

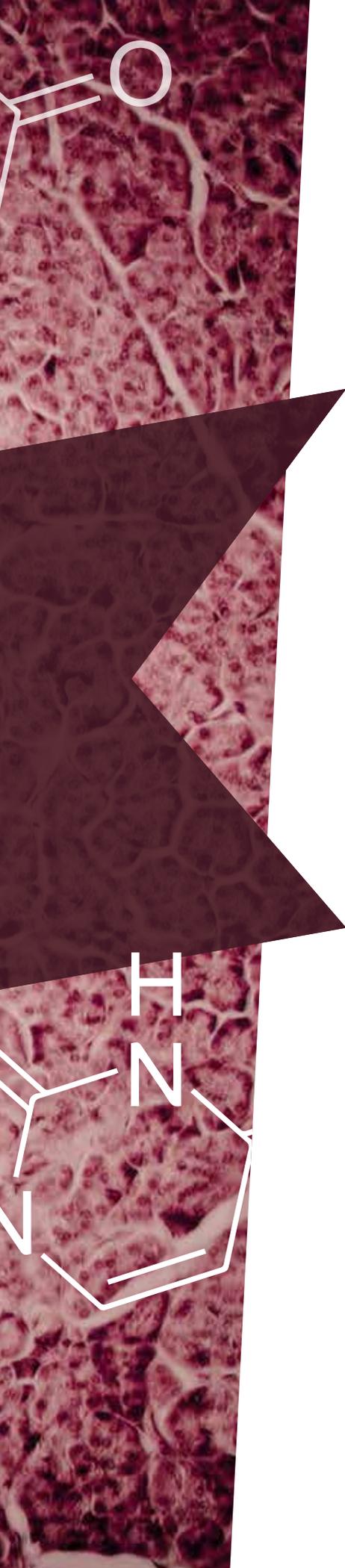
*Hepatitis*

**C:**

**YES,**

it's that

*Special*



## How one pharmacy is bringing specialty drugs to an independent community pharmacy setting

by LeAnn W. O'Neill, PharmD; Vanessa K. Hoffman, PharmD, CGP; Barry S. Bryant, RPh; and John A. Galdo, PharmD, BCPS, CGP

On June 6, NCPA CEO B. Douglas Hoey, Pharmacist, MBA, commented on the changing climate of hepatitis C treatment and community pharmacies in an *Executive Update* to NCPA members. Succinctly, Hoey stated how community pharmacists are poised to be an integral part of the treatment for hepatitis C. The article resonated with the clinical team at Barney's Pharmacy, and this article discusses how Barney's Pharmacy brought specialty tier pharmaceuticals to an independent community setting.

Worldwide, hepatitis C is one of the major causes of liver disease. According to the Centers for Disease Control and Prevention (CDC), an estimated 160 million people are infected with the virus worldwide, and as many as 3.9 million people in the United States are infected. Over the course of the typical 20-30 years of a chronic hepatitis C infection, 60-70 percent of patients will develop chronic liver disease, and as many as 5 percent of these patients will die due to liver cancer or cirrhosis. Not surprisingly, along with significant prevalence comes significant disease burden and cost of treatment.

In 2013, the total cost of treatment of hepatitis C in the United States was estimated to be \$6.5 billion, and more than \$64,000 for the lifetime of each patient. However, with the advent of sofosbuvir (Sovaldi), the treatment of hepatitis C is changing. A typical three-month treatment regimen of sofosbuvir costs an estimated \$84,000, and sofosbuvir is one drug of a two- to three-drug regimen. Patients with hepatitis C potentially represent a significant portion of any community pharmacy's patient population. However, the massive cost of sofosbuvir may intimidate community pharmacists. Because of this, many community pharmacies are missing out on the potential to improve care and outcomes for these patients along with the revenue associated with filling such a high cost medication.



**Table 1: Guideline Recommendations for Treatment of HC Genotypes 1–4**

Genotype	Treatment Naïve or Experienced Relapse after prior PEG/RBV Therapy (Level of Evidence)		Retreatment for Patients in Whom PEG/RBV Failed (Level of Evidence)	
	Recommended	NOT Recommended	Recommended	NOT Recommended**
<b>1</b>	<ul style="list-style-type: none"> <li>IFN eligible: SOF + PEG/RBV x 12 weeks (IA)</li> <li>IFN ineligible: SOF + SMV +/- RBV x 12 weeks (IB)</li> </ul>	<ul style="list-style-type: none"> <li>TVR + PEG/RBV x 24 weeks</li> <li>BOC + PEG/RBV x 28 or 48 weeks</li> <li>PEG/RBV x 48 weeks (IIbA)</li> <li>Monotherapy (IIIA)</li> <li>See note **</li> </ul>	<ul style="list-style-type: none"> <li>SOF + SMV +/- RBV x 12 weeks (IIaB)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV +/- TVR or BOC (IIbA)</li> <li>Monotherapy (IIIA)</li> </ul>
<b>2</b>	<ul style="list-style-type: none"> <li>SOF + RBV x 12 weeks (IA)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV x 24 weeks (IIbA)</li> <li>Monotherapy (IIIA)</li> <li>Any regimen with TVR, BOC, SMV (IIIA)</li> </ul>	<ul style="list-style-type: none"> <li>SOF + RBV x 12 weeks (IA)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV +/- TVR or BOC (IIbA)</li> <li>Monotherapy (IIIA)</li> </ul>
<b>3</b>	<ul style="list-style-type: none"> <li>SOF + RBV x 24 weeks (IB)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV x 24 – 48 weeks (IIbA)</li> <li>Monotherapy (IIIA)</li> <li>Any regimen with TVR, BOC, SMV (IIIA)</li> </ul>	<ul style="list-style-type: none"> <li>SOF + RBV x 24 weeks (IIaA)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV +/- any protease inhibitor (IIbA)</li> <li>Monotherapy (IIIA)</li> </ul>
<b>4</b>	<ul style="list-style-type: none"> <li>IFN eligible: SOF + PEG/RBV x 12 weeks (IIaB)</li> <li>IFN ineligible: SOF + RBV x 24 weeks (IIbB)</li> <li>Alternative: SMV x 12 weeks + PEG/RBV x 24 – 48 weeks (IIbB)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV x 48 weeks (IIbA)</li> <li>Monotherapy with PEG, RBV, or a DAA (IIIA)</li> <li>Any regimen with TVR or BOC (IIIA)</li> </ul>	<ul style="list-style-type: none"> <li>SOF + PEG/RBV x 12 weeks (IIaC)</li> <li>Alternate: SOF + RBV x 24 weeks (IIaB)</li> </ul>	<ul style="list-style-type: none"> <li>PEG/RBV +/- TVR or BOC (IIbA)</li> <li>Monotherapy with PEG, RBV, or a DAA (IIIA)</li> </ul>

Key: PEG–Peginterferon, RBV–Ribavirin, IFN–Interferon, SOF–sofosobuvir, SMV–simeprevir, TVR–telaprevir, BOC–boceprevir  
 Level of evidence: Level A through C is the estimate of certainty (i.e., data derived from multiple clinical trials versus consensus opinion).  
 Class I to III is the size of treatment effect (i.e., benefit versus risk ratio).  
 \*\* Do NOT treat decompensated cirrhosis with PEG

In response to sofosbuvir coming into the market, the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (IAS-USA) updated the treatment guidelines in early 2014. The guideline recommendations for treatment of hepatitis C genotypes 1-4 are summarized in Table 1.

Sofosbuvir is such a blockbuster because it shortens treatment duration to 3-6 months from the 6-24 months recommended for other therapies, and the medication improves the sustained viral response (aka "cure" rate) to more than 90 percent, compared to 40 percent with previous regimens. Additionally, sofosbuvir opens the door to exclusively oral-based hepatitis C treatment regimens. With some foresight of the changes to come, Barney's LTC Pharmacy in Augusta, Ga., began preparing to meet the needs of hepatitis C patients for whom sofosbuvir is indicated in November and December of 2013. The benefits of treating these patients are worth the challenges related to overcoming any barriers.

Some payers have put sofosbuvir into the specialty prescription drug tier. There is no widely-accepted definition of what makes a drug a specialty pharmaceutical. Currently, payers (primarily pharmacy benefit managers [PBMs] and the Centers for Medicare & Medicaid Services [CMS]), set the definition of specialty therapeutics based on a pay scale and specific criteria. CMS considers any therapeutic agent costing more than \$600 per month to be a specialty item, while PBMs consider the specialty market to include medications that cost approximately double that amount. However, there appear to be common themes throughout most descriptions: specific storage considerations, need for adherence tracking, monitoring of therapy, limited distribution, and high cost of treatment. The workflow at Barney's Pharmacy has

been adjusted to help overcome these barriers to care.

### **POTENTIAL BARRIERS TO DISPENSING DRUGS IN THE SPECIALTY TIER**

#### **Storage Considerations**

Potentially unique storage requirements are another rationale for the medications put into specialty drug tiers. Fortunately, the "unique" storage requirements for select hepatitis C medications are minimal and only require storage in the refrigerator like insulin. In the Barney's Pharmacy workflow, peginterferon (used for treatment of hepatitis C) is treated the same as other refrigerated items, thus making the storage barrier nonexistent. Boceprevir and telaprevir (first generation protease inhibitors) should also be refrigerated, but with the inclusion of sofosbuvir in therapy, these medications are no longer recommended by the guidelines, and most pharmacies should not carry them.

*The pharmacy must navigate through potential cash flow issues related to dispensing a \$28,000 medication and waiting a month for payments.*

#### **Need For Adherence Tracking**

Medication adherence has been one of the biggest "hot" topics in health care for years. Approximately 42 percent of Americans have a chronic condition requiring medications. Sadly, adherence to treatment plans is only 50 percent in developed countries, including the United States. For years, community

pharmacists and NCPA have advocated for monitoring of medication adherence and systems to facilitate medication synchronization. Barney's Pharmacy has a medication synchronization program, but the clinical department utilizes a unique method.

All claims for specialty tier drugs are billed through a designated technician, which allows the pharmacy staff to generate weekly reports of dispensing. Using the information from the reports, the pharmacy team makes adherence calls to patients three to four weeks after they receive their prescriptions. The weekly reports enable the staff to refill medications proactively and also help patients be more adherent to their therapy. However, hepatitis C treatment is on a 28-day cycle, which is important to remember when synchronizing therapy.

Additionally, patients with hepatitis C are followed individually for placement in therapy. Whether a patient needs a prior authorization, is on his/her third refill, or awaiting a start date, all patients with hepatitis C are tracked and their status in therapy is reported weekly to physicians. This system allows the pharmacy team to prevent patients from falling through the cracks in care.

#### **Monitoring of Therapy**

Monitoring of therapy is a vital service. The Barney's Pharmacy workflow process allows for a pre-check of therapy appropriateness and a one-week follow-up for side effects. Utilizing Table 1, the Barney's Pharmacy clinical team verifies that the therapy for hepatitis C is following AASLD/IDSA guidelines. If a patient is genotype 1b, the Barney's Pharmacy clinical team verifies that the therapy for hepatitis C is following AASLD/IDSA guidelines. If a patient is genotype 1b, the clinical team ensures the patient is on the recommended triple therapy of peginterferon, ribavirin, and sofos-



buvir. If they are not, documentation for the contraindication is noted on the physical prescription and in the prescription processing system. Numerous times, the clinical team has been able to adjust a regimen to another therapy with more evidence to support the treatment.

Once the medications are dispensed, the clinical team provides a seven-day follow-up call to assess side effects of therapy. To drive counseling, the team depends on the prime questions: "What did your doctor tell you the medication is for?" "How did your doctor tell you to take this medication?" and "What did your doctor tell you to expect?" The pharmacy staff created a drug information resource that outlines mechanism, indication, concomitant therapy, administration

notes, monitoring parameters, and usual adverse drug reactions for each drug, allowing any pharmacist or pharmacist intern to effectively and consistently care for the patients.

#### **Limited Distribution**

One aspect that is difficult to overcome within current rules and regulations is limited distribution. The limited distribution concept is not singular to hepatitis C therapy, or even specialty medications. Nuclear pharmacy could be considered a specialty pharmaceutical specialty pharmacy as defined by limited distribution. However, limited distribution in "specialty pharmacy" is essentially saying some pharmacists (and pharmacies) may be more qualified than others. The concept of limited distribution assumes that for the

high-cost medications, where storage and adherence are vital components to care, the designated pharmacy or pharmacies are better equipped than a community pharmacy to provide high-touch services. Additionally, the manufacturers of certain medications often require transmission of clinical patient data to ensure patient safety. Therefore, medications are allocated to the select pharmacies who will execute this service. Most community pharmacists have the ability to provide this data, if simply given the chance.

The largest disservice associated with limited distribution is when insurance dictates that a patient be on mail order for months two and three of therapy, but not month one. The forced switch of pharmacies potentially precipitates adverse outcomes. If a pharmacy is

not proactively filling prescriptions, the transition to mail order could cause a gap in therapy, thereby increasing the chance of treatment failure. Often, the pharmacy, providers, and patients are unaware of this change. For example, a retired teacher requested a timely refill of her medication, but the patient's local copay was \$29,000 compared to zero via mail order. Unfortunately, the patient went without therapy for a few days until the mail order shipment arrived, despite complaints from the pharmacy, patient, and health care providers to the insurance company. The best way to overcome this barrier is for the community pharmacist to speak out about the poor quality of patient care associated with limited distribution. The Barney's Pharmacy clinical team routinely works with professional organizations to bring the voice of community pharmacy and patients to the forefront of health care reform.

### **Cost**

The cost of the medications to treat hepatitis C is high for all parties: patients, payers, and pharmacies. Barney's Pharmacy staff provides insurance navigation services so that patients can obtain the benefits of their plans to potentially minimize their out-of-pocket costs. This service includes investigating the insurance benefits (both medical and prescription), filling out prior authorization forms, and conveying the information to patients and providers.

Costs can be difficult on the payer as well; within the first quarter, sofosbuvir generated revenues of \$2.1 billion, 97 percent of which was covered by CMS. By driving evidence-based recommendations, the Barney's Pharmacy clinical team helps payers provide effective therapy at a justifiable cost.

Finally, the pharmacy must navigate through potential cash flow issues related to dispensing a \$28,000 medication and waiting a month for

payments and explanation of benefits. Fortunately, wholesalers may be willing to help independent pharmacies with these issues by extending payment terms to compensate for the reimbursement delay.

### **MARKETING**

The marketing of a service is not vital, though incredibly helpful, when a pharmacy starts to enter the market. The Barney's Pharmacy clinical team employed an external sales associate to drive business to the pharmacy and promote communication between the clinical team and hepatitis C providers and used the external sales associate to sell the service. Once the connection is made, the clinical team continues the relationship and customizes workflow to better fit each practice. The service and external sales associate are used to facilitate communication and ensure providers in the Augusta community are aware of the clinical services offered by Barney's Pharmacy.

### **RETURN ON INVESTMENT**

Even if a pharmacy fills only one hepatitis C regimen per 10 referrals, the market can still be profitable. Based on the experience of the clinical team at Barney's Pharmacy, once a workflow is established to handle specialty tier drugs, the hands-on time from referral to dispensing is typically one to two hours. This takes into account the days it may take to overcome insurance barriers. Paid claims for the approximate \$30,000 (\$28,000 for sofosbuvir, \$1,800 for peginterferon, and \$200 for ribavirin) one-month course of hepatitis C therapy yield an average 7 percent margin (specialty drug tier margins are ~ 5-10 percent compared to the normal 20-25 percent of retail claims), and this translates to about \$2,100 per month per patient.

Many community pharmacists are striving to enter the market to dispense specialty drugs without even knowing they are probably already offering many services third party payers require of specialty pharmacies. Utilization of the NCPA Simplify My Meds® program, storing insulin correctly, providing evidence-based recommendations, and counseling patients on injection techniques are all services that community pharmacists execute daily and which patients taking specialty tier drugs need. Sofosbuvir is just the tip of the iceberg in regard to the treatment of patients with hepatitis C. New agents are on the horizon, such as ledipasvir, ABT-450/r-ombitasvir, and dasabuvir. This advancement effectively makes the treatment of the hepatitis C virus similar to that of the human immunodeficiency virus, which is managed with oral-based therapies with outstanding clinical results. By helping one patient at a time, community pharmacists are poised to bring hepatitis C therapy mainstream. ■

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***Editor's Note:** For the list of references used in this article, please contact America's Pharmacist Managing Editor Chris Linville at 703-838-2680, or at [cbrs.linville@ncpanet.org](mailto:cbrs.linville@ncpanet.org).)*