Research Letter

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Estimated changes in price discounts for tenofovir-inclusive HIV treatments following introduction of tenofovir alafenamide

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We estimated list and net prices for tenofovir disoproxil fumarate (TDF) products Truvada, Complera, and Stribild, and their tenofovir alafenamide (TAF) versions Descovy, Odefsey, and Genvoya. Gilead offered discounts for Descovy that resulted into lower net prices compared to Truvada. This strategy encouraged patients switching from Truvada to Descovy before the availability of generic Truvada. Conversely, Gilead offered lower discounts for Odefsey and Genvoya, which resulted into higher net prices compared to Complera and Stribild.

In 2015–2016, Gilead Sciences received approval for a series of revised HIV treatments that incorporated tenofovir alafenamide (TAF) instead of tenofovir disoproxil fumarate (TDF). TAF is a formulation of tenofovir that Gilead identified as possibly having lower toxicity [1]. These new approvals resulted into three evergreened TDF/TAF product lines: Truvada (TDF/emtricitabine) and Descovy (TAF/emtricitabine); Complera (TDF/emtricitabine/rilpivirine) and Odefsey (TAF/emtricitabine/rilpivirine); and Stribild (TDF/elvitegravir/cobicistat/emtricitabine) and Genvoya (TAF/elvitegravir/cobicistat/emtricitabine).

Patent protection for TDF expired in 2018, with a generic of TDF/emtricitabine launching in 2020. Patents for TAF are however claimed until 2032 [1]. In anticipation of generic competition, Gilead followed an explicit strategy of converting patients from the TDF-based originator products to the evergreened TAF-based combinations to avoid generic substitution [1]. This was particularly the case in pre-exposure prophylaxis (PrEP), where there is limited clinical justification to use TAF over TDF [2].

We analyzed Gilead's list and net pricing strategy for TDF and TAF products. We tested whether the pricing strategy differed between the Truvada/Descovy pair, approved for PrEP, and the HIV treatments Complera/Odefsey and Stribild/Genvoya.

We estimated list price, net price, and market share for Truvada, Descovy, Complera, Odefsey, Stribild, and Genvoya in 2011–2019. We used five data sources: net sales and total units from SSR Health [3]; claims for a 5% random sample of Medicare beneficiaries; Medicare Part D prescriber utilization files; Medicare and Medicaid spending dashboards; and Health Resources & Services Administration list of 340B eligible institutions.

List price was estimated as the average reimbursement rate per unit in Medicare Part D. Net price was estimated as the difference between list price and average commercial discount [Pharmacy Benefit Manager (PBM) rebate]. To estimate commercial discounts, we calculated the difference between gross (number of total units sold × list price) and net sales, and subtracted Medicaid and 340B discounts. The remaining difference was amortized across commercial and Part D units (full methodology in Supplemental Digital Content, http://links.lww.com/QAD/C654) [4]. Market share was the proportion of units represented by each drug in a TDF/TAF pair.

For the Truvada (TDF)/Descovy (TAF) pair, Descovy mirrored the list price of Truvada, but Gilead offered greater commercial discounts on Descovy, resulting in 12.0% lower average net price at launch (Fig. 1). By 2019, the year when Descovy was approved for PrEP, the new product Descovy had reached a market share of 20.3%.

For the Complera (TDF)/Odefsey (TAF) pair, Odefsey mirrored the list price of Complera; however, the average net price of Odefsey was 21.6% higher than Complera at launch. By 2019, the new drug Odefsey had reached a market share of 78.2%.

For the Stribild (TDF)/Genvoya (TAF) pair, Genvoya's list price was 7.5% lower than Stribild's; however, the average net price Genvoya was 5.7% higher than Stribild at launch. By 2019, the new drug Genvoya had reached a market share of 87.6%.

Gilead adopted different discount strategies for its TAF-based PrEP product (Descovy) than its HIV treatment products (Odefsey and Genvoya). Descovy received a PrEP indication in October 2019, 1 year before the launch of generic Truvada. By offering greater commercial discounts on Descovy than Truvada, Gilead reduced barriers to switching patients from Truvada to Descovy before generic availability, hindering insurers' ability to switch patients back to generic Truvada. This strategy was successful, as an analysis by the Centers for Disease Control and Prevention reported that in the nine months following the Descovy PrEP indication, 30% of PrEP prescriptions transitioned from Truvada to Descovy [1,5]. The aggressive discounting strategy followed for Descovy likely reflects the limited

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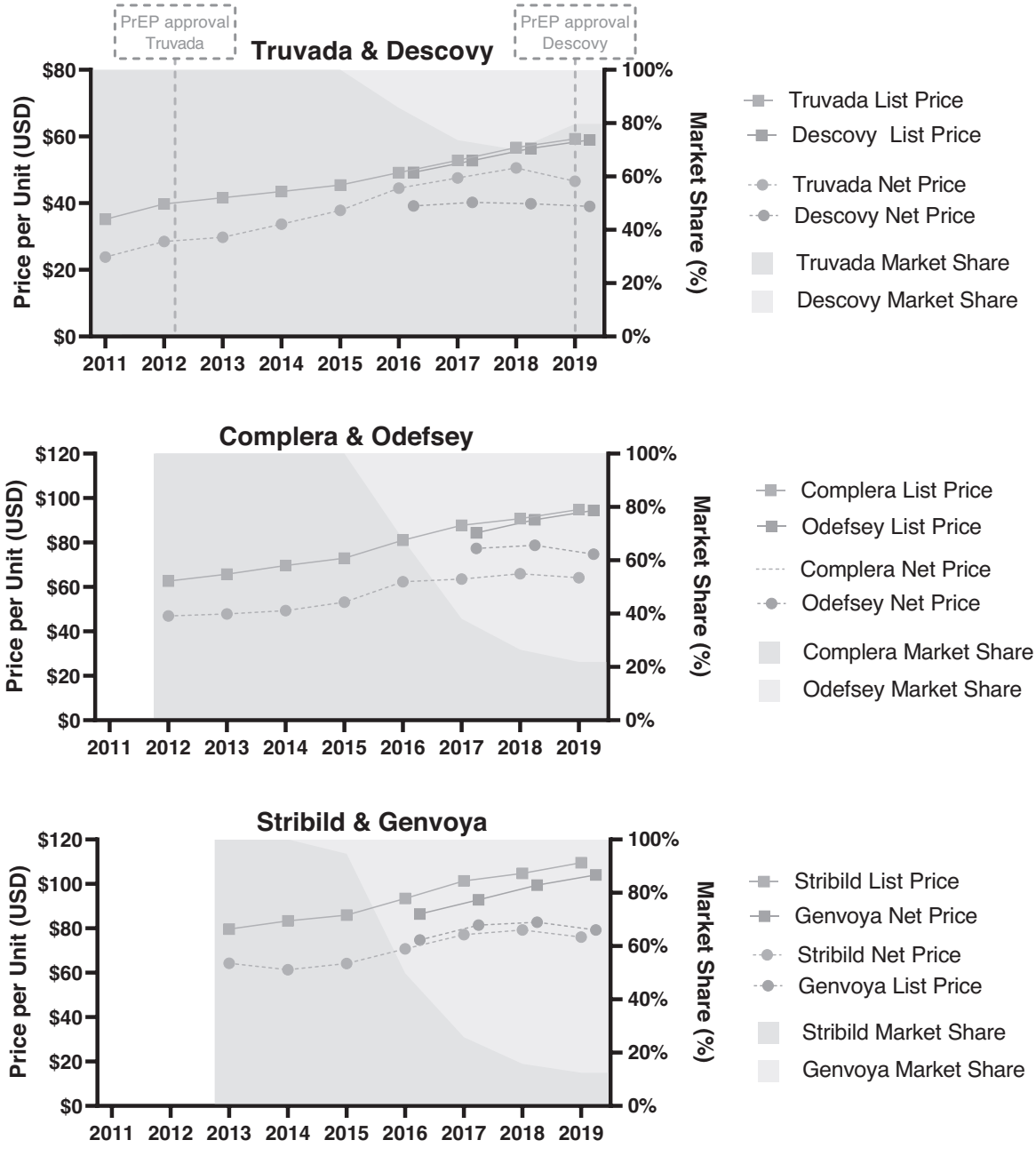

Fig. 1. Trends in list prices, Net prices and market share, 2011–2019. List prices were estimated as average reimbursement rates in Medicare Part D. Net prices were estimated using data from SSR Health, Medicare, Medicaid, and the Health Resources and Services Administration, as described in the Supplemental Digital Content, http://links.lww.com/QAD/C654. Market Share represent the proportion of units accounted by for each product, and was obtained using sales data from SSR Health. Drugs were grouped in pairs according to active ingredients.

clinical justification to use TAF over TDF for PrEP, where long-term toxicity is a lesser concern.[2]

Conversely, Gilead offered lower commercial discounts for its TAF-based HIV treatments, even though Genvoya had a lower list price. With greater clinical concern for long-term toxicity with TDF in HIV treatment than PrEP, insurers are less able to mandate the lower net cost TDF product or a future generic version. As a result, Gilead's introduction of TAF-based HIV treatments resulted in greater net spending for commercial insurers, even with similar or lower list prices than the TDF versions.

Our analysis demonstrates that evergreening through the introduction of new product formulations resulted in greater net spending for insurers, even with similar or

lower list prices than the TDF versions and the advent of generic formulations.

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Conflicts of interest

There are no conflicts of interest.

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