Happy July 4th! With a true national spirit of courage, integrity, sacrifice, liberty and independence, we wish you and your family a happy, safe 4th of July. We encourage you to plan events and activities using information provided in our July newsletter to create hepatitis awareness and prevention in your communities.

Our newsletter provides current information about viral hepatitis, opportunities for viral hepatitis continuing professional education and information about educational materials available. See all the exciting things happening here in the Kentucky Adult Viral Hepatitis Prevention Program in this issue of KY Hepatitis Connections.

Please feel free to forward and/or copy and distribute to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral hepatitis and its impact on our families throughout the Commonwealth. Follow us on Facebook at: KY Viral Hepatitis.

Kathy Sanders, RN MSN
REMINDER: It’s Not Too Late to Register

Kentucky Rural Health Association, in partnership with Kentucky Department for Public Health’s Adult Viral Hepatitis Prevention Program and Kentucky Immunization Program, is proud to present

Hepatitis: The Silent Epidemic in Kentucky

Hyatt Regency
401 West High Street, Lexington, KY 40507
July 24, 2014

FREE: All day training: Registration begins at 7:30

CMEs and CEUs will be offered

Target Audience: Family Medicine physicians, Internal Medicine physicians, Pediatricians, Infectious Disease physicians, Nurses, Nurse Practitioners, Physicians Assistants, Infection Preventionists, Employee Health staff, Local Health Department medical providers, Local Health Department Nurses, Regional Epidemiologists, and other health professionals involved in the screening, diagnosis, treatment, management, prevention, and control of hepatitis.

For additional information: Contact Julie Miracle at Julie.Miracle@ky.gov or Kathy Sanders at KathyJ.Sanders@ky.gov

Limited Space: REGISTRATION IS STILL OPEN!
https://ky.train.org
Course #1050937
No on-site registration
Reminder:

Hepatitis C: Perinatal and Children Aged Five Years or Less

The Kentucky Department for Public Health (KDPH) is requesting your ongoing assistance to report pregnant women and children aged five years and less who are infected with hepatitis C virus (HCV), and seen in birthing hospitals, medical practices, and clinics throughout the Commonwealth.

Please complete the reporting form at the end of this newsletter and fax to the Kentucky Department for Public Health at: 502-564-4760 to continue to report any HCV-positive individuals in the above categories.

If you have additional questions or concerns, please call Kathy Sanders, RN, MSN at 502-564-3261, ext. 4236 or Julie Miracle, RN, BSN at 502-564-4478, ext. 4260.

Vertical transmission primary source of HCV infection in children

More than one in 20 children delivered by women with chronic hepatitis C virus infection become infected themselves, suggesting that vertical transmission is the most common transmission route of the disease among children, according to the results of a recent meta-analysis.

“Following the implementation of blood and blood product screening, vertical transmission has gained importance as the primary HCV transmission route among children,” researchers wrote in Clinical Infectious Diseases. “Assessment of the burden of vertical transmission is essential in countries with high HCV prevalence, such as Egypt.”

A total of 109 studies published in the past decade were included in the analysis to provide an updated global estimate of the proportion of infants who contract HCV through vertical transmission.

Results indicated that HIV coinfection played a significant role in the risk for vertical transmission of HCV. For example, among children of HCV-antibody positive and RNA-positive mothers, the risk for vertical transmission of HCV was 5.8% (95% CI, 4.2-7.8) for children born to HIV-negative mothers and 10.8% (95% CI, 7.6-15.2) for children born to HIV-positive mothers.

In adjusted analyses, maternal HIV coinfection status was the most important determinant of acquiring HCV through vertical transmission (adjusted OR=2.56; 95% CI, 1.5-4.43).

“Additional risk factors warrant further examination in primary research, namely maternal HIV treatment and HCV genotype,” the researchers wrote. “Such research would contribute to quantifying the contribution of HCV vertical transmission to HCV incidence in high-burden countries and in high-risk populations globally.”

Hepatitis C Transmits Sexually in HIV-Positive Gay Men

A New York physician begins noticing a troubling pattern of what appears to be sexual transmission of a rapidly harmful virus among men who have sex with men (MSM). The doctor’s preliminary search for more information leads him to other physicians and scientists in the United States and abroad who have also started recognizing the pattern. He runs into skepticism along the way. Before long, it’s clear that a new, troubling route of disease transmission has emerged.

No, this isn’t a history piece about the early days of the AIDS crisis, it’s an article about the present day. Since around the turn of the 21st century, increasing evidence of a new epidemic in the gay community has surfaced: HIV-positive MSM are acquiring hepatitis C virus (HCV) sexually, and at alarming rates.

The physician in question is Daniel Fierer, MD, an infectious disease specialist at Mount Sinai in New York City, who, since first observing this epidemiological trend in 2005, has gone on to become one of the nation’s few experts on sexually transmitted hep C in the HIV-positive MSM population. These days he is frustrated to see himself as something of a Cassandra: sounding the alarm and challenging the assumption that sexual transmission of hep C is rare while others in his field may cling to the traditional risk factor orthodoxy that puts contaminated needles front and center.

Read More:  http://www.hepmag.com/articles/sexual_transmission_HCV_2502_25673.shtml

The Power to Cure, Multiplied

Ten years ago Dr. Sanjeev Arora, a hepatologist at the University of New Mexico in Albuquerque, realized that he would need to change the way he practiced medicine if he was going to prevent his patients from dying.

Under the Affordable Care Act, 32 million Americans are expected to gain coverage. How will they be cared for? Today, the solution he developed could transform health care. Arora had been specializing since 1990 on the treatment of chronic hepatitis C, a disease that affects 3 million Americans (and 170 million people around the world). Most Americans don’t know they’re infected, which is one reason why it remains the leading cause of cirrhosis and liver cancer, resulting in 15,000 deaths each year in the United States and 350,000 deaths globally.

In 1990, when drugs started emerging to treat the disease, the cure rate was just 6 percent. By 2003, however, the cure rate had climbed to 45 percent for some patients, and 70 percent for others (depending on their genotypes). “It had become a curable disease,” Arora recalled. (New medications have further improved the efficacy, safety and ease of treatment for hepatitis C, but high costs remain a barrier.)

The few specialists in New Mexico who treated it were in urban centers, and most patients went without treatment. Those who sought help had to wait six to eight months to get an appointment in a clinic. Many could not afford to drive hundreds of miles to Albuquerque, let alone make an average of 12 to 18 trips to complete a course of treatment

http://opinionator.blogs.nytimes.com/2014/06/11/the-doctor-will-stream-to-you-now/?_php=true&_type=blogs&_php=true&_type=blogs&_r=1&
The strides of freedom and courage, shall be remembered today … and every day. Happy July 4th!

**Hepatitis Website: Referral Guide**

The KY Department for Public Health Adult Viral Hepatitis Prevention and Control Program is in the process of updating our Website. We are adding a referral guide for individuals who have most recently been diagnosed with HCV. If your organization will evaluate and treat individuals diagnosed with HCV and you want your name added to our Referral Guide, please email your organizations name, address, phone number, and contact person to kathyj.sanders@ky.gov.

**HEPATITIS WEBINARS:**

![AIDS Institute Logo]

The AIDS Institute Announces Speakers and Invites you to Participate in our Upcoming Viral Hepatitis Webinar:

**Deconstructing HCV Treatment**

**Webinar Description**

As treatment for HCV has entered a new period of more FDA-approved therapies (and many more in Phase III clinical trials), TAI's next quarterly Viral Hepatitis webinar will devote the entire 90 minutes to an HCV treatment update.

**Webinar Date:** Wednesday July 9, 2014

**Webinar Time:** 3:30PM to 5:00PM

[Register Here]
The strides of freedom and courage, shall be remembered today … and every day. Happy July 4th!

**HEPATITIS C TREATMENTS: LATEST UPDATE**

**Achillion Kicks Off Phase 1 Trial of Hep C Drug**

Achillion Pharmaceuticals Inc. announced the company has begun dosing ACH-3422, a uridine-analog nucleotide polymerase inhibitor, for seven days in patients with genotype 1 chronic hepatitis C viral infection (HCV) in its ongoing Phase 1 clinical trial. Proof-of-concept results from this trial are expected to be reported during the fall of 2014. Furthermore, Achillion announced that the U.S. Food and Drug Administration (FDA) has removed the clinical hold on sovaprevir, an NS3/4A protease inhibitor, to permit the conduct of trials in patients with HCV. Sovaprevir doses of 200 mg once daily, the previously evaluated dose that was well-tolerated with clinical activity in two completed Phase 2 studies, may be used in additional therapeutic clinical trials.

"We believe Achillion is uniquely positioned with clinical candidates in each of the nucleotide, NS5A and protease inhibitor categories needed to advance both dual and triple commercially competitive combination therapies that can treat the spectrum of patients with HCV. We remain focused on developing regimens utilizing ACH-3422 and ACH-3102, our second-generation Phase 2 NS5A inhibitor, and the second half of 2014 will feature multiple milestones in that program," commented Milind Deshpande, president and CEO. "Our HCV pipeline also provides the opportunity to add a NS3/4A protease inhibitor, such as sovaprevir or ACH-2684, in order to explore triple-direct acting antiviral regimens that can potentially shorten treatment durations to less than eight weeks. We will determine how best to integrate our protease inhibitors into our combination development programs as data from our on-going trials emerge."

"With the start of patient dosing with ACH-3422, our Phase 1 uridine-analog nucleotide, we remain on track to report proof-of-concept results in the fall, and plan on initiating all oral combination studies with ACH-3422 by the end of 2014. We are also very pleased that the effort by the Achillion team, working in collaboration with the FDA, has resulted in this response for the sovaprevir program," commented David Apelian, executive vice president and chief medical officer.

Sovaprevir is a Phase 2 NS3/4A protease inhibitor being developed for the potential treatment of chronic HCV infection. To date, approximately 550 subjects have been exposed to sovaprevir with clinical activity reported in two Phase 2 12-week treatment duration studies, one in combination with pegylated-interferon/ribavirin and one in combination with ACH-3102 in which the combination achieved 100% SVR12 in patients with genotype 1b HCV. The FDA removed the clinical hold to permit the conduct of therapeutic trials with a maximum of 200 mg once daily of sovaprevir in HCV patients and in single dose trials in healthy volunteers, but maintained a partial clinical hold for multiple dose studies that may be conducted in healthy volunteers, requiring prior review and approval of the protocol by the FDA. Achillion expects to continue to work collaboratively with the FDA on the continued clinical development of sovaprevir.

New hepatitis C wonder drug shakes up the health care industry

In the article, Clay Black from Fulton, Kentucky was interviewed for this article!

WASHINGTON — When the harsh side effects of his hepatitis C medication forced Joel Roth to stop treatments last year, the only hope for his ailing liver was Sovaldi, a new wonder drug by Gilead Sciences Inc. that would hit the market later that year.

In December 2013, Sovaldi won approval from the U.S. Food and Drug Administration, and Roth, of San Rafael, Calif., was placed on a 24-week treatment regimen. The cost: $168,000, or an eye-popping $1,000 per pill.

In the first quarter of 2014, 30,000 U.S. patients were treated with Sovaldi, generating a whopping $2.3 billion in sales for Gilead, of Foster City, Calif.

Read more here: http://www.mcclatchydc.com/2014/06/12/230213/new-hepatitis-c-wonder-drug-shakes.html#storylink=cpy

Gilead’s Sovaldi-Ledipasvir Pill Safe With Major HIV Drugs

Gilead Sciences’ fixed-dose combination pill of Sovaldi (sofosbuvir) and ledipasvir to treat hepatitis C virus (HCV) does not have a clinically significant impact on five common HIV antiretrovirals, the National AIDS Treatment Advocacy Project (NATAP) reports. Currently pending U.S. Food and Drug Administration approval—a decision is expected October 10—the combination pill of the analog polymerase inhibitor Sovaldi and the NS5A inhibitor ledipasvir has boasted near-perfect cure rates in recent trials.

Gilead conducted three multi-dose randomized crossover trials to look for drug-drug interactions between the combination hep C treatment and Isentress (raltegravir), Atripla (efavirenz/emtricitabine/tenofovir) and Complera (rilpivirine/emtricitabine/tenofovir).

Atripla was found to lower concentrations of ledipasvir by about 30 percent, and Sovaldi/ledipasvir lowered Isentress concentrations less than 20 percent. However, Gilead determined that neither of these effects was clinically relevant. Sovaldi/ledipasvir raised tenofovir levels about 1.8- to 2.6-fold when tenofovir was in Atripla and 1.3- to 1.9-fold when the drug was in Complera. Nevertheless, the researchers concluded that the tenofovir dose needed no adjusting.

Gilead found that the hep C combo pill may be prescribed in combination with Atripla, Complera, Isentress or Truvada (emtricitabine/tenofovir) without the need for adjusting any of the medications’ dosages.

Read More: http://www.natap.org/2014/Pharm/Pharm_06.htm
Patient Assistance and Co-Pay Programs for Viral Hepatitis Drugs

In recent years, the Fair Pricing Coalition (FPC) has been working closely with the pharmaceutical industry to streamline access to co-pay programs and PAPs for people living with viral hepatitis. The FPC has negotiated co-pay programs with virtually every major hepatitis drug manufacturer. Below is a list of co-pay and patient assistance programs for hepatitis B and C, including contact information for these programs. This page will be updated as new treatments are released and in the event that these programs evolve over time.

Different pharmaceutical company programs have different eligibility criteria based on the federal poverty level (FPL). The 2013 FPL income for an individual is $11,490. The figure is adjusted based on family or household size. A complete table is available here. Unless otherwise stated, companies ask for verification of income, usually in the form of a federal income tax return. Companies also generally consider household income, meaning that a married couple that files joint taxes will be judged on their combined income. People who file individual income tax returns will only have their individual income considered. If you are told you are ineligible for assistance, this does not mean there is still no chance for you; you can always appeal and hope to have the decision reversed.

CO-PAY PROGRAMS

These programs offer assistance to people with private insurance for the co-payments or coinsurance costs required to obtain hepatitis B or hepatitis C drugs at the pharmacy.

Hepatitis B Virus (HBV)

<table>
<thead>
<tr>
<th>Bristol-Myers Squibb</th>
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<tbody>
<tr>
<td><strong>Drugs covered:</strong> Baraclude</td>
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<tr>
<td><strong>Contact Information:</strong> 855-898-0267. Ask the operator to speak to someone about the Baraclude Co-pay Benefits Program and ask for a card to be mailed to you.</td>
</tr>
<tr>
<td><strong>Program Details:</strong> The program covers the first $200 per month of co-pays. For people who pay for their prescriptions in full, the program will also cover the first $200 per month. Currently the program runs through December 31, 2014.</td>
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<tr>
<th>Gilead Sciences</th>
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<tr>
<td><strong>Drugs covered:</strong> Viread</td>
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<tr>
<td><strong>Contact Information:</strong> 877-627-0415</td>
</tr>
<tr>
<td><strong>Program Details:</strong> The program starts after the first $50 and covers up to $200 per month co-payment for Viread for HBV treatment for patients who are uninsured or pay their prescription costs in full. The program renews automatically for enrolled patients.</td>
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<tr>
<th>ViiV Healthcare</th>
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<tr>
<td><strong>Drugs covered:</strong> Epivir</td>
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<tr>
<td><strong>Contact Information:</strong> 877-844-8872 or <a href="http://www.mysupportcard.com">www.mysupportcard.com</a></td>
</tr>
<tr>
<td><strong>Program Details:</strong> The program covers up to $200 dollars per prescription per month and includes non-HBV drugs.</td>
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The strides of freedom and courage, shall be remembered today ... and every day. Happy July 4th!

## Hepatitis C Virus (HCV)

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<th>Gilead Sciences</th>
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<tr>
<td><strong>Drugs covered:</strong></td>
<td>Sovaldi (sofosbuvir)</td>
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<tr>
<td><strong>Contact Information:</strong></td>
<td>855-769-7284 or <a href="http://www.MySupportPath.com">www.MySupportPath.com</a></td>
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<tr>
<td><strong>Program Details:</strong></td>
<td>Support The Sovaldi Copay Coupon Program can bring copays down to $5 in most cases for those who qualify. Financial aid for as much as $16,000 is also available to go toward prescription deductibles and coinsurance obligations. The program is open to those with a maximum household income of $100,000 for up to a family of three, and 500 percent of federal poverty level for families with four or more members.</td>
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<th>Johnson &amp; Johnson/Janssen</th>
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<tr>
<td><strong>Drugs covered:</strong></td>
<td>Olysio (simeprevir)</td>
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<tr>
<td><strong>Contact Information:</strong></td>
<td>855-5-OLYSIO or <a href="http://www.olyso.com">www.olyso.com</a></td>
</tr>
<tr>
<td><strong>Program Details:</strong></td>
<td>The Janssen Therapeutics Patient Savings program assists those who qualify by reducing their copays or coinsurance for Olysio to no more than $25 a month. This translates to a total of $75 for the three-month regimen of the drug in most cases. The maximum financial assistance is $25,000 for the 12-month period after you qualify, or until you've filled three bottles of Olysio, whichever comes first. To qualify, your household income must be under 500 percent of the federal poverty level, although you can appeal for total coverage if your income is higher. This offer is not available for those enrolled in Medicare or Medicaid.</td>
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<tr>
<th>Merck &amp; Co.</th>
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<tr>
<td><strong>Drugs covered:</strong></td>
<td>PegIntron and Victrelis</td>
</tr>
<tr>
<td><strong>Contact Information:</strong></td>
<td>866-939-4372 or <a href="http://www.victrelis.com">www.victrelis.com</a> and <a href="http://www.pegintron.com">www.pegintron.com</a></td>
</tr>
<tr>
<td><strong>Program Details:</strong></td>
<td>Victrelis: People can print out a card at <a href="http://www.victrelis.com">www.victrelis.com</a> and at merck-cares.com which offers eligible patients savings of up to 20 percent of the total cost of each Victrelis prescription, on up to 12 prescriptions (which would be a full 44 weeks of treatment for those who need it for that duration). PegIntron: People can print out a card at <a href="http://www.pegintron.com">www.pegintron.com</a> and at merck-cares.com, which offers eligible patients up to $200 savings on their copayment for each Pegintron prescription, on up to 12 prescriptions.</td>
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<tr>
<th>Vertex Pharmaceuticals</th>
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<tr>
<td><strong>Drugs covered:</strong></td>
<td>Incivek</td>
</tr>
<tr>
<td><strong>Contact Information:</strong></td>
<td>855-837-8394 or <a href="http://www.incivek.com">www.incivek.com</a></td>
</tr>
<tr>
<td><strong>Program Details:</strong></td>
<td>Vertex will cover co-pay costs up to $10,000 for people who have private insurance plans that cover Incivek, regardless of their household income.</td>
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PAP PROGRAMS

These programs offer free hepatitis B or C drugs to lower-income people with who are uninsured or underinsured and who do not qualify for insurance programs such as Medicaid or Medicare.

**Hepatitis B Virus (HBV)**

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<tr>
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<tr>
<td><strong>Drugs covered:</strong> Baraclude</td>
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<tr>
<td><strong>Contact Information:</strong> 855-898-0267 or visit <a href="http://www.bmspaf.org">www.bmspaf.org</a></td>
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<tr>
<td><strong>Program Details:</strong> The PAP is for people who do not qualify for other assistance or health insurance programs and covers people with incomes up to 300 percent of the FPL. Most programs have limits based on the total household income compared to established FPL percentages. Generally, programs will accept appeals for special circumstances if a person does not initially qualify and is turned down.</td>
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<tr>
<th>Gilead Sciences</th>
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<tr>
<td><strong>Drugs covered:</strong> Hepsera, Viread</td>
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<tr>
<td><strong>Contact Information:</strong> 800-226-2056 or visit <a href="http://www.gilead.com/us_advancing_access">www.gilead.com/us_advancing_access</a></td>
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</tr>
<tr>
<td><strong>Program Details:</strong> The PAP is for people who do not qualify for other assistance or health insurance programs and is limited by income. Most programs have limits based on the total household income compared to established FPL percentages. Generally, programs will accept appeals for special circumstances if a person does not initially qualify and is turned down.</td>
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<tr>
<td><strong>Drugs covered:</strong> Epivir</td>
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<tr>
<td><strong>Contact Information:</strong> 877-784-4842 or <a href="http://www.viivhealthcareforyou.com">www.viivhealthcareforyou.com</a></td>
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<tr>
<td><strong>Program Details:</strong> The PAP is for people who do not qualify for other assistance or health insurance programs and is limited by income. Most programs have limits based on the total household income compared to established FPL percentages. Generally, programs will accept appeals for special circumstances if a person does not initially qualify and is turned down.</td>
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**Hepatitis C Virus (HCV)**

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<tr>
<th>Genentech/Roche</th>
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<tr>
<td><strong>Drugs covered:</strong> Pegasys and Copegus</td>
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<tr>
<td><strong>Contact Information:</strong> 888-941-3331 or <a href="http://www.pegasysaccesssolutions.com">www.pegasysaccesssolutions.com</a>.</td>
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<tr>
<td><strong>Program Details:</strong> The PAP is for people who do not qualify for other assistance or health insurance programs and is limited by income. Most programs have limits based on the total household income compared to established federal poverty levels. Generally, programs will accept appeals for special circumstances if a person does not initially qualify and is turned down.</td>
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<td><strong>Drugs covered:</strong> Sovaldi (sofosbuvir)</td>
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<tr>
<td><strong>Contact Information:</strong> 855-769-7284 or <a href="http://www.MySupportPath.com">www.MySupportPath.com</a>.</td>
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### The strides of freedom and courage, shall be remembered today ... and every day. Happy July 4th!

**Program Details:** Called Support Path, Gilead's program may provide Sovaldi coverage for free to those with a maximum household income of $100,000 for up to a family of three, and 500 percent of federal poverty level for families with four or more members. You can also contact Support Path for assistance finding other sources of health coverage, such as through Medicaid, Medicare or the new health exchanges available through Obamacare.

**Johnson & Johnson**

**Drugs covered:** Procrit*, Olysio (simeprevir)

**Contact Information:** 800-652-6227 or www.jjpaf.org.

**Program Details:** The Johnson & Johnson Patient Assistance Foundation will provide free coverage of Olysio to those who qualify. The income limit is 500 percent of the federal poverty level, although you can appeal if your income is higher than that. For Procrit, the income cap is 400 percent FPL.

*Procrit is a treatment for anemia—a side effect commonly caused by the drug ribavirin, which is a component of many hepatitis C regimens.

**Merck & Co.**

**Drugs covered:** Pegintron and Victrelis

**Contact Information:** 866-363-6379 or www.merckhelps.com

**Program Details:** The ACT Program can help you answer questions related to insurance coverage and reimbursement. Program Specialists can also help you apply for the PAP. The PAP is for people who do not qualify for other assistance or health insurance programs and is limited by income. Most programs have limits based on the total household income compared to established federal poverty levels. Generally the program will accept appeals for special circumstances if a person does not initially qualify and is turned down, provided they fall within the 500% FPL income eligibility requirement.

**Vertex Pharmaceuticals**

**Drugs covered:** Incivek

**Contact Information:** 855-837-8394 or www.incivek.com

**Program Details:** The PAP is for people who do not qualify for other assistance or health insurance programs and is limited by income. Most programs have limits based on the total household income compared to established federal poverty levels. The Incivek PAP helps people whose household income is less than $100,000 per year. Generally, programs will accept appeals for special circumstances if a person does not initially qualify and is turned down.

### HEPATITIS IN CORRECTIONS

The Federal Bureau of Prisons released its updated clinical practice guidelines May 30, 2014. See the links below:


[http://www.bop.gov/resources/pdfs/hepatitis_c_previous.pdf](http://www.bop.gov/resources/pdfs/hepatitis_c_previous.pdf) - Treatment of Hepatitis C with Pegylated Interferon and Ribavirin, with or without Boceprevir or Telaprevir.

HEPATITIS C TESTING: LATEST UPDATE

Why Hepatitis C Tests May Give False Results

While generally accurate, the standard hepatitis C test is still subject to false negatives and false positives. In the vast majority of cases, the result of the hepatitis C virus (HCV) test is definitive, accurately stating whether an individual has contracted the virus that can cause serious liver damage over time. However, in more rare cases false positive results occur—when someone tests positive but is not actually infected. Then there are false negatives, in which someone tests negative but actually is carrying hep C. In the event that either scenario applies to you, here is some information to help explain each phenomenon.

First, a bit about the two main kinds of hep C tests and how they work. The initial test that is typically used is called an enzyme-linked immunosorbent assay, or ELISA, screen. It looks for the antibodies to hep C that the immune system develops in response to an infection. Second, there is a hep C RNA test, which detects evidence of the actual virus in the bloodstream. The RNA test is more expensive to conduct, so for general screening purposes it is typically only used as a confirmatory test: If an ELISA tests positive, an RNA test is conducted to either confirm or deny the actual presence of an infection.

Natural Clearance: Approximately one in four people who contract hep C will clear the virus on their own. When tests are taken after this process is complete, the ELISA will test positive while the RNA test will come up negative. These contradictory results happen because the antibodies to hep C remain in the body even though the virus itself is gone. Research suggests that someone who spontaneously clears the virus has no greater risk of liver disease or death than someone who never had the virus. (Hep C raises the risk of both outcomes.) It is highly unlikely that someone who has cleared the virus will have the capacity to infect others with the virus after doing so. Spontaneous clearance does not mean someone is immune to reinfection with hep C. It is very difficult to determine whether someone has spontaneously cleared the virus or is testing false positive for another reason.

Read More: http://www.hepmag.com/articles/false_test_result_2502_25760.shtml

Joint Commission Issues Alert on Unsafe Injection Practices

The Joint Commission wants healthcare organizations to pay more attention to risks associated with improper use of injectable medicines, and to do something about the problem.

"Patients visiting a clinic for an injection to relieve their pain or for chemotherapy don't expect to leave with a new condition such as hepatitis, but unfortunately thousands of patients have been adversely affected in this way when they received an injection at their doctor's office or in the hospital," the commission notes in a statement.

In a Sentinel Event Alert issued June 16, entitled "Preventing Infection from the Misuse of Vials," the commission describes factors that contribute to the misuse of vials and offers strategies to curb the problem.

HEPATITIS:  IN THE NEWS

Hepatitis C testing continues as NKY rate soars

A recent dip in hepatitis C cases in Northern Kentucky is small comfort to a region that has endured climbing cases for three years – particularly since it now boasts nearly 10 times the nation’s rate of hepatitis C cases and three times that of the commonwealth’s.

“We’ve seen an 80 percent increase in 2013 (over) 2010,” said Jessica Schultz, the health department’s epidemiologist who investigates hepatitis C.

It’s another potentially deadly symptom of the heroin epidemic gripping the nation – which itself was fueled by the country’s battle with prescription painkiller abuse.

When legislation and law enforcement stemmed the supply of painkillers, it unwittingly drove hundreds of thousands of people to heroin. Today Northern Kentucky, a center of the heroin epidemic, is facing the results.

Northern Kentucky’s rate of hepatitis C was three times the state’s in 2011 and about 10 times above that of the United States when compared to the Centers for Disease Control and Prevention’s 2010 rate. The region had 9.5 reported cases per 100,000 population in 2011, and Kentucky had three cases per 100,000 population. In 2010, the most recent CDC statistic available, the reported the United States had one case per 100,000 population.

Hepatitis C is most commonly contracted through contaminated needles, according to the CDC, caused by a virus that attacks the liver. The CDC reported in 2010 between 2.7 million and 3.9 million cases of chronic hepatitis C had been diagnosed in the U.S., and 16,627 people died with hepatitis C listed as cause of death. That’s less than 1 percent; however, the CDC noted, the percentage is low because many people have liver failure, rather than hepatitis C, listed as their cause of death.

The Northern Kentucky Health Department learned of 10 new cases of acute hepatitis C in the first quarter of this year. That’s generally low compared to recent years. But the window of relief from high numbers isn’t an indication of any trend, said Joyce Rice, the health department’s epidemiology manager.

The strides of freedom and courage, shall be remembered today ... and every day. Happy July 4th!

**Feds taken to task over heroin crisis**

As focus on the nation’s heroin crisis sharpens, some critics argue the agency charged with regulating powerful prescription painkillers could be further fueling the deadly epidemic.

In recent months, government officials at all levels have begun calling for more resources to stem the flood of cheap heroin into communities across the country. Congressional hearings have been convened. New laws to better control prescription opioids – blamed for fueling the addiction crisis – have been proposed. And lawmakers are sounding off over the rising overdose deaths to heroin and painkillers in their home districts.

Against this backdrop, the U.S. Food and Drug Administration recently approved a powerful new opioid – Zohydro – a move that has gained considerable condemnation from top lawmakers, law enforcement and medical experts.

"I think people will die from this as soon as it begins to get prescribed," said Dr. Andrew Kolodny, president of Physicians for Responsible Opioid Prescribing, one of 40 medical and drug addiction experts who sent a letter in February urging the FDA to rethink its decision.


**Curing Hepatitis C Lowers Central Nervous System Fatigue**

Curing hepatitis C virus (HCV) reduces central fatigue, which is weakness originating in the central nervous system rather than in the muscles (known as peripheral or physical fatigue), aidsmap reports. Results from a study of those treated with Sovaldi (sofosbuvir) were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London.

The researchers looked at differences in fatigue levels before and after treatment with either a combination of Sovaldi plus pegylated interferon and ribavirin in the NEUTRINO trial, which included genotypes 1, 4, 5 and 6, or a combination of just Sovaldi and ribavirin in the FUSION trial, which included genotypes 2 and 3.

The investigators’ analysis included data on 423 participants who achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). At the beginning of the study, 12 percent of the participants reported fatigue.

Read More: [http://www.natap.org/2014/EASL/EASL_90.htm](http://www.natap.org/2014/EASL/EASL_90.htm)
The strides of freedom and courage, shall be remembered today ... and every day. Happy July 4th!

CMS Targets Boomers, Those At High Risk For Hepatitis C Screenings

Modern Healthcare

By Virgil Dickson

The CMS has finalized its coverage decision to reimburse for hepatitis C virus screenings for two target populations, including baby boomers.

That decision comes amid controversy surrounding the costs of treatment that could result from screening, since screening may identify asymptomatic people who carry the virus but may not need to be treated.

FDA approval of Gilead Sciences' Sovaldi—which can cure the ailment but costs about $84,000 for a full 12-week course of treatment—has focused healthcare attention on the cost issue. If all 300,000 Medicare patients projected to be diagnosed by 2015 were to seek treatment with the latest drug after being screened in the new program, the total expenditure could exceed $25 billion. That does not include the cost of screening, doctor visits and other fees.

Hepatitis C is an infection that attacks the liver and leads to inflammation. About 80% of people exposed to the disease develop chronic infection. Of these, 3% to 11% will develop liver cirrhosis within 20 years. In 2010, the Centers for Disease Control and Prevention estimated that 2.7 million to 3.9 million persons in the United States were living with hepatitis C.

The CMS said it will only reimburse for screening for beneficiaries who fall into two categories. The first are those individuals who are considered at high risk for the disease, including individuals who have a current or past history of illicit injection drug use or those who had received a blood transfusion prior to 1992.

The second is for those individuals who were born from 1945 through 1965. This group was singled out since about two-thirds of patients with hepatitis C were born between these years, according to the U.S. Preventive Services Task Force.

The coverage determination brings Medicare into alignment with private insurers who have already been reimbursing for screenings for these individuals.

The decision follows the release of a proposed coverage determination and subsequent comment period.

Bristol-Myers Squibb Receives Positive CHMP Opinion for Daklinza® (daclatasvir) for Treatment of Chronic Hepatitis C in the European Union -

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**Hep C Takes 15 Years Off Life Span, Raises Death Risk 12-Fold**

People with hepatitis C virus (HCV) die 15 years earlier and have a 12-times greater risk of death when compared with those without the virus, the National AIDS Treatment Advocacy Project (NATAP) reports. The Centers for Disease Control and Prevention (CDC) conducted a multicohort analysis, examining electronic medical records of adults who received treatment at least once between 2006 and 2010 in four health care systems. The researchers then compared the findings of their so-called Chronic Hepatitis Cohort Study (CHeCS) with the national Multiple Cause of Death (MCOD) study covering the same period of time. They presented their findings at the IDWeek 2013 conference in San Francisco.

Looking at the records of 11,703 people with hep C, who made up a half of a percent of the 2.1 million people in the CHeCS cohort, the investigators found that 1,590 (14 percent) died during the study period. Sixty percent were between 45 and 59 years old, and 34 percent were 60 and older. When compared with the MCOD group, those in CHeCS had a 12-times greater mortality rate. With an average age at death of 59, those in the CHeCS group died an average of 15 years earlier than the typical American.

Hep C, the researchers found, is vastly unreported as a cause of death, registered in only 19 percent of death certificates among those in the cohort who died. Based on this finding, the investigators extrapolated that more than 80,000 Americans who died in 2010 had hep C. They also projected that 53,000 people died as a consequence of hep C in 2010.


**HEPATITIS EDUCATIONAL MATERIAL:**

The HCV Advocate publishes a variety of Hepatitis Educational Materials which you can download and distribute. This month the top downloads were:

**First Steps with HCV- for the Newly Diagnosed:**

[http://www.hcvadvocate.org/hepatitis/First%20Steps/First_Steps_with_Hepatitis_C%20for_the_Newly_Diagnosed.pdf](http://www.hcvadvocate.org/hepatitis/First%20Steps/First_Steps_with_Hepatitis_C%20for_the_Newly_Diagnosed.pdf)

**A Guide to Hepatitis C: Treatment Side Effect Management:**


**A Guide to Understanding HCV:**

HEPATITIS PREVENTION: SPREAD THE WORD

IV DRUG ABUSE and HEPATITIS C go HAND in HAND

TEEN MEDICINE ABUSE IS AN EPIDEMIC - ONE THAT IS NOT POISED TO GET BETTER.

MORE TEENS ARE ABUSING PRESCRIPTION MEDICINE THAN EVER. RECENT FINDINGS FROM THE PARTNERSHIP ATTITUDE TRACKING STUDY, SHOW THAT

ONE IN FOUR TEENS

HAS MISUSED OR ABUSED A PRESCRIPTION DRUG AT LEAST ONCE IN THEIR LIFETIME.

THAT IS A 33 PERCENT INCREASE SINCE 2008.

ONE STEP WE CAN ALL TAKE IS TO HAVE FREQUENT CONVERSATIONS WITH THE TEENS IN OUR LIVES ABOUT THE DANGERS OF MEDICINE ABUSE.

IT IS IMPORTANT THAT PARENTS MONITOR, SAFEGUARD AND PROPERLY DISPOSE OF THE MEDICINES THEY KEEP AT HOME, AS MORE THAN FOUR IN TEN TEENS WHO HAVE MISUSED OR ABUSED A PRESCRIPTION DRUG HAS TAKEN IT RIGHT OUT OF THEIR PARENT’S MEDICINE CABINET. KIDS WHO ABUSE MEDICINE ARE STARTING EARLY. IN FACT, ONE IN FIVE KIDS HAS DONE SO BEFORE THE AGE OF 14. PARENTS ARE THE FIRST LINE OF DEFENSE IN PROTECTING TEENS FROM THIS DANGEROUS BEHAVIOR.
The strides of freedom and courage, shall be remembered today ... and every day. Happy July 4th!

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## Kentucky Reportable Disease Form

**Department for Public Health**
**Division of Epidemiology and Health Planning**
**275 East Main St., Mailing HS2E-A**
**Frankfort, KY 40621-0001**

**Hepatitis Infection in Pregnant Women or Child (under the age of five)**
**Fax Form to 502-564-4760**

### DEMOGRAPHIC DATA

<table>
<thead>
<tr>
<th>Patient’s Last Name</th>
<th>First</th>
<th>M.I.</th>
<th>Date of Birth</th>
<th>Age</th>
<th>Gender</th>
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<table>
<thead>
<tr>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
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<tr>
<th>Phone Number</th>
<th>Patient ID Number</th>
<th>Ethnic Origin</th>
<th>Race</th>
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<tr>
<td></td>
<td></td>
<td>☐ His. ☐ Non-His.</td>
<td>☐ W ☐ B ☐ A/PI ☐ Am.Ind. ☐ Other</td>
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### DISEASE INFORMATION

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<tr>
<th>Describe Clinical Symptoms:</th>
<th>Date of Onset:</th>
<th>Jaundice:</th>
<th>Date of Diagnosis:</th>
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<tbody>
<tr>
<td></td>
<td>/ /</td>
<td>☐ Yes ☐ No</td>
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<thead>
<tr>
<th>Is Patient Pregnant?</th>
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<th>No</th>
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<td>If yes, # wks_____</td>
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<table>
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<th>Physician Provider Name:</th>
<th>Address:</th>
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<td>Phone:</td>
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### LABORATORY INFORMATION

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<th>Hepatitis Markers</th>
<th>Results</th>
<th>Date of test</th>
<th>Viral Load *if applicable</th>
<th>Name of Laboratory</th>
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<tbody>
<tr>
<td>HBsAg</td>
<td>☐ Pos ☐ Neg</td>
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<tr>
<td>IgM anti-HBc</td>
<td>☐ Pos ☐ Neg</td>
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<td>IgM anti-HAV</td>
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<tr>
<td>HCV Antibody</td>
<td>☐ Pos ☐ Neg</td>
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<td></td>
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<tr>
<td>HCV RNA Confirmation</td>
<td>☐ Pos ☐ Neg</td>
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### SERUM AMINOTRANSFERASE LEVELS

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<th>ALT (SGPT) U/L</th>
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<th>Name of Laboratory</th>
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<tr>
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<td>U/L</td>
<td>U/L</td>
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### Hepatitis A vaccination history:
- ☐ Yes
- ☐ No
- ☐ Refused
- Dates Given: / /

### Hepatitis B vaccination history:
- ☐ Yes
- ☐ No
- ☐ Refused
- If yes, how many doses: 1 2 3
- Year completed: / /

### Mother: Hepatitis Risk Factors
- ☐ IDU
- ☐ Multiple Sexual Partners
- ☐ Tattoos
- ☐ STD
- ☐ HIV
- ☐ Foreign Born / Country
- ☐ Exposure to known HBV/HCV Pos contact

### Child: Hepatitis Risk Factors
- ☐ Mother HBV Pos
- ☐ Household member exposure HBV Pos
- ☐ Mother HCV Pos
- ☐ Household member exposure HCV Pos
- ☐ Foreign Born / Country

### Mother: Hepatitis A vaccination history:
- ☐ Yes
- ☐ No
- ☐ Refused
- Dates Given: / /

### Hepatitis B vaccination history:
- ☐ Yes
- ☐ No
- ☐ Refused
- Dates Given: / /

### Child: Hepatitis A vaccination history:
- ☐ Yes
- ☐ No
- ☐ Refused
- Dates Given: / /

### Was PEP Infant of Positive HBV mother given at birth? 
- ☐ Yes
- ☐ No