As the market expands with approvals for the next generation of therapies in the rapidly changing landscape of hepatitis C treatment, it is valuable for us to share the current Walgreens Specialty Pharmacy experience—supporting patients, healthcare providers and payers alike, from before the first dose fill through post-treatment follow-up.

**Walgreens offers individualized treatment support to each patient, regardless of patient care touch points**

- Via direct to home
- >100 Walgreens hepatitis C-specialized pharmacies
- >8000 retail pharmacies nationwide

While we recognize that newer therapies will assist in relieving some of the treatment burden associated with past hepatitis C therapies, it is important to consider that even these novel therapies will not be free of potential challenges. Identification and prevention of drug-drug interactions and adverse events, management of chronic comorbidities and concomitant medications, and adherence will remain part of Walgreens holistic care for patients.

Regardless of the unique attributes of the newer therapies recently approved for hepatitis C virus (HCV), Walgreens Specialty Pharmacy programs and services will continue to focus on the heart of the equation—our patients.

**The cost burden**

Past assessments have shown that an estimated 3 million to 4 million people in the United States are chronically infected with HCV, and that up to 75% are unaware of their status. In 2007, the annual HCV-related mortality rate exceeded deaths from HIV/AIDS, with the HCV infection rate estimated to double all-cause mortality. Further, indirect costs of the disease accrue due to a loss of productivity when those infected can no longer work.

Razavi et al developed a model in 2011 to examine the costs associated with HCV disease progression (excluding the cost of antiviral treatment) in order to better prepare for the coming changes in HCV treatment. The analysis built upon previous models, while incorporating more variables, an increased number of age cohorts and recent healthcare cost data. While total healthcare costs associated with HCV were close to $6.5 billion in 2011, the model indicated that these costs are expected to peak at $9.1 billion in 2024, with the peak driven by advanced liver complications, such as compensated cirrhosis, decompensated cirrhosis and hepatocellular carcinoma (HCC).
A commitment to providers and patients

A retrospective study (from July 2010 through July 2011) performed by Walgreens of patients naive to HCV therapy showed that, whether at the central or retail pharmacy level, active involvement in a patient support program for a minimum of 90 days was a predictor of higher medication adherence to dual HCV therapy with interferon and ribavirin. This analysis showed that patients managed for at least 90 days in a specialty patient support program offered by Walgreens achieved significantly higher mean adherence rates per adjusted mean proportion of days covered.

Early on, Walgreens recognized the growing need for support within the HCV community and established a call to action by developing a specialty patient support program—the basis of the study reported above. This program officially became known as the Walgreens Connected CareSM hepatitis C program in 2011. Walgreens is proud of the program and the organization’s history of assisting patients and healthcare providers to manage complex treatment regimens and overcome barriers to access (such as connecting patients with financial assistance options for copays/coinsurance).

Walgreens Specialty Pharmacy delivers a continuum of convenient, individualized care geared to ease barriers to achieving sustained viral response by coordinating with the healthcare provider before, during and after treatment.

Walgreens Connected CareSM hepatitis C program services

Health plans and other payers are increasingly mandating that specialty pharmacies ensure the availability of consistent management services to their members. In the Walgreens Connected CareSM hepatitis C program, patient support has always been the primary focus, with a breadth of information, relationships with third-party patient assistance programs, and patient education to clarify complex treatment regimens and help patients navigate cost and coinsurance/insurance coverage concerns. The Walgreens Connected CareSM hepatitis C program offers proactive solutions to the barriers that may hinder medication adherence, with the ultimate goal of improving virologic outcomes.

In addressing barriers, Walgreens Specialty Pharmacy aims to efficiently coordinate with clinical practices by ensuring that Walgreens staff has expertise in billing and prior authorizations (PA) to help patients promptly initiate therapy. The Walgreens pharmacist facilitates the PA process and proactively helps to manage renewals and appeals. If a PA is declined, the pharmacist contacts the practice immediately to inform them of the denial and to obtain the information required to help the patient make an appeal.

* Drug information, including any applicable boxed warning, is available at http://dailymed.nlm.nih.gov/dailymed.
Walgreens Specialty Pharmacy also assists patients in need in accessing the support that financial assistance organizations provide for obtaining their medications. In 2013, patients across all disease categories, working with both central and local specialty pharmacies, secured more than $61 million in financial assistance.11

Walgreens has excellent access to limited-distribution drugs (LDDs), including many that may be needed for comorbidities associated with HCV. In special cases of LDD unavailability, Walgreens Specialty Pharmacy identifies LDD sources, and works with healthcare providers to obtain access. In addition to making certain that patients receive their needed medications, Walgreens also ensures that they receive the benefit of pharmacist-provided counseling and follow-up care/assistance on the rare occasion that an LDD needs to be obtained through these outside means.

Walgreens Connected CareSM hepatitis C program fosters high completion rates

From the time of initial prescription fill, a comprehensive HCV patient assessment facilitates drug monitoring and patient tracking. This allows Walgreens Specialty Pharmacy to coordinate care with the healthcare provider to deliver information regarding prescription fills and refills, medication adherence, possible drug-drug interactions and potential adverse events.

Through a one-on-one discussion between the patient and an HCV-trained pharmacist, Walgreens Specialty Pharmacy obtains a robust patient medical background, including past history, current comorbidities and concomitant medications, which is captured and uploaded into the pharmacy record. This information allows the pharmacist to help identify and alert the care team to potential barriers that could occur, whether the barriers are insurance/cost-based or compliance/adherence-based.

“I have been using specialty pharmacies for many years since the early days of interferon* for hepatitis C. With the new anti-HCV regimens, we are no longer dealing with as many side effects and adverse events as we did back then, but we still need specialized pharmacy services to assist providers on the front end with prior authorizations and the administrative burden. In addition, collaboration with specialty pharmacists to support patient adherence through treatment completion remains a valuable asset to patients and providers. Programs that support patients and providers, such as the Walgreens Connected CareSM hepatitis C program, will be very important in achieving optimal clinical outcomes.”

– Zobair M Younossi, MD, MPH, FACP, AGAF
Chairman, Department of Medicine, Inova Fairfax Hospital
Vice President for Research, Inova Health System
Professor of Medicine, VCU-Inova Campus
Walgreens Connected Care℠ hepatitis C program fosters high completion rates (continued)

The Walgreens Connected Care℠ hepatitis C program includes reporting on treatment completion rates. The completion rates were based on a review of each patient’s dispensing history and assessment data. These numbers were calculated by the total number of patients that completed therapy, divided by the number that completed therapy plus the number that discontinued therapy.

Data were collected and analyzed from Walgreens Specialty Pharmacy Central Distribution for the period of December 2013 through August 2014 on the direct-acting antiviral agents therapy status of 946 patients with HCV who underwent treatment with sofosbuvir (Sovaldi®).11*

Results show11:
- 5.4% overall treatment discontinuation rate (Figure 1)
- 1.3% (12 of 946) discontinuation rate specifically attributed to adverse effects

Only 0.5% (5 of 946) of patients voluntarily discontinued therapy—a result further attesting to the effectiveness of a total care approach in encouraging adherence (Table 1).11 Additional results that include analyses of discontinuation patterns by treatment regimen, patient demographics and history, patient coverage and other variables are being prepared for publication in the near future.

Table 1: Reasons for discontinuation of direct-acting antiviral therapy11

<table>
<thead>
<tr>
<th>Event</th>
<th>Number</th>
<th>% of discontinued</th>
<th>% of all patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse events</td>
<td>12</td>
<td>23.5</td>
<td>1.3</td>
</tr>
<tr>
<td>Insurance terminated</td>
<td>6</td>
<td>11.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Voluntary</td>
<td>5</td>
<td>9.8</td>
<td>0.5</td>
</tr>
<tr>
<td>New condition</td>
<td>2</td>
<td>3.9</td>
<td>0.2</td>
</tr>
<tr>
<td>PA denied</td>
<td>2</td>
<td>3.9</td>
<td>0.2</td>
</tr>
<tr>
<td>Failed therapy</td>
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<td>2.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Financial issues</td>
<td>1</td>
<td>2.0</td>
<td>0.1</td>
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<tr>
<td>Unknown</td>
<td>22</td>
<td>43.1</td>
<td>2.3</td>
</tr>
<tr>
<td>Total†</td>
<td>51</td>
<td>100</td>
<td>5.4</td>
</tr>
</tbody>
</table>

* Drug information, including any applicable boxed warning, is available at http://dailymed.nlm.nih.gov/dailymed.
† Due to rounding, numbers may not add up to total.
Walgreens proactive commitment

As newer agents used to treat HCV emerge from the clinical development pipeline, Walgreens Specialty Pharmacy will introduce an updated patient assessment tool as part of our comprehensive and unique Walgreens Connected CareSM hepatitis C program. This consistent and time-sensitive method of documenting clinical data will include the ability to flag trends in adverse events, providing a more detailed historical use of HCV therapy by the patient, and add other functionalities intended to prompt additional physician inquiry.

In this treatment progression, Walgreens Specialty Pharmacy programs and services will continue to take a longitudinal approach to patient care, promptly respond to changes in treatment guidelines, integrate new therapies as they become available and maintain our proactive commitment to helping improve health outcomes for all patients. (Figure 2 shows a recently approved and a few new unapproved HCV products in the pipeline, with anticipated timing for FDA approval based on PDUFA reporting.)

These continued efforts will allow Walgreens Specialty Pharmacy to deliver upon our commitment to and collaboration with payers, healthcare providers, and patients to provide clinically appropriate, cost-effective care.

Figure 2: HCV specialty product pipeline

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BLA, Biologic License Application; FDC, fixed-dose combination; NDA, New Drug Application.
* This report is not intended for use by patients.
† Walgreens PDUFA Tracking Program is currently pending patent review and approval.
‡ Drug information, including any applicable boxed warning, is available at http://dailymed.nlm.nih.gov/dailymed.
References


