



# PERSPECTIVE ON THE **RX** PIPELINE

Understanding changes in the medication market and their impact on cost and care.

EnvisionRx continuously monitors the drug pipeline. As treatment options change, we evaluate and share our perspective on the clinical benefits, cost-effectiveness and overall impact to payers and patients. Our Perspective on the Rx Pipeline report provides ongoing actionable insights from our team of clinical experts and the steps we are taking to protect and improve plan performance.

## Included in this Edition

- ▶ CDC Advisory Committee Makes First Product-Specific Recommendation for Shingles Vaccine
- ▶ First Hepatitis C Medication to Offer Eight Week Treatment Now Available

# SHINGRIX

zoster vaccine

**Class:** Vaccines

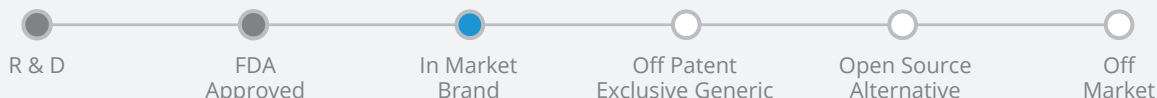
**Manufacturer:** Glaxo-SmithKline

**Mode:** Intramuscular

## CDC Advisory Committee Makes First Product-Specific Recommendation for Shingles Vaccine

New recombinant, adjuvanted vaccine preferred over live, attenuated version.

### PIPELINE STAGE



### TIMING

When will payers be impacted?



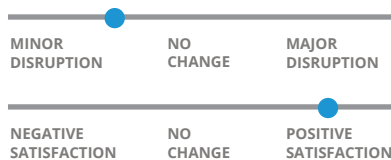
### CLINICAL EFFECTIVENESS

Compared to available options, is this drug better for treatment?



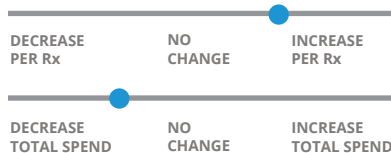
### PATIENT EXPERIENCE

Will this positively or negatively impact members?



### PAYER IMPACT

How will this influence Rx spend?



### Situation Summary

Shortly after the Food and Drug Administration's (FDA's) approval of Shingrix for the prevention of herpes zoster (shingles) on October 20, 2017, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted to recommend the vaccine over Zostavax® for adults 50 years of age and older. The group also voted in favor of immunizing this adult population with Shingrix even if they have already been vaccinated with Zostavax.

This is the first time this committee has ever shown preferential status for a specific brand product.

**From chickenpox to shingles:** Shingles comes from the same virus that causes chickenpox and in fact, you can only get shingles if you've had chickenpox. As you age, your immune system becomes weaker and the chickenpox virus that was lying dormant can move from your nervous system to your skin as a painful, blistering rash. Even after the rash is gone, people commonly experience post-herpetic neuralgia, or severe pain in areas of the rash, as a long lasting complication.<sup>[1]</sup>

**Highly prevalent with a hidden impact on employers:** The CDC reports that one out of every three people in the U.S. will develop shingles, which costs approximately \$1 billion in direct and indirect medical expenses each year.<sup>[2]</sup> It also results in an average of three weeks of missed work per patient per episode.

**Shingrix vs Zostavax:** Zostavax is a live attenuated vaccine and Shingrix is a recombinant adjuvanted vaccine. A live attenuated vaccine uses a small protein from the live virus to trigger the immune system to mount a defense against the virus, whereas a recombinant adjuvanted vaccine uses a protein that is created in a lab using genetic material to simulate the virus. As a result, the Shingrix vaccine has fewer restrictions of patient

# SHINGRIX

*zoster vaccine*

## PAYER ACTION PLAN

- **Review Plan**

EnvisionRx recommends that plan sponsors review their coverage policies on vaccinations to ensure that shingles prevention is available to members. It is also important to review policies to verify if the plan design for vaccine coverage is in the correct benefit (medical vs. pharmacy) based on cost/reimbursement. Please note, for those using EnvisionRx formularies, Shingrix has been assigned to a preferred tier and no action is required.

populations, such as people with immunosuppression issues or who are pregnant, and it boosts effectiveness. Shingrix is a two-dose vaccine series given two to six months apart intramuscularly versus the one-dose of Zostavax administered subcutaneously.

In clinical studies, Shingrix showed similar effectiveness in all age groups and had much higher rates of effectiveness compared to Zostavax, which has a marked decrease in efficacy in the older population. Based on CDC estimates, the effectiveness of Shingrix in patients 60-69 years old was 97%, while it was only 64% for Zostavax. In patients over 80 years old the difference is much more dramatic, with an estimated efficacy of 91% for Shingrix and only 18% for Zostavax.

## Impact to the Pharmacy Care Experience

**Formulary:** Due to the superior clinical effectiveness of the new vaccine, along with the recommendations of the ACIP, EnvisionRx is moving Shingrix to a preferred tier. This indicates that the new vaccine should be the first option for protection against an active shingles infection and post infection complications. By providing a simpler path for members to receive the superior product, occurrences of the disease can be decreased, along with the cost burden.

The cost for a single injection of Zostavax is approximately \$233 and the price for a two-dose series of Shingrix injections will be about \$280. While the cost of the Shingrix vaccine is more, those receiving Zostavax would have to be re-vaccinated with Shingrix, making Shingrix more cost effective.

**Member Engagement:** Even though Shingrix costs slightly more than Zostavax, with Shingrix in a preferred tier, members may actually receive a lower cost share for using Shingrix in order to encourage them to choose this more effective option. By moving Shingrix to a preferred status, EnvisionRx is also reducing the number vaccines a patient will need and providing better protection against the disease. Additionally, because the vaccine design has fewer limitations on the patient populations who can receive it, the treatment is more accessible to members. Similar to Zostavax, Shingrix can be administered by doctors or pharmacists at retail locations, including Rite Aid.

**Clinical:** Shingrix should be administered to patients over 50 years of age, regardless of their immunization history with Zostavax. Shingrix can be given as soon as eight weeks after Zostavax was administered.

# MAVYRET™

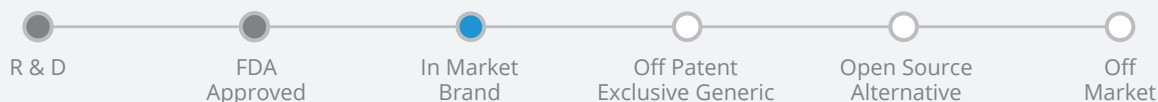
glecaprevir/pibrentasvir

**Class:** HCV NS5A Inhibitors;  
HCV NS3/4A Protease Inhibitors  
**Manufacturer:** Abbvie  
**Mode:** Oral

## First Hepatitis C Medication to Offer Eight-Week Treatment Now Available

Mavyret offers breakthrough treatment at a lower cost, spurring improved prices.

### PIPELINE STAGE



### TIMING

When will payers be impacted?



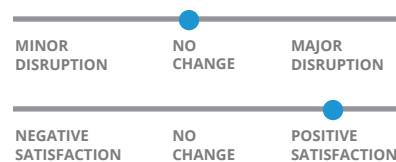
### CLINICAL EFFECTIVENESS

Compared to available options, is this drug better for treatment?



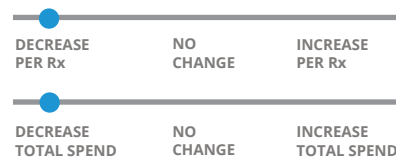
### PATIENT EXPERIENCE

Will this positively or negatively impact members?



### PAYER IMPACT

How will this influence Rx spend?



### Situation Summary

The FDA has approved Mavyret, a pan-genotypic (treats genotypes 1-6) medication for the treatment of Hepatitis C Virus (HCV) in adult patients without cirrhosis and who have not previously been treated.

**An expensive, but curable condition:** HCV is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. According to the CDC, an estimated 2.7 to 3.9 million people in the United States have chronic HCV.<sup>[3]</sup> Advances in medicine have provided several treatment options, offering a cure for this once incurable disease, but HCV is one of the most costly therapeutic classes.

**New option brings big savings and faster therapy:** The Average Wholesale Price (AWP) for HCV medications ranged from \$65,500 to \$113,400 per treatment prior to the introduction of Mavyret, which is being offered at a staggeringly low AWP of \$31,700. This is causing manufacturers of other therapies to offer rebates and incentives to compete. Additionally, Mavyret, a once-daily, interferon-free medication is the first treatment that provides a regimen of only eight weeks—significantly shorter than 12+ weeks of other treatments.

### Impact to the Pharmacy Care Experience

**Formulary:** Due to its clinical effectiveness and lower cost, Mavyret was added to the EnvisionRx Standard and Select formularies as a preferred medication alongside Harvoni® and Epclusa® effective January 1, 2018. All three medications are remaining on our formularies due to their varying clinical values—Harvoni has a pediatric indication, Epclusa can be used in decompensated cirrhotic patients and Mavyret can be used in end-stage renal disease patients.

# MAVYRET™

glecaprevir/pibrentasvir

## PAYER ACTION PLAN

- **Review Formulary Design**

Mavyret has been added to a preferred tier for EnvisionRx clients using Standard or Select formularies. For clinical reasons, coverage should include Mavyret, Harvoni and Epclusa.

- **Specialty and Prior Authorization Considerations**

EnvisionRx recommends that payers review their plans and include a mandate that HCV drugs be filled at a specialty pharmacy that offers an aggressive, patient-centered, reportable Hepatitis C clinical program in order to achieve optimal outcomes. Additionally, prior authorizations are recommended to ensure the patient is a fit for this therapy.

Please note, for those using Envision formularies, Mavyret has been assigned to a preferred tier with prior authorization and no action is required.

Additionally, EnvisionRx was able to leverage Mavyret's low cost to negotiate significantly higher rebates on Gilead's Harvoni and Epclusa that were implemented in October 2017 and have substantially lowered spend within the HCV therapeutic class for plan sponsors.

**Pharmacy Network:** As with other curative therapies, Mavyret is available at many retail pharmacies, but due to its complex nature, a specialty pharmacy should be mandated. A specialty pharmacy will be more knowledgeable on the treatment and better able to monitor and manage adherence and side effects.

**Plan Design:** Because Mavyret is not optimal for all patients, EnvisionRx has instituted a prior authorization to ensure the correct clinical parameters are matched with the correct treatment by reviewing liver status, genotype, prior treatment history, concurrent drugs, renal function and other concerns. These clinical parameters will also determine the appropriate length of therapy so the correct amount is dispensed.

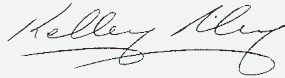
**Clinical:** In clinical studies of 2,300 adults with genotype 1-6 HCV infection without cirrhosis or mild cirrhosis, Mavyret resulted in no virus detected in the blood work for 92% to 100% of participants after completing eight, 12 or 16 weeks of treatment, suggesting that the infection was cured.<sup>[3]</sup>

**Member Engagement:** This update will not result in any member disruption and will generate a positive change by providing access to the only pan-genotypic, eight-week therapy for HCV. Due to the complexity, we recommend that all chronic HCV treatment regimens are managed at a specialty pharmacy that offers a high-touch care model with an assessment prior to therapy, monitoring during treatment and followup post therapy. By utilizing a specialty pharmacy, prior to treatment, pharmacists counsel patients on the medication and manage any side effects, over-the-counter drug-drug interactions, alcohol consumption or high-risk behaviors that can compromise the therapy's outcomes. During therapy, pharmacists monitor for any barriers to adherence and provide side effect mitigation strategies. After the last dose is taken, pharmacists confirm the therapy is complete and provide next steps, as well as options to avoid re-infection.

## Our Clinical Steering Committee

The Envision Clinical Steering Committee brings together leaders from across our national pharmacy care company to monitor the drug landscape, provide recommendations on how to address changes, and to ensure our clients and patients are prepared—in advance.

With any new development, we partner with our Pharmacy & Therapeutics (P&T) Committee and consult with our best-in-class specialty pharmacy, to provide a balanced perspective on the clinical effectiveness of all available options, the cost impact to our plan sponsors and patients, and the impact on the overall patient experience.



**Kel Riley, MD**  
*Chief Medical Officer*



Learn more ways to improve patient and plan outcomes  
**visiblydifferent.envisionrx.com**

### Sources

[1] Centers for Disease Control and Prevention. (October 2017). Herpes Zoster Vaccination Information for Health Care Professionals. <https://www.cdc.gov/shingles/hcp/clinical-overview.html>

[2] Centers for Disease Control and Prevention (October 2017). About Shingles (Herpes Zoster). <https://www.cdc.gov/shingles/about/overview.html>

[3] U.S. Food & Drug Administration (2017). FDA approves Mavyret for Hepatitis C. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570038.htm>

### ABOUT ENVISIONRX | ENVISIONRX.COM

EnvisionRx is a Pharmacy Benefit Manager (PBM), providing affordable and effective prescription drug coverage for employers and health plans. Using its proprietary EnvisionCare model, EnvisionRx optimizes all aspects of the pharmacy care experience to consistently achieve better patient and plan outcomes.

