenge is that the reimbursement system can be different for each medication acquisition method. For example, "white bagging" is typically billed under medical benefits while "brown bagging" is reimbursable under pharmacy benefits. This can make it difficult for practices to understand their patient's insurance coverage, so it is important to be aware of those methods.

Be aware that Pharmacy Benefit Managers (PBMs) could deny future refills if they observe non-compliance upon review of fill history.

Develop Coding and Billing Support and Resources

Depending on the specialty and familiarity with buy-and-bill products, healthcare providers may require information and assistance in billing for unspecified ICD-10 codes. Therefore, coding and billing resources should be integrated into your solution.

If your patients have insurance, they can take advantage of the United States Preventive Services Task Force (USPSTF) and Affordable Care Act's preventive health services coverage. Almost all new (non-grandfathered) health insurance plans must cover recommended preventive services, like HIV testing, for everyone regardless of age or risk and without additional cost-sharing.

Options for Off Site Injection Services

If you or your patient prefer that injections be administered outside of your office setting, an **HIV PrEP Network Alternative Site of Administration**, or ASA, may be an appropriate option for you and your patients.

An HIV PrEP Network ASA is a site where people who are at risk of getting HIV can get PrEP medication. These sites can be located at a healthcare provider's office, community-based organization (CBO), health facility, or lab.

ASAs present providers with an ability to prescribe a PrEP injectable without having to acquire and administer the medicine in their office. ASAs may provide your patients with a more convenient location to receive their injectable PrEP.

Is your facility interested in becoming an Alternative Site for Administration?

If your facility is interested in administering an injectable, please download and complete the ASA Locator Agreement Form: viivconnect.com/injectable/asa-locator/

Patient Flow Chart from Treatment to Administration

The patient flow chart below from the American Academy of HIV Medicine offers a step-by step guide for offering PrEP injectables. It guides you from discussions with your patient to ordering the medication and then administering the injectable to your patient.

STEP 1:

The patient expresses interest with the clinician.

STEP 2:

Discuss and assess the patient's qualifications/appropriateness of therapy and pre-screen testing.

a. Amenable to 2 gluteal injections at monthly appts
b. Has a suppressed VL (VL < 50 copies/mL) for at least 3 months
c. Lacks drug resistance mutations to cabotegravir/rilpivirine
d. Lacks any drug interactions with cabotegravir/rilpivirine (e.g. PPIs)
e. Lacks any contraindications to therapy
f. Lacks HBV coinfection
g. Is not pregnant
h. Ideally BMI < 30
i. HIV subtypes other than A6/A1

STEP 3:

Arrange a detailed counseling session with the care team and discuss the following:

a. The process to obtain the medication
b. Patient benefits discussion
c. CAB/RPV lead-in dosing
d. Injection window
e. Expectations
f. Side Effects
g. Adherence
h. Discuss Patient questions/concerns
i. Pregnancy counseling
j. Remind patient they must alert the team of any changes in coverage (gain/loss) while prescribed Cabenuva
k. Educate about EOB statements from private insurance necessary to submit for ViiV Patient Savings Program

Health HIV

HIV PCP

STEP 4:

Enroll the patient in ViiVConnect.

a. Assign team member to keep track of PA expiration/benefit approval dates

b. Coordinate with the specialty pharmacy (SP) or specialty distributor (SD), according to each patient's insurance requirements

4

STEP 5:

Order the optional oral lead-in medication to be delivered to the patient.

a. Oral lead-in of CAB 30 mg plus RPV 25 mg once daily with food for at least 28 days

b. Order by contacting TheraCom via phone (844-276-6299), fax (833-904-1881), or ePrescribe

5

6

STEP 6:

Order the medication to be delivered to the clinic.

a. Schedule/confirm 1st injection visit on receipt of medication

1. Schedule first IM injection visit (day 28-30 of oral lead-in phase) for at least 60 minutes.

b. Clinic Storage: Document on Cabotegravir/rilpivirine storage log:

1. Date/time received
2. Person accepting
3. Patient name
4. Date/time dispensed
5. Person dispensing

7

STEP 7: **First Injection Visit (60 min)**

a. Confirm negative HIV-1 RNA Assay

b. Give loading dose of CAB 600 mg (3 mL) and RPV 900 mg (3 mL) (day 28-30 of oral lead-in)

i. Given as two separate injections in separate ventrogluteal sites

c. RN to pull Cabenuva kit from **fridge~30 min before appt** to allow time to warm-up to room temperature.

d. Unopened kit should be labeled with time it was removed from fridge

i. The vials may remain in the carton at room temperature for up to 6 hours.

ii. Medication must be discarded if not used within 6 hours

e. Administer CAB and RPV at separate gluteal injection sites (on opposite sides or 2 cm apart)

f. Allow 10 to 15 minutes to monitor for adverse effects post-injection

g. RN to chart against order that Cabenuva dose was given and then document visit

i. If patient DNKA; return unopened Cabenuva kit to fridge **within 60 min of appt.**

h. Schedule 2nd injection date (+/- 7 day window from 1st injection)

8

STEP 8:

Second Injection Visit and Regular Follow-ups

a. Continuation therapy with monthly CAB 400 mg (2 mL) and RPV 600 mg (2 mL)

i. Given as two separate ventrogluteal IM injections

b. Schedule 28 days from initial appt (+/- 7 day window from 1st injection)

c. **Confirm negative HIV-1 RNA Assay & other necessary labs**

d. RN to pull Cabenuva kit from **fridge~30 min before appt** to allow time to warm-up to room temperature.

e. Unopened kit should be labeled with time it was removed from fridge

i. The vials may remain in the carton at room temperature for up to 6 hours.

Health HIV

HIV PCP

9

STEP 9: If patient misses appointment for injection (planned):

a. Patient to receive oral medications from Theracomm (or local pharmacy) for up to 2 months.

i. Call ViiVConnect for planned missed dose approval

1. ViiV supplies cabotegravir (PO) through TheraCom Pharmacy

2. Rilpivirine (PO) Rx and copay card (if eligible) must be sent to local pharmacy

b. Care team must schedule next injection as soon as possible

10

STEP 10: If patient misses appointment for injection (unplanned):

a. Contact patient x 3 and attempt to schedule within one week of missed appt

b. If unable to schedule within a week period (dependent upon clinical factors), assess patient plan for continuation

i. Refill of previous oral therapy sent to patient's preferred pharmacy; **or**

ii. Patient to receive oral medications from TheraComm for up to 2 months

iii. Care team must schedule next injection as soon as possible

1. If **≤ 2 months since last injection,** can continue with maintenance dose (400 mg / 600 mg kit)

2. If **> 2 months** since last injection, loading dose (600 mg / 900 mg kit) must be given

11

STEP 11: Injection Discontinuation

a. Residual concentrations of CAB/RPV (aka "the tail") may remain in systemic circulation for up to 12 months

b. Alternative ART needed to prevent drug resistance

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