Feds to Medicaid: Stop HCV Treatment Restrictions

On November 05, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a notice advising states on the rules regarding coverage of prescription drugs to Medicaid beneficiaries. The letter was intended to address all of the restrictions that most states have placed on access to hepatitis C medications.

This comes on the heels of the recently updated guidelines issued by the Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) that “treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies…..”

Medicaid is a government program that provides health insurance to low-income people. Medicaid can negotiate drug discounts from pharmaceutical companies for the medications—of at least 23.1%.

CMS sent letters to Gilead, AbbVie, Johnson & Johnson (Janssen), and Merck asking for ideas that could help the states reduce the costs of the current drugs and the ones that will be approved next year. The costs of the current HCV drugs have strained the state healthcare budgets.

This will have many implications as every state will have to comply with the directive from CMS. At the same time, the states will struggle to stay within their health budgets. The big question is will the pharmaceutical companies negotiate to keep the state’s financially solvent?

Importantly, patients should contact their medical providers to find out if they can reapply for treatment coverage. This will eventually affect how insurance companies cover HCV treatment since the government is investigating drug pricing.

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Gilead Applies for FDA Approval

—By Alan Franciscus

On September 21, 2015 Gilead submitted their Phase 3 data of a once-daily combination of sofosbuvir (polymerase inhibitor) and velpatasvir (NS5A inhibitor) with and without ribavirin to treat genotype 1 through 6 patients to the Food and Drug Administration (FDA) for marketing approval. Patients with decompensated cirrhosis were treated with sofosbuvir plus velpatasvir and ribavirin. The treatment duration was 12 or 24 weeks. The FDA has designated the combination as Breakthrough Therapy. The designation will speed up the drug approval process. This combination will be approved in 2016.

The Phase 3 clinical trials—ASTRAL-1, ASTRAL-2, and ASTRAL-3. There were 1,035 of whom 116 patients received placebo (sugar pills). There were 267 people in the ASTRAL-4 trial—this trial included the patients with genotypes 1 through 6 with decompensated cirrhosis. There was not a breakdown by genotype. The breakdown is listed below.

ASTRAL-1 Trial included 121 (19%) patients – with cirrhosis: The overall cure rates were 99% (618 of 624 pts) – all patients received sofosbuvir plus velpatasvir

<table>
<thead>
<tr>
<th>Genotype 1</th>
<th>Genotype 2</th>
<th>Genotype 4</th>
<th>Genotype 5</th>
<th>Genotype 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>98% cured</td>
<td>100% cured</td>
<td>100% cured</td>
<td>97% cured</td>
<td>100% cured</td>
</tr>
<tr>
<td>(323 of 328 pts)</td>
<td>(104 of 104 pts)</td>
<td>(116 of 116 pts)</td>
<td>(34 of 35 pts)</td>
<td>(41 of 41 pts)</td>
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ASTRAL-2 Trial included 266 genotype 2 patients – (14%) with cirrhosis:

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<tbody>
<tr>
<td>Sofosbuvir plus velpatasvir – 12 weeks</td>
<td>99% cured (133 of 134 pts)</td>
</tr>
<tr>
<td>Sofosbuvir plus ribavirin – 12 weeks</td>
<td>94% cured (124 of 132 pts)</td>
</tr>
</tbody>
</table>

ASTRAL-3 Trial included 552 genotype 3 patients – 30% with cirrhosis:

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<tr>
<td>Sofosbuvir plus velpatasvir – 12 weeks</td>
<td>95% cured (264 of 277 pts)</td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir plus ribavirin – 24 weeks</td>
<td>80% cured (221 of 275 pts)</td>
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ASTRAL – 4 Trial included 267 genotype 1 through 6 patients with decompensated cirrhotic patients (Child-Pugh class B) patients.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>SVR12 (pts)</th>
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<tbody>
<tr>
<td>Sofosbuvir plus velpatasvir – 12 weeks</td>
<td>83% (75 of 90 pts)</td>
</tr>
<tr>
<td>Sofosbuvir/velpatasvir plus ribavirin – 12 weeks</td>
<td>94% (82 of 87 pts)</td>
</tr>
<tr>
<td>Sofosbuvir plus velpatasvir – 24 weeks</td>
<td>86% (77 of 90 pts)</td>
</tr>
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The most common side effects were headache, fatigue and nausea. Thirty-one percent of patients in the arms that contained ribavirin experienced anemia. Anemia was also reported in 3% of the patients in the arms that contained sofosbuvir and velpatasvir, but not ribavirin. According to the press release, the majority of the serious side effects (18%) and deaths (9) were associated in people with advanced liver disease.

Note: There was no information given about prior treatment experience in the genotype 3 patients with cirrhosis—people with hepatitis that are in need of better treatment options. This information will be given at The Liver Conference.

Social Security and Medicare Changes for 2016

By Jacques Chambers

Each year Social Security revises its numbers and those of Medicare to reflect inflationary trends in the past year. Due to very low inflation this past year thanks primarily to lower gasoline prices, there will be NO Cost of Living Allowance (COLA) change for persons currently receiving Social Security benefits. They will continue to receive the same amount as they did in 2015. Other amounts, however, will change.

Trust Fund Reallocation

As in past years, your payroll taxes that are deducted for Social Security and Medicare will remain at 7.65% each for employees and employers and 15.30% for self-employed individuals.

That money has been split with most of it going into the Retirement Trust Fund to pay retiree benefits and the Disability Trust Fund to pay Disability (SSDI) benefits. However, because medical costs have risen so much faster than general inflation, the amount allocated to the Disability Trust Fund has not been enough to maintain the disability benefits. In fact the Fund is in danger of being emptied completely.

This column reported last spring that, due to this disparity, Disability benefits would have to be cut by almost 20% beginning around December, 2016, unless Congress makes changes.
Social Security and Medicare Changes for 2016 — CONTINUED FROM PAGE 3

This column is now happy to report that the recent budget passed by Congress and signed into law by the President does fix that reallocation problem, so that a greater portion of payroll taxes (F.I.C.A.) will be directed to the Disability Trust Fund than before. Therefore, Disability benefits will continue to be paid at the same level as in the past, and with the new reallocation, it will continue to be able to do so for the foreseeable future.

For Individuals Still Working
The taxable limit on earnings for contributions to Retirement, Survivors, and Disability (OASDI) per individual remains at $118,000. There continues to be no maximum limit on earnings for Medicare withholding.

Social Security Benefits
Although the benefits will not increase next year, a few of the other numbers that Social Security uses will change.

Supplemental Security Income (SSI) – This monthly income benefit paid by the federal government to low income individuals age 65 and older as well as disabled persons under 65 will remain at $733 per month for a single person and $1,100 per month for a couple. Some states supplement that federal amount, but it is not anticipated that many, if any, will increase their portion either.

The Resources or Asset Limit remains at $2,000 for an individual or $3,000 for a couple.

• Working Disabled Individuals – For persons who are collecting Disability Benefits (SSDI) and attempting to work, it will now take $810 in countable earnings in a month for that month to be considered a Trial Work Month. There are nine Trial Work Months during which a disability beneficiary can earn an unlimited amount of earnings and not have it affect their benefits.

• Substantial Gainful Activity (SGA) – The monthly SGA for 2016 is $1,130 for a non-blind individual and $1,820 for a blind individual. Disability (SSDI) benefits will continue after the Trial Work Months are exhausted if the countable earnings remain below the SGA.

• Working on Supplemental Security Income (SSI) – This calculation has not changed. SSI does not count the first $65 of countable monthly earnings ($85 if SSI is the only source of income). After that, they will reduce the SSI benefit $1 for every $2 of earnings.

• Students Collecting SSI – Students collecting SSI benefits have a different limit that allows them to earn more money during school breaks. That amount has not changed from 2015 and remains at $1,780 per month and no more than $7,180 in any one year.

Changes to Medicare
There are important changes to the Medicare premiums for 2016 due to a quirk in federal law. Federal law prohibits Medicare from increasing the Part B Medicare premium, which is currently $104.90, if there is no Cost of Living Increase, as is the case for 2016. However, that prohibition only applies to persons paying the Part B premium through deduction from their Social Security benefit. It does not apply to Part B premiums paid in another manner.

Disability benefits will continue to be paid at the same level as in the past, and with the new reallocation, it will continue to be able to do so for the foreseeable future.
To keep Part B premiums in line with expected Part B claims, they would have had to raise everyone else’s Part B premium, including people newly eligible for Medicare after 2016 to about $223 per month.

The new federal budget corrects this dramatic shift as well, through advancing money from the General Fund to cover the shortage. To summarize the Medicare Part B premiums:

- $104.90 will continue to be deducted from the monthly Social Security benefits of people currently receiving Medicare and paying through deduction from their benefits;
- $120 will be charged each month to persons who are either directly paying the premiums, persons who become eligible for Medicare after January 1, 2016, and persons whose Part B premiums are paid by a third party such as Medicaid; and,
- Medicare beneficiaries with high incomes ($85,000 single, $170,000 joint or higher) will continue to pay a surcharge on their Part B premiums.

For Medicare Part D, Prescription Drug Coverage for 2016, the annual deductible cannot exceed $360. Also, during the Coverage Gap (aka Donut Hole) the manufacturers and drug plans will continue to pay a ever higher share of the drug costs, moving towards the year 2020 when the Coverage Gap will be eliminated completely.

Also, the eligibility for Part D’s Low Income Subsidy (also called Extra Help) is tied to the Federal Poverty Level (FPL). The FPL for 2016 will not be released until the first quarter of 2016.

As of early November, Medicare has not yet published any changes to their hospital or medical deductibles. One trustee of the plans believes that the Medicare Part B (Medical) annual deductible may have a substantial jump from 2015’s $147 per year to over $200, but that is only an estimate. Hopefully, those numbers will be published shortly. You may want to periodically check at www.medicare.gov and search for “2016 Medicare Changes”).

Even though the actual numbers of some portions of Medicare are not yet available, overall the news for persons collecting Social Security benefits now is good in that the Medicare Part B premium will not increase for most of them. Also, for individuals collecting Social Security Disability, the fear of seeing their benefits drop by 20% in late 2016 is gone thanks to the restructuring of the Disability Trust Fund.
Three Weeks to Cure!
There was a news story on October 30, 2015, about a study that will be presented at the upcoming Liver Conference this month in San Francisco, CA about curing hepatitis C in as little as three weeks! It sounds too good to be true, but, in this case, it just might be true. The study included 18 genotype 1b patients treated with a combination of drugs—everyone received sofosbuvir (HCV polymerase) as the backbone of therapy. Sofosbuvir was either combined with ledipasvir or daclatasvir—both NS5A Inhibitors. The third drug was either simeprevir or asunaprevir—both protease inhibitors. The result is that you are inhibiting the virus at multiple viral entry sites. Also, the patients enrolled in the study had the lowest viral loads. Originally 26 patients were enrolled in the study. After two weeks, those patients who had the steepest decline in viral load—HCV RNA—were allowed to stay in the 3-week trial. The others were treated for 12 weeks. Taken together this was actually a response-guided therapy trial on steroids. Still, it is pretty impressive, and all 18 patients achieved a cure.

More studies are needed to understand if this approach can be used in a larger population of people with hepatitis C. There are also questions regarding this approach about harder to treat genotypes such as genotype 3 and genotype 1a.

As far-fetched as a 3-week treatment to cure sounds I believe this will come to pass. Soon many drugs will be available to pick and choose from to create a drug cocktail to treat patients based on a patient’s characteristics. The only roadblock will be the business practice by some pharmaceutical companies that combines two drugs into one pill.

Source: Article: Study suggests unprecedented 3-week hepatitis C cure.

Viekira Pak and Technivie: Safety Warning
On October 22, 2015, The Food and Drug Administration (FDA) issued a warning on Viekira Pak and Technivie that “can cause serious liver injury mostly in patients with underlying advanced liver disease.” The liver injury occurred within 1 to 4 weeks of starting therapy. As a result, the package prescribing label has been updated for Viekira Pak and Technivie. We have posted the updated labels on our website: Technivie - Viekira Pak.

Just to be clear—the warning was for people who had had underlying advanced liver disease, and the liver injury happened after starting treatment within the first week through the 4th week. The best thing to do if you have concerns about your treatment – talk with your medical provider.

Source: FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie.

Achillion/Janssen – Starts New Trial
On October 16, 2015, Achillion and Janssen announced the initiation of a Phase 2a clinical trial of AL-335, odalasvir (formerly ACH-3102) and simeprevir to treat HCV genotype 1a/b. There will be three treatment arms with three treatment durations—four, six or eight weeks. Sixty treatment-naive patients will be enrolled. This study is not yet enrolling.

Bananas!

It is probably not a big surprise that many drugs have originated from common herbs or other sources. However, at first glance the headlines “Scientists ‘go bananas’ for a new application of fruit protein as a method for treating viruses” made me think it was a joke. However, it was not a joke! The reality—scientists have been able to extract a substance found in bananas—banana lectin or BanLec—that can read the sugars on the surface of cells and viruses. The scientists were able to adjust Banlec to work against certain viruses such as HIV, hepatitis C and influenza. The scientist used a certain type of the BanLec to protect mice from getting a certain type of the flu. This could be a VERY, VERY, BIG discovery.

Source: Article: Scientists ‘go bananas’ for new application of fruit protein as a method for treating viruses.

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**SNAPSHOTS**

---Alan Franciscus, Editor-in-Chief

**Article: Chronic hepatitis C virus infection is associated with increased risk of preterm birth: a meta-analysis of observational studies**—Q Huang et al.


**Results and Conclusions**
The authors of the study conducted a meta-analysis (combining previous studies) on the relationship between chronic hepatitis C infection and premature birth. The authors reviewed electronic records of nine studies of 4,186,698 people of whom 5,218 were pregnant women with HCV. After controlling for alcohol use, smoking, drug use, and women coinfected with HBV or HIV it was found that women with HCV had a high risk for preterm birth.

**The Bottom Line**
HCV-positive women who are pregnant are at high risk for pre-term birth even after controlling for the above-listed co-factors.

**Editorial Comment**
What I was not able to discern from the abstract was the level of pre-natal care the HCV-positive women received. There are some studies currently being conducted across the U.S. on HCV-positive women who are pregnant that may shed more light on this issue and some emerging issues on HCV, pregnancy, childbirth and HCV in children.
Statins are a class of drugs often prescribed by doctors to help lower cholesterol levels in the blood. By lowering the levels, they help prevent heart attacks and stroke. Studies show that, in certain people, statins reduce the risk of heart attack, stroke, and even death from heart disease by about 25% to 35%. Statins are known to have side effects such as fatigue, muscle pain, cramps, nausea, gas, diarrhea, and constipation. For some people, cholesterol levels can be managed with diet and exercise. For those with inherited high cholesterol or who can not control it with diet and exercise, cholesterol medication(s) have to be taken for life.

**Results and Conclusions**
This was a study conducted in Taiwan on 226,856 people with chronic hepatitis C infection who were followed from 1997 to 2010. The aim was to identify the risk of cirrhosis among those who took statins. A total of 34,273 cases of cirrhosis were identified among the group. It was found that statin use was safe and reduced the risk of the development to cirrhosis.

**The Bottom Line**
There was some concern in the past that statin use in people with chronic hepatitis C might be harmful. This study and many previous studies have debunked this concern. In fact, studies including this one have shown that statin use can reduce the risk of progression to cirrhosis.

**Editorial Comment**
Every medication can have side effects and statins are known to have some side effects as listed in the side bar. If we can treat people with hepatitis C and cure them, we would not even have to talk about this.

*A new cholesterol drug was recently approved that costs $14,000/year. It does not cure high cholesterol. Hepatitis C can be cured, and it can cure up to 90% of people who are treated. Something for us all to chew on!*

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**THE 5 FIVE**

The Five: Pan-Genotypic Drugs

*In this month’s The Five I will discuss pan-genotypic drugs. I will begin with a brief discussion of hepatitis C (HCV) genotypes, a definition of pan-genotypic drugs, why they have emerged as an important part of treatment, what pan-genotypic drugs are approved and ones in the pipeline to treat HCV.*

1. **Genotypes** — there are seven genotypes—numbered 1 through 7—although some experts believe there may be as many as 11 genotypes. The difference in the genotypes is due to a 1/3 difference in the genetic makeup of the HCV virus.

The most common genotype worldwide and in the United States is genotype 1. Genotype 3 is the second most common in the U.S. followed by genotype 2. Genotype 4, 5 and 6 accounts for less than 1% of
HCV the U.S. population. There have been only four people identified with genotype 7—one person—an immigrant in Canada from the Democratic Republic of the Congo and three other people who live in the Democratic Republic of the Congo.

2. Pan-genotype Drugs – these are drugs that work against every genotype. The drugs may not have the same amount of antiviral activity against every genotype. For instance, one pan-genotypic drug may have a high rate of antiviral activity against genotype 1, but have a low level of antiviral activity against genotype 3. There will need to be clinical trials conducted to find out how well a particular drug works on every genotype. Most likely there will be a combination of different types of HCV inhibitors combined with the pan-genotypic drugs and different treatment durations because of the different levels of antiviral activities of the drugs.

3. The Future – Pan-genotypic drugs are the next leap forward in the treatment of hepatitis C. This is for many reasons. As stated above they can be combined with other drugs to treat many different genotypes. We know that some people have multiple genotypes. This is an area that needs much more research, but it is believed that about 5% to 25% of people have multiple genotypes. This can happen if people received blood transfusions before the blood products and organ transplants were screened for hepatitis C, and in people who inject drugs who share needles and works, and have multiple exposures. Treating hepatitis C with pan-genotypic drugs will treat these multiple genotypes.

4. Current Pan-genotypic Drugs – Sofosbuvir and daclatsavir are examples of current drugs that are FDA approved that are in fact pan-genotypic drugs. While they are active against all genotypes, they work better against some genotypes more than others. That is the main reason they are combined with other direct acting antiviral drugs.

5. Pan-genotypic Pipeline – There are currently two combinations that are under review by the Food and Drug Administration for marketing approval. The combination of sofosbuvir plus velpatasvir—formerly GS-5816 (with and without ribavirin) has cure rates from 80% to 100% in genotypes 1 to 6 (see the article on page 2). Merck’s combination of grazoprevir plus elbasvir is expected to be approved in January 2016 to treat genotypes 1, 4 and 6 – the cure rates from the phase 3 clinical trials were 92% to 99%.

There are many pan-genotypic drugs in development. Janssen, Achillion, and Johnson and Johnson are collaborating on various drug combinations that include pan-genotypic drugs. AbbVie and Enanta are also developing a combination of two drugs (including a pan-genotypic drug) to treat hepatitis C.

The future of hepatitis C has never been more promising in HCV drug development. The only dark cloud is the price and subsequent access to treatment. Hopefully, as more drugs become available, the prices will come down so that everyone will have access.
Check out our newly revamped Blogs!

Check out our newly redesigned HCV Blog, HBV Blog and our Hepatitis & Tattoos Blog – same blogs—with all of the latest news.

Hepatitis C Blog

Welcome to HBV Advocate’s blog where you’ll find the latest news about hepatitis B. Please submit questions and post comments.

Hepatitis B Blog

The Official Blog of the Hepatitis and Tattoos Website
Part of the Hepatitis C Support Project and the HCV Advocate

Hepatitis Tattoo Blog

Please Note: In the transition from our old website to our new website there was a glitch in the blog daily digest. It has now been fixed. However, the people who signed up on the old website you will have to re-enter your information. The daily digest is a great way to stay informed on all the information that pertains to either hepatitis C, hepatitis B or tattoos in one daily email. Sorry for any inconvenience.

Hepatitis C Training Workshop Schedule

DECEMBER

Houston, TX . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . December 3, 2015
Tyler, TX . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . December 4, 2015

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