Future of HIV Treatments
Innovative Drugs, Higher Costs

An estimated 1.2 million people in the United States are living with the human immunodeficiency virus (HIV). The disease has gone from being considered a death sentence to a chronic disease that can be effectively managed with the right medication therapy. Because there is no cure, patients must continue treatment over the course of their lifetime. The Centers for Disease Control and Prevention (CDC) estimates that the average lifetime cost of treating one patient with HIV is nearly $380,000, in 2010 dollars.

HIV medications are now a $17 billion market

Taming what was once a fatal disease has been possible because of new and innovative treatments that are continually coming to market.

The HIV drug pipeline has seen dramatic shifts in recent years, as more effective medications were developed to treat the disease, and even to prevent it. In the near-term pipeline is ibalizumab, for patients with multi-drug resistant (MDR) HIV. It’s the first drug in a decade to offer a different mechanism of action for treating the virus. Also in development are new generics and additional single-tablet regimens (STRs), which combine several antiretroviral drugs into a single pill that can be taken once a day. We expect the pipeline and the drug market for HIV to remain robust. Ongoing monitoring, effective utilization management (UM) strategies, and a focus on adherence can help control costs for payors, while supporting improved outcomes.

Trend Toward Safety, Simplicity

In 1987, AZT was the first drug approved to treat HIV, and since then more than 25 antiretroviral agents, in six mechanistic classes, have been approved. Established in the 1990s, the game changer was combination highly active antiretroviral therapy (HAART), also called combination antiretroviral therapy (cART), which led to a dramatic decrease in deaths from HIV/AIDS.

In recent years, the market has seen a shift to more expensive single-pill regimens. In 2006, Atripla was the first once-daily STR approved by the U.S. Food and Drug Administration (FDA). It was followed by several others, including Strivid, Triumeq, Genvoya, Odefsey, and Complera. STRs have been shown to improve adherence, which can help decrease the need for hospitalization, and reduce health care costs. Non-adherence is a particularly concerning threat for HIV patients due to the risk of disease complications and drug resistance.

In 2015, Gilead Sciences, Inc. launched Genvoya, which became the most prescribed HIV drug for patients who were either new to therapy or switching from another regimen. Odefsey and Descovy, both tenofovir alafenamide (TAF)-based drugs, by the same manufacturer, were launched last year and also captured large market shares.

TAF-based medications have demonstrated better safety profiles for patients’ bones and kidneys than previous tenofovir disoproxil fumarate (TDF)-based regimens, like Viread, and so have captured market share. Because of their long-term tolerability and safety, we expect TAF-based regimens to continue to see increased development and use.

Preventive Drugs for HIV

Currently, Truvada is the only drug approved for pre-exposure prophylaxis (PrEP) therapy. It is a top trend driver based on per-member-per-month costs, according to CVS Health analysis, followed by Atripla. In June, the FDA granted Teva Pharmaceuticals the right to produce generic Truvada. Following patent litigation, Teva reached a confidential settlement with Gilead, but it is unclear when the first generic version of Truvada will launch.

Insights offers context and perspective about key pharmacy and health care topics.
At CVS Health, we carefully monitor the specialty pipeline to estimate the impact of new drugs on spend and trend. Our suite of specialty management tools, such as UM, copay benefit design, and formulary management — which includes new-to-market review — help ensure appropriate therapy alternatives and drive to the lowest net cost while improving outcomes.

Our patient support programs, such as embedded care management nurses* through CareTeam Choice HIV, help improve adherence to medications and enable better management of symptoms and comorbidities, reducing downstream costs for payors and improves outcomes for patients.

### In the Pipeline

Although there are several drugs for resistant HIV currently available, including Fuzeon, Aptivus, and Intelect, ibalizumab has a unique mechanism of action and would be administered every two weeks by intravenous infusion. If approved, ibalizumab could fill a critical need for patients with multi-drug resistant HIV given its unique mechanism of action. It is also the first-ever HIV treatment not to require daily dosing. The FDA is expected to make a decision in the first quarter of 2018.

There are three new STRs in the near-term pipeline, including an investigational once-daily STR by Gilead, which is comparable in efficacy and its safety profile to existing drugs in phase 3 trials. However, it has existing competitors in Genvoya and Triumeq, so is unlikely to significantly impact spend or trend. Approval is expected in the first quarter of 2018.

Janssen’s in-development drug, which combines Tivicay and Edurant, has the potential to be a blockbuster because it would be the first two-drug STR, and it has demonstrated similar efficacy to three- and four-drug regimens in phase 3 trials. Because it would be a complete regimen with two drugs, instead of three or four, it is expected to have fewer side effects. However, it would be limited for use as a maintenance therapy in patients who are already virologically suppressed on an alternative HIV regimen. A decision from the FDA is expected in the fourth quarter of 2017.

Symtuza, which is expected to launch in the third quarter of 2018, is projected to be priced about the same as other drugs in that category and so is also unlikely to provide much cost relief.

There are a few generics in the pipeline. However, these agents represent a small percentage of the HIV market, so they are unlikely to result in a significant impact on drug spend. Anticipated in the fourth quarter of this year are the following generic versions of existing drugs:

- **TDF, generic for Viread**
- **Atazanavir, generic for Reyataz**
- **Efavirenz, generic for Sustiva**

Generic components for some of the expensive single-pill regimens, such as Atripla, may become available in the coming years, although exact launch times are unclear due to uncertainties around patents. We will continue to monitor the intelligence around the availability of these generic components and evaluate possible cost savings opportunities.

### Ongoing Monitoring

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**What impact could the drugs in the HIV pipeline have on your plan? Ask Us**

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*The rare disease management nurse is providing support to CVS Specialty under the Embedded Accordant Model.

Adherence results may vary based upon a variety of factors such as plan design, demographics and programs adopted by the plan. Client-specific modeling available upon request.

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