HEPATITIS C SUPPORT PROJECT

HCV Advocate

May 2013 • Vol. 16, Issue 5

Celebrating 15 years of Living Positively—Being Well!

The Next Wave: Janssen/Tibotec and Gilead File for FDA Approval

—Alan Franciscus, Editor-in-Chief

Recently, Janssen/Tibotec and Gilead applied to the Food and Drug Administration for marketing approval of new therapies to treat chronic hepatitis C genotypes 1, 2, 3, 4, 5 and 6.

SIMEPREVIR

On March 28, 2013, Janssen announced that they had submitted a new drug application to the Food and Drug Administration (FDA) for approval of simeprevir (TMC435—an HCV protease inhibitor) administered once a day (QD) in combination with pegylated interferon (PEG-injected weekly) plus ribavirin (RBV-dosed twice a day (BID)) for the treatment of chronic hepatitis C genotype 1 patients (pts).

The treatment duration was based on "response-guided treatment (RGT)"—that is the length of treatment was dictated by whether or not HCV RNA became undetectable at certain time points during therapy.* All of the patients in the group received the study drug—simeprevir—plus PEG/RBV for 12 weeks plus an additional treatment duration of either 12 or 36 weeks based on RGT. There was also a placebo group (control group) that received PEG/RBV, but **not** simeprevir for 48 weeks.

Topline treatment response rates (SVR or viral cure) from the three studies are listed below.

Treatment-naïve:

- QUEST-1: **SVR12 – 80%** (264 pts) in the simeprevir group (130 pts) vs. 50% (130 pts) in the placebo group
- QUEST-2: **SVR12 – 81%** (257 pts) in the simeprevir group vs. 50% (134 pts) in the placebo group

*85% of the people in QUEST-1 and 91% in QUEST-2 who received simeprevir and PEG/RBV were able to stop treatment at week 24.

Prior-relapsers:

- PROMISE: **SVR12 – 79%** (260 pts) in the simeprevir groups vs. 37% (133 pts) in the placebo group

*93% of people who received simeprevir and PEG/RBV in the PROMISE study were able to stop all treatment at week 24.

The side effects were similar between the simeprevir groups and the control groups that did not receive simeprevir. Importantly, 22 to 31% of the patients in the simeprevir -containing groups had F3-F4 METAVIR scores (fibrosis/cirrhosis)

Comment: Simeprevir brings a lot to the table—once-a-day dosing, fewer side effects compared to the current protease inhibitor combination therapy and a shorter duration of therapy for almost all of the patients.

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SOFOSBUVIR

Gilead announced on April 8, 2013 that they had also submitted a new drug application to the FDA for sofosbuvir (GS-7977—an HCV polymerase inhibitor) QD plus ribavirin BID for the treatment of chronic HCV genotype 2 and 3 treatment-naïve patients and the combination of sofosbuvir QD plus PEG/RBV for the treatment of HCV genotype 1, 4, 5 and 6 treatment-naïve patients.

Genotypes 2 and 3

The press release did not contain information about the phase III treatment results, but topline results for the POSITRON trial in treatment-naïve chronic HCV genotypes 2 and 3 were released in November 2012. The treatment duration for the patients who received sofosbuvir plus ribavirin was 12 weeks. The reported SVR 12 results were 93% for HCV genotype 2 and 61% for HCV genotype 3.

Comments: The high SVR12 rates for HCV genotype 2 are remarkable. The SVR12's for HCV genotype 3 are not as high, but when you factor in that the therapy is interferon-free and the treatment duration is only 12 weeks the end-game is that this is a huge advancement in the treatment of HCV genotype 2 and 3 people. The treatment-related side effects were not listed in the press release, but prior studies of sofosbuvir plus ribavirin have found a much lower rate of treatment side effects compared to treatments that include interferon.

Genotypes 1, 4, 5, and 6

The data submitted to the FDA included the phase III data of sofosbuvir plus PEG/RBV for the treatment of chronic HCV genotype 1, 4, 5, and 6 treatment-naïve patients. The press release did not contain information about the SVR12 results but a previous press release stated that the overall SVR12 results were 90% (295 out of 327 pts) compared to 60% SVR12 in the group that did not receive sofosbuvir.

There was no information on side effects, but prior studies have found similar side effects in the groups that received sofosbuvir-containing regimes compared to the groups that received PEG/RBV without sofosbuvir.

Comments: The possibility of higher cure rates, shorter treatment duration and fewer side effects than the current HCV protease inhibitor combination therapies with PEG/RBV, make these drugs an attractive and much needed new therapy. Gilead is also testing an interferon-free phase III combination therapy with sofosbuvir and their NS5A inhibitor ledipasvir. The study will be conducted with and without ribavirin.

FDA APPROVAL

The FDA is expected to review and approve both drugs within 8 to 12 months depending on whether or not the FDA expedites the review process.

EASL

The European Association for the Study of Liver Diseases (EASL) Conference will take place in Amsterdam towards the end of April 2013. Information about the phase III studies of simeprevir and sofosbuvir as well as many other drugs under study to treat hepatitis C will be presented.

FINAL THOUGHTS

The Janssen and Gilead FDA submissions are good news for people with HCV.

Cure rates are for the most part increasing, and less side effects in the interferon-free therapy for HCV genotype 2 and 3 and in HCV genotype 1, 4, 5, 6 than the current HCV protease inhibitor, PEG/RBV therapy. Hopefully, interferon-free regimes in people with HCV genotype 1 will continue to show a better safety profile, less side effects and better efficacy and be available within the next 3-5 years.

Source: Tibotec and Gilead press releases

HEALTHWISE

Mother's Day in the Shadow of Hepatitis C

—Lucinda K. Porter, RN

Imagine that you just gave birth to your first baby. Motherhood is a rite of passage, one that allows you to participate in that time-honored annual occasion—Mother's Day. However, instead of celebrating, you are worried. When you were pregnant, a blood test confirmed that you have chronic hepatitis C virus (HCV) infection. There is a small chance that you may have passed HCV to your child, but you don't know yet whether you did or not.

HCV is the most common blood-borne virus in the U.S. It may be transmitted if a person's blood is exposed to blood that carries HCV. This includes from mother to baby, known as *vertical transmission*. The risk is small, especially compared to more common ways HCV is transmitted. The Centers for Disease Control and Prevention (CDC) estimates vertical transmission risk at about 4%.

Erika Barth Cottrell and colleagues reported in a recent article in the *Annals of Internal Medicine,*[1] "Mother-to-infant transmission is the leading cause of childhood HCV infection, with up to 4000 new cases each year in the United States." Cottrell estimated that 40,000 children are born to HCV–positive women each year with vertical transmission rates from 3% to 10%.

The highest rates of vertical transmission occur in women with high HCV viral loads or co-infected with HIV. Multiple studies suggest that vertical transmission risk is greatest when HCV viral load levels are $>10^6$ copies/mL. Women with HIV and HCV have a 2–3 times greater risk of vertically transmitting HCV.

Vertical transmission occurs at the time of birth, leading researchers to assess differences between vaginal and cesarean births. The risk appears similar for both modes of delivery; no medical organizations endorse a particular delivery method to reduce HCV transmission risk. Prolonged rupture of membranes for more than 6 hours may increase risk of transmitting HCV. Internal fetal monitoring does not appear to affect transmission risk.

Decisions regarding mode of delivery in HIV/HCV-co-infected pregnant women should be based on standard obstetric and HIV-related indications. HIV co-infected women who had caesarean deliveries were 60% less likely to have an infected child than those delivered vaginally.

There may be a slight increase in risk for HCV-positive women who are pregnant with twins. A very small study of four twin pregnancies was reported in the February 2007 *Journal of Clinical Virology*. E. Boxall and colleagues observed that there is a higher risk of HCV transmission for the second twin who is born.

AFTER THE BIRTH

Nearly all newborns of mothers with HCV will test positive for antibodies. Newborns acquire HCV antibodies from their mothers, but this does not mean they are infected. HCV antibodies gradually decline and are usually gone when the infant is 18 months of age.

Naturally, mothers are anxious to know the HCV status of her baby. Most authorities recommend HCV antibody testing after infants are 18 months old. This uncertainty may be burdensome. Some mothers may opt for HCV viral load testing before the child turns 18 months, which may be performed as early as age 1–2 months. HCV RNA testing should be repeated at a subsequent visit, independent of the initial HCV RNA test result.

Most infants infected with HCV at birth have no symptoms and do well during childhood. Currently there is no perinatal strategy to prevent or lower risk of HCV vertical transmission.

BREASTFEEDING

Experts agree that mothers with HCV may breastfeed their babies. HCV RNA has been detected in breast milk, but no definite case of mother-to-infant transmission

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of HCV via breast milk has been reported. Babies who are bottle-fed versus breastfed, showed the same 4% incidence of HCV.

Most experts advise refraining from breastfeeding if a nipple is cracked or bleeding. Safe breastfeeding goes hand-in-hand with good nipple care. Talk to a medical provider or lactation specialist about how to prevent sore, cracked, or bleeding nipples.

HIV co-infected women who breastfed were about four times more likely to infect their children than those who did not. Bottle-feeding, rather than breastfeeding is recommended for women who are HIV/HCV co-infected.

We know that HCV treatment, particularly ribavirin, is contraindicated during pregnancy (see *Black Box Warning*). What about those interested in HCV treatment who are breastfeeding? There are no data on the excretion of ribavirin into human milk. Drug manufacturers recommend that due to the potential for serious adverse reactions in nursing infants, breastfeeding mothers either discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Personally, I can't think of a harder time to undergo HCV treatment than when one's children are young (or teenagers for that matter). I waited until my daughter was in college before starting HCV treatment, and it was a wise decision.

EMOTIONAL ISSUES

For some, the hardest part of HCV to deal with is not the physical disease, but the emotional aspects. This is particularly true for HCV-positive mothers. Those who acquired HCV by way of injection drug use, feel greater guilt and shame over the fact that they may have infected their child. Even if their drug use was a long time ago, there does not seem to be a statute of limitations on how horrible women feel about it. If I could give one Mother's Day gift to women, it would be this: let go of guilt; love yourself as much as you love your child. You don't have to carry this burden any longer.

> ***Black Box Warning:***
> *"Hepatitis C treatment carries a Black Box Warning: Ribavirin may cause birth defects and fetal death; avoid pregnancy in female patients and in female partners of male patients."*

The fact that the risk of vertical transmission is low is not necessarily reassuring. Let's face it, women worry about their children, regardless of the size of the risk. Pregnant women and mothers are hard-wired to protect their offspring, and when it comes to HCV, a small risk is still a risk.

When talking to a new mother with HCV who did not know the status of her baby, I asked her if she had any advice for HCV-positive women who are pregnant or new to motherhood, "Don't let Hep C stop you from experiencing one of the most amazing things. Breathe and don't let your emotions take over you. You need to be as positive as you can for your baby."

Lucinda K. Porter, RN, author of *Free from Hepatitis C* is a long-time contributor to the *HCV Advocate*. Her blog is http://lucindaporterrn.com

Resources

- HCSP Factsheet: *Being a Positive Mother* www.hcvadvocate.org/hepatitis/factsheets_pdf/Wm_Mother.pdf
- HCSP Factsheet: *Pregnancy, Childbirth and Breastfeeding* www.hcvadvocate.org/hepatitis/factsheets_pdf/Wm_pregnancy.pdf
- Hepatitis C New Drug Research and Liver Health: *Hepatitis C in Pregnancy* www.hepatitiscnewdrugresearch.com/hepatitis-c-in-pregnancy.html
- WomensHealth.gov: *Breastfeeding* www.womenshealth.gov/breastfeeding

Endnotes

[1] Reducing Risk for Mother-to-Infant Transmission of Hepatitis C Virus: A Systematic Review for the U.S. Preventive Services Task Force by Erika Barth Cottrell, et al. *Annals of Internal Medicine* January 15, 2013 *http://annals.org/article.aspx?articleid=1402436*

Snapshots

—Lucinda K. Porter, RN

May is *Hepatitis Awareness Month;* May 19 is *Hepatitis Screening Day*. *Snapshots* honors the occasion by dedicating the first *Snapshot* to all Hepatitis Educators.

Article: Formal Hepatitis C Education Enhances HCV Care Coordination, Expedites HCV Treatment and Improves Antiviral Response – Samali Lubega, et al.

Source: Liver International 19 March 2013 Online ISSN: 1478-3231

This study surveyed 94 primary care providers in San Francisco and performed a retrospective analysis of 118 HCV patients; 60 participated in a 2-hour HCV class, and 58 did not. The education session was presented by a liver clinic nurse practitioner and covered topics such as the symptoms, diagnosis and transmission of HCV, and response to and side effects of therapy.

Class participants had a significantly shorter time to HCV treatment initiation than those who did not participate (median 136 days vs. 284 days). Sustained virologic response (SVR) rates were higher among those who participated in the class (68% vs. 50%). Side effect discontinuation rates were lower among participants (3% vs. 12% of cases). Participants had fewer relapses (16% vs. 28%).

The Bottom Line: HCV education may be an important tool for successful HCV treatment.

Editorial Comment: This study measures something that HCV and other health educators know—education is a powerful ally in the fight to wellness. Support is part of this. The cornerstone of the Hepatitis C Support Project/HCV Advocate is education. Good education leads to support, empowerment and change.

Article: HIV, Age, and the Severity of Hepatitis C Virus-Related Liver Disease: A Cohort Study – Gregory D. Kirk, et al.

Source: Annals of Internal Medicine 26 February 2013 published at www.annals.org

HIV-positive persons develop age-related diseases at younger ages than people without HIV. The purpose of this study was to explore whether those with HIV develop hepatitis C virus (HCV)-related liver disease at younger ages than HCV-positive persons without HIV.

This study enrolled 1176 current and former injection drug users over age 17 years old who were HCV antibody-positive. Enrollment began in 1988, with subsequent recruitments in 1994 to 1995, 1998, 2000, and 2005 to 2008. Liver fibrosis was measured by elastography using a FibroScan machine. Liver fibrosis was compared by age among those who have HCV with and without HIV.

The Bottom Line: Persons who are co-infected with HIV/HCV have liver fibrosis stages similar to those with HCV who are nearly ten years older.

Editorial Comment: What can I possibly say other than thank goodness that treatment is improving for all people with HCV, including those who are co-infected with HIV and HCV. Ten years is too much life to lose.

Article: Laboratory-based Surveillance for Hepatitis E Virus Infection, United States, 2005–2012 – Jan Drobeniuc, et al.

Source: Emerging Infectious Diseases February 2013; Vol. 19, No. 2 wwwnc.cdc.gov/eid/article/19/2/12-0961_intro.htm

From June 2005–March 2012, the Centers for Disease Control and Prevention (CDC) tested blood samples for hepatitis E virus (HEV) from 154 persons in the U.S. who were negative for acute hepatitis A and B. They found that 26 (17%) were HEV-positive. Of these, 11 had recently traveled abroad; 15 had not. Compared with travelers, non-travelers were older (median 61 vs. 32 years of age) and more likely not to show signs of jaundice (53% vs. 8%); the non-traveler group also had

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DISABILITY & BENEFITS

Why Is Social Security Disability So Difficult to Get?

—Jacques Chambers, CLU

What is going on with the disability programs under Social Security, why are they so hard to get, and what is in their future?

This article attempts to examine the status of the two main Social Security programs for the disabled as accurately and impartially as possible despite the fact that many of the issues I raise are being argued over for political reasons.

The first program is the one the Social Security Administration calls simply "Disability" or "Disability Insurance Benefits," which the general public calls Social Security Disability Insurance, usually abbreviated by SSD or SSDI. The other is Supplemental Security Income (SSI) for disabled persons under age 65 who either don't qualify for or receive very little from SSDI.

You would hope that since these programs exist to provide financial assistance to people unable to work due to disability, that there would be some effort to make the process simple and relatively fast. Unfortunately, that is not the case, and the future does not hold any real hope of improvement anytime soon. There are major hurdles to cross before the benefits begin.

The Psychological Hurdle

The first hurdle in the Disability process is for the claimant to decide to leave work and file for disability. I purposely use the term "decide" because with HCV, there is no single event that allows a person to work one day and be unable to work the following day. You must stop working to apply for disability benefits; if you gross more than $1,040 per month (net income for self-employed persons), Social Security assumes automatically that you are not disabled.

Not all employees have private short-term or long-term disability benefits that can tide them over six months to two years while their Social Security claim works its way through the system.

Also, leaving work is usually a traumatic and emotional experience. The ripple effects can bring on depression and alter family relationships. The Puritan ethic ingrained in most workers must battle messages such as you're "giving up" or "surrendering" to the disease; you are no longer being a "contributing member of society."

Friends and family have trouble understanding the severity of the disability when no visible signs are obvious, and this can exacerbate the claimant's emotional fragility. It is not unusual to hear comments like "early retirement must be nice" or "I wish I could be like you and just sit home and collect checks."

No wonder many employees work far longer than they should, pushing themselves to continue working despite getting weaker and more fatigued. Too many actually work harder to hide the symptoms at work so "no one notices," which eliminates any help supervisors and fellow employees could provide about decreasing productivity and increasing mistakes.

The Administrative Hurdle

Social Security is a very large bureaucracy with all the problems that implies. For example, in February, 2013, Social Security made payments to a total of 62,000,000 beneficiaries of which only 14,000,000 were for disability. There are over 66,000 employees in the Social Security Administration in over 2,000 offices around the country. There is no one person who sits down and spends time examining a claimant's situation, talking to your doctors, researching your condition, and carefully weighing all factors of the claim.

Social Security does not even examine or make the decision as to whether the claimant is medically disabled by their standard. They contract that out to individual states. Each state has a Disability Determination Services (DDS) office, and those employees order and examine a claimant's medical record for Disability claims. Each analyst will be working on dozens or even hundreds of claims at one time, and that is just at the initial and first appeal stages.

DDS analysts are state employees, not federal, and are at the mercy of each state's employment policy. During the recent economic downturn several states forced their employees to take unpaid furlough days, sometimes two or more a month. Even though the states are fully reimbursed for the cost of the DDS employees from the federal government, as state employees they were forced onto unpaid furloughs too.

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Disability claims each have their own issues, but to maintain uniformity in processing, they must follow the rules in the "Program Operations Manual System (POMS)"; the primary source of information used to process claims for Social Security benefits. This is a very detailed and extremely complicated set of rules as to how claims should be handled based on the type of medical condition and multiple other factors. This is the main reason it seems so difficult to get a specific answer from Social Security and why different employees will give different answers to the same question because even detailed rules are subject to different interpretations. If just the Disability portion of the POMS were printed on paper, it wouldn't be a shelf or two, it would be a full room of shelves. You can see the public version on line at: https://secure.ssa.gov/apps10/poms.nsf/Home?readform

Because of the limit on new hires, the backlog of disability claims has grown to over 800,000 claims that are waiting for a decision at one level or another in the application and appeals process. While Social Security has made several changes to address this, the backlog is slow to shrink.

In an effort to reduce the backlog, an additional 7,000 employees have been hired and they are being placed in specially created Extended Service Team (EST) offices around the country to help the state DDS offices process claims. They also are expanding the Compassionate Allowance claims; which speeds the processing of very serious medical conditions such as ALS, terminal cancer, and other catastrophic diseases.

There are three main levels of appeals, and two more above that including a suit in federal court. At the initial application stage, two-thirds of all claims are denied. At the first level of appeal, Reconsideration, 85% of those appeals are denied. Only when a claim reaches the Administrative Law Judge does the denial rate drop to about 40% of those put before a judge. It is not unusual for it to take a claimant two years from the time of application before a final decision is made at the Administrative Law Judge Level. Even initial claims are taking three to six months to process, the time varying by state.

The result of all of this is that claims are being reviewed much faster and less thoroughly than they should be. Why else would the denial rate be so high until it reaches the level where a judge and claimant and his or her advocate actually meet face to face and discuss the issues.

At the initial and reconsideration level, trained personnel review the claim and make a recommendation. Doctors only review their recommendation and agree with it or send it back for more information. Time constraints limit the amount of follow-up that can be made to the treating physicians who haven't submitted their medical records to DDS. And, of course, at the doctors' offices, requests for medical records from Social Security or disability insurance companies are not a high priority.

The various DDS offices contract with local physicians to give physical and mental examinations to claimants whose medical records don't contain enough information to make a decision. Unfortunately, these physicians are also rushed and underpaid. The examinations tend to be very cursory, some lasting as little as 8 to 10 minutes. For someone without a lot of physical signs of their condition such as people with HCV, these Consultative Examinations (CE) rarely generate a claim approval. It is amazing to see an examination of less than ten minutes blossom into a 9 to 12 page examination report, thanks to computers and templates.

The Looming Financial Hurdle

SSI payments come from a different source so this applies only to SSDI benefits. SSDI benefits are paid from a Disability Insurance Trust Fund. A portion of the F.I.C.A. payroll taxes workers pay is set aside into that trust fund with the remainder going into the Retirement Trust Fund.

As you may have read, there are well-publicized estimates that the Retirement Fund will be exhausted sometime around 2020 to 2025 unless changes are made in the funding and/or payment of retirement benefits.

If you think that is serious, you should know that the Disability Trust Fund is running out of money much faster and that is not a remote possibility. In fact, current estimates are that, without some major revisions, the Disability Trust Fund will be empty in 2016, three years from now.

If more money isn't directed into the fund either through higher F.I.C.A. payroll taxes or a larger allocation of the current taxes, even persons currently on SSDI could have their benefits reduced by up to 20%. This is because once the Disability Trust Fund is depleted the

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income from current payroll taxes will only generate 79% of the Disability benefits being paid out.

Contributing to this looming shortfall has been the dramatic increase in people applying for Disability benefits. In 2001, 1.5 million people applied for Disability benefits. By 2011, because of the aging population and the severe economic recession, the number of applicants grew to almost 3 million applicants. The number of people actually collecting Disability Benefits has increased by more than 23% in the past five years to approximately 11 million disability beneficiaries.

And Then, of Course, There Is the Political Issue

As you are well aware, Congress has not been eager to increase spending on any social programs, particularly expensive programs like Social Security, Medicare, and Medicaid. They tend to be cautious about cutting programs for seniors as they are a huge voting block. However, the number of people collecting Disability Benefits is extremely small compared to the number of persons collecting Retirement Benefits and using Medicare. The Disability Program is a much easier target.

Disability claims always rise during periods of economic downturns. During such times, elected officials love to trot out the issue of abuse of the system as we are starting to see now with more anecdotes than facts. There are too many undeserving recipients of benefits, "cheaters" they call them. Remember the stories of the welfare queens driving their Cadillacs to collect their checks? More are starting to be heard. By extension, the implication is many, or even most, disability recipients are malingering.

There are also complaints about the poor handling of claims making benefits too easy to obtain. Senator Tom Coburn of Oklahoma discovered a man hired by him to trim trees at his home was also collecting Disability Benefits. An "investigation" was launched to learn how widespread cheating was. The investigation ended up so flawed in its sample and conclusions the chairperson of the Congressional subcommittee investigating refused to sign off on it.

Anyone who claims it's too easy to get Disability has not applied or helped a friend or family member through the process.

Snapshots

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fewer persons of South Asian ethnicity (7% vs. 73%) and more solid-organ transplant recipients (47% vs. 0).

The Bottom Line: This research provides valuable information about HEV in the U.S., particularly about HEV unrelated to traveling outside the country. Chronic HEV may lead to cirrhosis, and is increasingly found among solid-organ transplant recipients.

Editorial Comment: Although research about HCV/HEV co-infection is scant, presumably the presence of a second virus with HCV may have serious consequences, as is the situation with hepatitis B virus or HIV. Anyone with signs or symptoms of any liver disease or another virus should see a medical provider. Those with recent travel history or recipients of solid-organ transplant may be at higher risk. For more information: www.cdcnpin.org/scripts/hepatitis/index.asp

Article: Telaprevir to Boceprevir Switch Highlights Lack of Cross-Reactivity – Amanda Carlson, et al.

Source: Clinical Infectious Diseases 15 February 2013:56(4):552–4

Case studies usually involve only one patient and a subjective design, so information contained in them is not compelling evidence. However, this is a pertinent case study worth discussing.

A 54 year-old man was treated for HCV with telaprevir, peginterferon and ribavirin. He developed a rash after 8 days, and was treated with topical cortisone cream and oral diphenhydramine. After 4 weeks, the patient developed intolerable rectal pain and bleeding and an increasing eosinophil count. He wanted to discontinue telaprevir. At this point, the patient's HCV viral load was undetectable, so he was switched from telaprevir to boceprevir while continuing peginterferon and ribavirin. Although boceprevir is a chemically similar protease inhibitor, the itching, skin rash, and anal pain resolved in less than a week. The eosinophil count normalized in 2 weeks. The patient developed mild anemia but otherwise tolerated boceprevir and achieved an SVR.

The Bottom Line: Switching from telaprevir to boceprevir may be a way to manage telaprevir's side effects.

Editorial Comment: Now that we have two HCV-protease inhibitors and more HCV drugs in development (Janssen's simeprevir, an NS3/4A protease inhibitor and Gilead's sofosbuvir have been submitted to the FDA), our choices are growing exponentially.

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The HCV Advocate offers information about various forms of intervention in order to serve our community. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

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