Hepatitis C – The Changing Landscape in Treatment Options

Advances in the treatment of Hepatitis C including a shift in therapy from injection to oral medications have led to changes in the treatment landscape of the disease. How this impacts plan sponsors is explained below.

What is Hepatitis C?
Hepatitis C is a liver disease caused by the Hepatitis C Virus (HCV). This virus may be acquired through illicit drug use, blood transfusions, tattooing, and/or needle-stick injuries. Once acquired, HCV can cause both acute and chronic hepatitis infections. Approximately 25% to 35% of patients have an acute episode and clear the virus from their body naturally within a few months. Of those who do not naturally clear the virus from their body (65-75%) progress to the chronic phase – Chronic Hepatitis C (CHC) which could potentially lead to cirrhosis or cancer. At present there is no vaccine for HCV.

Hepatitis C Demographics
The majority of infected people do not know they have the virus because, there will either be no symptom or symptoms may be latent and not show for decades. During this time, HCV can spread to others via blood contact. In Canada, an estimated 242,500 individuals are infected with HCV. Approximately 21% of these individuals do not know they are infected and remain undiagnosed.

Hepatitis C Genotype and Treatment Options
The goal of CHC therapy is to eliminate the infection thereby preventing liver cirrhosis and liver cancer which can lead to death. As part of the treatment course, it is critical that genotyping of HCV be done because different variations of the virus warrant different treatment. To date, six HCV genotypes have been identified. The most common of all in Canada is genotype 1, followed by genotypes 2 and 3. Genotype 1 represents 60-65% of patients, genotype 2 represents 14% and genotype 3 represents 20%. Since the vast majority of patients have genotype 1, the focus of new treatment advances has been geared towards that population.

In the past, standard therapy for HCV genotype 1 involved the use of Peg-Interferon’s (i.e. Pegasys or Pegetron – subcutaneous injections) as baseline therapy plus oral protease inhibitors (PI – e.g. Victrelis). However, the compliance rate for these therapies was low, mainly due to side effects experienced by patients. Lack of compliance means many patients do not complete the treatment duration of 48 weeks which is necessary to achieve optimal results and obtain viral clearance.

New oral only treatment options (i.e. Harvoni or Holkira) are now available and are becoming the preferred method of treatment. The advantage of these new oral regimens is that they carry the promise of easier dosing, shorter lengths of therapy, better tolerability, increased patient compliance and improved efficacy (97% vs 70%). High response rates means a significant decrease in the need to re-treat and as new oral therapies are considered “cures”, they have drastically changed the treatment landscape of CHC.

Currently Available Treatment:

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>Supply</th>
<th>Duration of Standard Treatment</th>
<th>Cost of Treatment</th>
<th>Cure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vicirelis (tab) Peg-Interferon (Inj) RBV (tab)</td>
<td>3 separate drugs including 1 injection</td>
<td>48 weeks</td>
<td>$70,000</td>
<td>70%</td>
</tr>
<tr>
<td>Sovaldi (tab) Peg-Interferon (Inj) RBV (tab)</td>
<td>3 separate drugs including 1 injection</td>
<td>12 weeks</td>
<td>$64,000</td>
<td>91%</td>
</tr>
<tr>
<td>Harvoni (tab)</td>
<td>Combination of 2 drugs in one tablet</td>
<td>12 weeks</td>
<td>$72,000</td>
<td>97%</td>
</tr>
<tr>
<td>Holkira PAK (tab)</td>
<td>4 oral tablets</td>
<td>12 weeks</td>
<td>$56,000</td>
<td>97%</td>
</tr>
</tbody>
</table>

* Based on the Financial Impact Analysis per 100,000 lives covered
Cost Impact of New Hepatitis C Oral Treatment Options on Private Plans

Treatment cost is comparable between the old and new treatment regimen; however, for traditional treatment regimens i.e. Victrelis and Peg-Interferon, the amount needed for an entire treatment course is spread over 48 weeks whereas for oral regimens, it is only 12 weeks. As a result, it is likely private plans will experience greater impact within a short period of time with new oral therapies than with older options.

The launch of new oral CHC therapies has caused an impact on drug claims experience as there has been an increase in the number of CHC patients requesting treatment. From 2013 to 2014, there was a 50% increase in Special Authorization requests for CHC medications and we anticipate this increase may continue in the future. In the near future, advances in the treatment of CHC genotype 1 will extend to other genotypes – with an increased availability of oral therapies with high cure rates.

Protect your Plan

At ClaimSecure Inc., Special Authorization is in place for plan sponsors and members who have subscribed to Managed Formulary, Specialty Drug, and/or Stop Loss Programs to ensure appropriate, cost-effective use of these high cost drugs, and at the same time coordination with available provincial and manufacturer drug programs. These new oral CHC therapies (e.g Sovaldi, Harvoni and Holkira Pak) have been added to the ClaimSecure Special Authorization Drug listing for ClaimSecure clients that subscribe to the Managed Formulary, Specialty Drug, and/or Stop Loss Programs.

For ClaimSecure groups with an open drug formulary that do NOT have Special Authorization service in place, Harvoni and Holkira are fully covered without restriction; as with any other anti-viral medications. If you wish to better manage the access and costs for new biologics and high cost therapies, which includes the Hepatitis C drugs, please contact your Account Manager directly.

If you require additional information about treatment for Hepatitis C, please contact the Clinical Services Department, at (905)-949-3014 or 1-888-479-7587 ext. 3014.

ClaimSecure reserves the right to amend in part or in its entirety stated special authorization clinical guidelines