POINT OF VIEW:

Gilead creates a subsidiary through which to offer authorized generics for hepatitis C virus (HCV) products Harvoni and Epclusa

Gilead is pursing authorized generics (AGs) as part of a two-fold strategy:

1. To combat competition from AbbVie's Mavyret® (glecaprevir/pibrentasvir), priced at a significant discount to Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg) tablets and Epclusa® (sofosbuvir 400 mg/velpatasvir 100 mg) tablets and with shorter treatment duration for certain indications (8 weeks vs 12 weeks)
2. To capture a greater proportion of market share in the untapped HCV Medicaid population

Drug prices (REDBOOK):

	WAC (1 month)	WAC (full treatment)	AWP (1 month)	AWP (full treatment)
Harvoni	$ 31,500	$ 94,500	$ 37,800	$ 113,400
Epclusa	$ 24,920	$ 74,760	$ 29,904	$ 89,712
Mavyret	$ 13,200	$ 26,400*	$ 15,840	$ 31,680*

AWP=average wholesale price; WAC=wholesale acquisition cost.

*Treatment duration ranges from 8 weeks to 16 weeks depending on the patient case. In this case, an 8-week treatment duration was assumed.

Impact

Creating an AG in light of the rapid decline in the market's price allows Gilead to lower its price faster and capture more Medicaid market share. It takes time for manufacturers to lower the list price of the branded option in light of best price and existing contracts with various payers. Other manufacturers have simply lowered their drug prices and/or created an additional NDC at a lower price.

Given the high Medicaid payer mix in the HCV patient population, and Medicaid's reluctance to encourage HCV screening given the high cost of therapy, Gilead has decided to pursue a strategy of providing a lower cost drug option to serve this customer segment. Beneficiaries with a co-insurance payment requirement would benefit from a lower WAC price, and we know that affordability can influence adherence.

It is worth noting that Amgen recently lowered the price of Repatha by 60% citing patient affordability and its impact of patients staying on therapy. Amgen's reported reason for the discounts was to drive more volume at the expense of margin. It is likely that the decision to decrease the price was driven

by other factors including new and effective competitive entrants, ICER press, and provider reluctance to prescribe in the face of significant utilization management hurdles.

Gilead CEO John Milligan recently made this public statement:

> "*Over the past several months, we have searched for a viable path to reduce the list price of our branded HCV medications so that their cost to payers is more easily understood. Unfortunately, existing contracts with insurers, together with laws associated with government pricing policies, make it unacceptably difficult to quickly lower the list price to reflect the discounted cost of our medications. As a result, we made the decision to launch a generic version of our leading HCV medications in January 2019. These generics will be marketed by a subsidiary and will have a list price of $24,000 for the most common course of treatment – a price that is similar to what health insurers and governments will pay for our branded HCV medicines after rebates and discounts and a $50,760 reduction off the list price of Epclusa. Health insurers will have the choice of covering our branded medications or the authorized generics. This choice can make a meaningful difference, particularly for patient populations with the greatest need… We also expect these authorized generics to open up access to our medications for people insured by Medicaid, by offering substantial savings to state managed Medicaid plans that do not currently benefit from negotiated rebates.*"

Considerations for manufacturers

Payers we spoke to believe that Gilead's AG strategy was a last resort given that the current Harvoni price was being driven out of the HCV market by new and equivalent entrants. The same may be true in the other therapeutic classes with new entrants on the horizon. Lower price points may ease access barriers for patients and thereby create the opportunity to capture additional market share.

Medicare and commercial payers prefer rebated discounts to list price reduction. Depending on the price level, a low WAC price strategy is not likely to appeal to these customers. Authorized generics, as a manufacturer strategy, may proliferate if the Trump administration is successful in pushing through anti-kickback legislation relative to rebating.

Entrée Health Point of View

According to the lay press and company statements, the AG list price will be about 25% less than the current list price for Harvoni. As such, payers with rebate agreements in place are not likely to opt for the AG. The AG price is not as attractive as the rebated discount. Moreover, commercial and Medicare plans generally value the spread pricing/net cost benefit associated with rebate agreements. Field intelligence has indicated Harvoni discounts can be as high as 50%, but this is not substantiated. The lower price that an AG brings to the market will support lower out-of-pocket exposure for patients.

In contrast to Medicaid, Medicare plans will not prefer the AG at 25% off list price. Medicare and commercial plans value net price and rebates from manufacturers. Rebates are not fully passed through CMS and add to Medicare Part D plans' revenue stream.

Embarking on an AG strategy years before LOE may be an option for manufacturers seeking to lower pricing outside of rebating. Consideration of an AG strategy must anticipate additional competitive entrants in the near future with similar or superior clinical benefit.

The price point for HCV products has precluded growth in the market, and many patients remain untreated. A lower price will help bring more patients to treatment by lowering patient out-of-pocket cost exposure. With the lower price, wholesalers are likely to get a lower percentage of the sales, and PBMs will not receive the rebates that they are accustomed to with sales of the branded drug, although an authorized generic is still a brand and can be rebated.

Additional background on authorized generics

The term "authorized generic" drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the lack of brand name, it is the exact drug product as the branded product and is marketed under the same New Drug Application (NDA). A manufacturer may choose to sell the AG at a lower cost than the branded drug. NDA holders must notify the FDA of any AG drugs marketed under their approved NDAs.

According to the FDA, "…the innovator may continue to market the brand name version while also marketing a lower-cost "generic" version of the innovator drug". This is a strategy for the manufacturer of the innovator product to maintain a larger share of the market and compete with generics from other manufacturers.

For more information on how Entrée Health can help your organization navigate market access and communicate value to payers, contact Andrew Gottfried at agottfried@entreehealth.com ***or 212-896-8026.***