

HIV antiviral drugs

2024 annual report

This report was formerly called "HIV antivirals"

Engrossed Substitute Senate Bill 5187; Section 211(46); Chapter 475; Laws of 2023

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Clinical Quality and Care Transformation P.O. Box 45502 Olympia, WA 98504 Phone: (360) 725-1612 Fax: (360) 586-9551 hca.wa.gov

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Executive summary

This is the second annual report submitted by the Health Care Authority (HCA) to the fiscal committees of the Washington State Legislature as directed in Engrossed Substitute Senate Bill 5187; Section 211(46); Chapter 475; Laws of 2023.

"...beginning January 1, 2023, upon initiation or renewal of a contract with the authority to administer a Medicaid managed care plan, a managed health care system shall provide coverage without prior authorization for all federal Food and Drug Administration-approved HIV antiviral drugs. By December 1, 2023, and December 1, 2024, the authority must submit to the fiscal committees of the legislature the projected and actual expenditures and percentage of Medicaid clients who switch to a new drug class without prior authorization..."

This report describes the actual and projected utilization, expenditures, and percentages of Apple Health (Medicaid) clients who start or switch to a new human immunodeficiency virus (HIV) treatment or preexposure prophylaxis (PrEP) drug since removing prior authorization.

Apple Health fee-for-service and managed care plans cover all drugs used for HIV treatment or PrEP without prior authorization as of January 1, 2023. This report includes:

- Historical data from 2019 through 2022, before removal of prior authorization.
- Eighteen months of data (January 2023 through June 2024) after removal of prior authorization.

Key findings in the data analysis include:

- Net costs for HIV medications rose from \$86.35 million in 2022 to \$92.66 million in 2023. Net costs are projected to be \$94.05 million in 2024.
- Net cost per client-month (NCPCM) in 2022 was \$1,887.30. After removing prior authorizations in 2023, the NCPCM rose to \$1,964.52, and the observed cost in the first half of 2024 was \$2,151.40. This aligns with the conclusion in the Institute for Clinical and Economic Review (ICER) report that the Biktarvy—a brand-name medication for treating HIV—had an unsupported price increase from 2022 to 2023.
- Since 2023, single-tablet regimens (STR) have overtaken multi-tablet regimens (MTR) as the most used regimen for the treatment of HIV, increasing from 49.5 percent of regimens in 2022 to 58.1 percent of regimens in 2024. For this analysis, once-daily and twice-daily MTR dosing regimens were grouped together. Most MTR are once-daily regimens. Twice-daily MTR is used for people with drug-resistant HIV.
- In 2024, the average cost per year for a client on an MTR is projected to be \$11,589.24, whereas the average cost per year for a client on STR is projected to be \$19,448.52.
- HCA and Department of Health (DOH) lack robust health outcomes data to properly measure the impact of removing prior authorization on viral suppression.

Based on data analysis, removing prior authorization for HIV medications has coincided with a shift in drug utilization and an increased net cost per client-month. Without access to health outcome data for relevant populations, we are unable to infer whether there are gains in health outcomes, such as viral suppression.

Background

Drugs used to treat human immunodeficiency virus (HIV) or for pre-exposure prophylaxis (PrEP) were added to the Apple Health Preferred Drug List (AHPDL) in January 2018. These medications were covered by Apple Health before the creation of the AHPDL, but preferred status and coverage criteria were different between the fee-for-service (FFS) program and managed care organizations (MCOs). January 2018 marked the first time all Apple Health clients had access to the same preferred medications with the same coverage criteria.

In August 2020, as part of routine drug class reviews, HCA applied a clinical policy to guide patients and providers to less costly, equally effective treatments. Data from clinical trials on safety and efficacy, plus pharmacy claims data showing costs and utilization, suggested preferring lower cost therapies over more expensive therapies would save the state money without decreasing health outcomes. Patients or providers unable to use or tolerate the preferred medications could request prior authorization for a higher cost regimen. By providing documentation showing an equally effective, less costly regimen was inappropriate, patients could access the appropriate medications on the AHPDL.

Federal agencies charged with addressing the HIV epidemic recommend states minimize barriers and include all HIV treatment regimens on their preferred drug lists, including but not limited to single-tablet regimens. In adherence to ESSB 5187 Section 211(46), effective January 1, 2023, HCA changed the AHPDL to ensure all drugs used for HIV or PrEP were covered without prior authorization.

Findings

For this report, HCA analyzed pharmacy claims data from January 2019 through June 2024. This is an additional 12 months of data since the 2023 report. The additional data continues to show the same trends in HIV costs and utilization since removing prior authorization criteria for HIV medications.

Overall financial findings

The HIV Summary Data in Table 1 shows the utilization of HIV medications in the Apple Health population from 2019 through mid-2024 and forecasts to 2025. The modeling for the remainder of 2024 through 2025 uses annualized pharmacy claims data from 2023 and an assumption of flat costs per client-month for future years. Table 2 presents this information as a percentage change from the prior year.

Table 1: HIV summary data, treatment and PrEP, 2019 to 2025 projections

| Calendar year | Paid amount (millions) | Paid amount net of rebates (millions) | Distinct HIV client count | Client- months | Net cost per client-month (PCPM) | Utilization rate |
|------------------|------------------------------|---|---------------------------------|-------------------|--|---------------------|
| 2019 | \$103.02 | \$68.00 | 5,874 | 36,123 | \$1,882.47 | 0.27% |
| 2020 | \$114.44 | \$73.31 | 5,937 | 39,041 | \$1,877.80 | 0.28% |
| 2021 | \$114.29 | \$80.33 | 6,592 | 41,894 | \$1,917.34 | 0.34% |
| 2022 | \$119.56 | \$86.35 | 7,429 | 45,751 | \$1,887.30 | 0.40% |
| 2023 | \$126.43 | \$92.66 | 8,057 | 47,167 | \$1,964.52 | 0.43% |
| 2024* | \$63.38 | \$47.98 | 6,237 | 22,304 | \$2,151.40 | 0.42% |
| 2024** | \$124.23 | \$94.05 | 7,758 | 45,419 | \$2,070.80 | 0.42% |
| 2025+ | \$122.84 | \$93.00 | 7,672 | 44,912 | \$2,070.80 | 0.42% |

The table shows actual and forecasted annual expenditures and utilization for HIV drugs starting in 2019.

*Actual amounts through June 2024.

**Projected using corresponding half-year versus full-year ratios from calendar year (CY) 2023. CY 2024 total number of clients was obtained from the February 2024 Medical Assistance Expenditure Forecast. CY 2024 projected total values are based on expectations for increased rebate trends based on average invoiced rebate percentage from Q1 2024.

⁺Projected

Table 2: Percent change in HIV summary data, 2019 to 2025 projections

| Calendar year period | Change in paid amount | Change in paid amount net of rebates | Change in distinct HIV client count | Change in client- months | Change in net cost per client- month (pcpm) | Change in utilization rate |
|-------------------------|-----------------------------|--|--|--------------------------------|---|----------------------------------|
| 2019 to 2020 | 11.1% | 7.8% | 1.1% | 8.1% | -0.2% | 1.1% |
| 2020 to 2021 | -0.1% | 9.6% | 11.0% | 7.3% | 2.1% | 23.2% |
| 2021 to 2022 | 4.6% | 7.5% | 12.7% | 9.2% | -1.6% | 15.6% |
| 2022 to 2023 | 5.7% | 7.3% | 8.5% | 3.1% | 4.1% | 7.7% |
| 2023 to 2024** | -1.7% | 1.5% | -3.7% | -3.7% | 5.4% | -1.1% |
| 2024** to 2025+ | -1.1% | -1.1% | -1.1% | -1.1% | 0.0% | 0.0% |

This table shows the percent change between years for Table 1.

**Projected using corresponding half-year versus full-year ratios from CY 2023. CY 2024 total number of clients was obtained from the February 2024 Medical Assistance Expenditure Forecast. CY 2024 projected total values are based on expectations for increased rebate trends based on average invoiced rebate percentage from Q1 2024.

+Projected

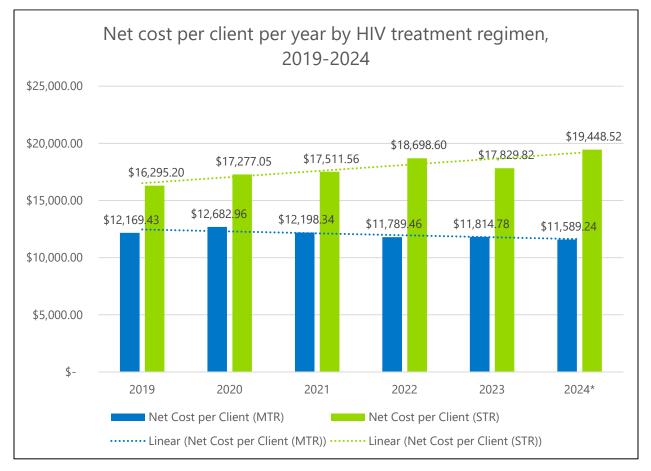
This data shows steady increases from 2019 to 2022 in Apple Health clients utilizing HIV medications and a corresponding increase in the **paid amount net of rebates**. In 2023, the increase in **client-months** slowed and **cost per client-month** increased sharply. The projected 2024 utilization continues the trend, with a projected increase in **paid amount net of rebates** despite declines in both **clients** and **client-months**. It appears the main driver of increasing **cost net of rebates** since the removal of prior authorization criteria is the **net cost per client-month**, which increased from \$1,887.30 in 2022 to \$2,151.40 in the first half of 2024, a 14 percent increase.

HIV treatment financial findings

To investigate the factors driving the increase in **net cost per client-month**, HCA reviewed data from clients who were using MTR, which includes drug regiments that may be dosed once-daily or twice-daily, and STR for the treatment of HIV. Most MTR are taken once daily. Twice a day MTR is used for drug resistant HIV.



This graph shows the change in net cost per client per year by HIV treatment regimen from 2019 to 2024.



*Projected costs for the full calendar year based on partially available 2024 claims data.

In 2022, the average cost per year for a client on an MTR was \$11,789.46 whereas the average cost per year for a client on STR was \$18,698.60, a 58.6 percent increase over the cost of MTR regimens. In 2024, the average cost per year for a client on an MTR is projected to be \$11,589.24 whereas the average cost per year for a client on STR is projected to be \$19,448.52, a 67.8 percent increase over the cost of MTR regimens.

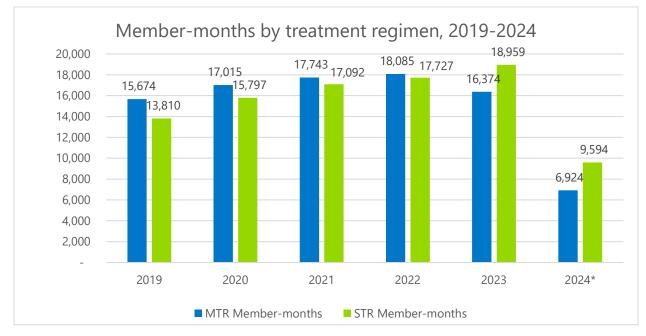
The trendlines for MTR and STR **net cost per client per year** appear to be moving in opposite directions. The cost of MTR is decreasing over time, partly due to the introduction of less costly generic alternatives, whereas the cost of STR is increasing.

This observation is supported by the Institute for Clinical and Economic Review (ICER), who published a report in December 2024 with a review of drug price increases. The report concluded that Biktarvy, an

STR in this analysis, had an unsupported price increase between 2022 and 2023, meaning the price of the drug increased without evidence of additional benefits or reduced harms.

Next, HCA analyzed the shift in utilization between the MTR and STR treatment regimens. The graphs below show more detail about which types of drug regimens Apple Health clients used from 2019 through the first half of 2024. Graph 2 shows the change in member-months, a measure of how many months a drug was filled for clients during the study period. Graph 3 is specific to patients on existing therapies switching from MTR to STR or from STR to MTR. Graph 4 is specific to patients who were new to HIV medications and whether they started with an MTR or an STR.

Graph 2: Member-months by HIV treatment regimen, 2019–2024

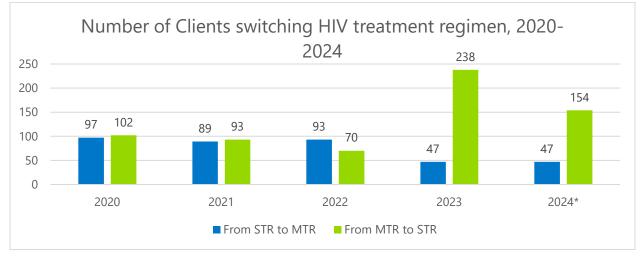


This graph shows the change in member-months by HIV treatment regimen from 2019 to 2024.

*January to June 2024.

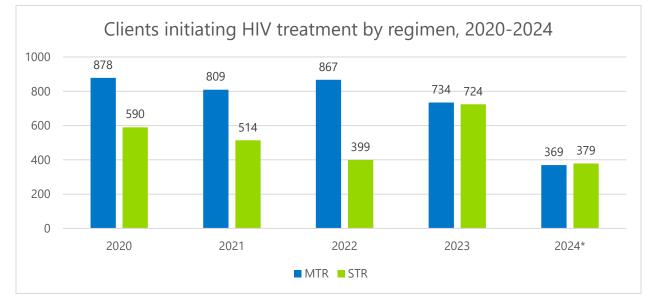
Graph 3: Analysis of switching HIV treatment regimens, 2020–2024

This graph shows the number of distinct clients who switched from MTR to STR or from STR to MTR for the treatment of HIV, starting in 2020.



*January to June 2024.

Graph 4: Analysis of clients starting new HIV treatment regimens, 2020–2024



This graph shows the annual count of new starts who initiated treatment on MTR or STR starting in 2019.

*January to June 2024.

These graphs show a change in the way patients start and switch HIV regimens. Graph 2 shows a shift in drug utilization between treatment regimens in 2023, the first year after prior authorization requirements were removed. Graph 3 shows a noticeable change in behavior beginning in 2023. MTR to STR was only 48.7 percent of switches from 2020 to 2022 and rose to 80.7 percent of switches in 2023. Graph 4 shows the number of new starts for STR has also increased relative to MTR since 2023, where 37.1 percent of new starts were STR from 2020 to 2022 before rising to 50.0 percent starting in 2023.

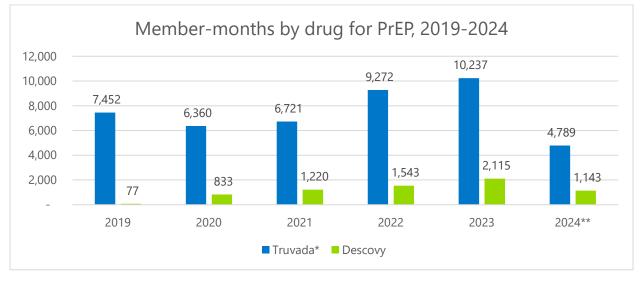
These three graphs show that the removal of prior authorization in 2023 was associated with a shift in behavior. Clients shifted from lower-cost MTR regimens to higher-cost STR regimens.

From these data analyses, HCA observed an increase in net costs since 2019, the first year included in this data analysis. From 2019 to 2022, the increase in net costs (\$68 million in 2019 to \$86.35 million in 2022) appears to be attributable to increases in the number of clients seeking treatment (5,874 clients in 2019 to 7,429 clients in 2022). Since 2023, when prior authorization was removed for HIV antiretrovirals¹ on the AHPDL, we observed a shift in the types of drug regimens clients are using and a corresponding increase in the net cost per client-month (from \$1,887.30 per client-month in 2022 to \$2,151.40 per client-month in 2024).

HIV PrEP financial findings

To investigate how PrEP is being used in Apple Health, HCA reviewed claims data for changes in costs and utilization. Two medications dominate the utilization for PrEP in Apple Health. Truvada (and its generics), the once-daily MTR preferred options on the AHPDL prior to 2023, and Descovy, an STR which was non-preferred on the AHPDL prior to 2023, represented 99.4 percent of PrEP utilization in 2023. Therefore, this analysis will focus on these two medications.

Graph 5: Member-months by PrEP, 2019–2024



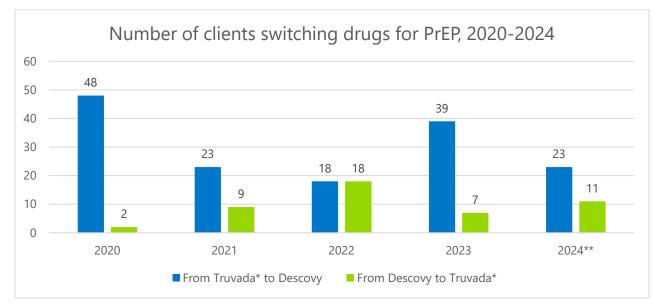
This graph shows the change in member-months by drug for PrEP from 2019 to 2024.

*Includes both brand-name Truvada and generic

**January to June 2024

¹ Antiretrovirals are a class of prescription drugs that target and treat retroviruses, such as HIV.

Graph 6: Analysis of switching HIV treatment regimens, 2020-2024



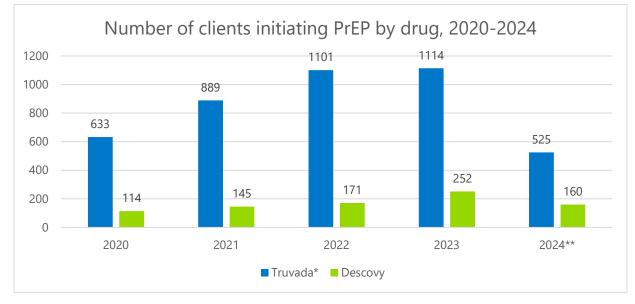
This graph shows the number of distinct clients who switched between drugs for PrEP starting in 2020.

*Includes both brand-name Truvada and generic

**January to June 2024

Graph 7: Analysis of clients starting PrEP, 2020-2024

This graph shows the annual count of new starts who initiated PrEP from 2020 to 2024.



*Includes both brand-name Truvada and generic

**January to June 2024

These graphs show a change in the pattern of how clients are using drugs for PrEP. Graph 5 shows most of the utilization remains with Truvada and its generics for PrEP. However, there is an increasing shift towards Descovy, that began before the removal of prior authorization in 2023. In the two-year period

HIV antiviral drugs December 1, 2024 from 2021 to 2022, approximately 14.7 percent of patients used Descovy for PrEP, whereas the 18 months of data we have for 2023-2024 shows 17.8 percent of patients used Descovy for PrEP. Graph 6 shows most of the switches are from Truvada and its generics to Descovy. The largest increases are in 2020, when Descovy was first released to market, and in 2023, when prior authorizations were removed. Graph 7 shows the number of new starts for PrEP. It shows an increase in the proportion of new starts for Descovy compared to Truvada and its generics. In 2022, the percentage of PrEP new starts using Descovy was 13.4 percent, which increased to 18.5 percent in 2023.

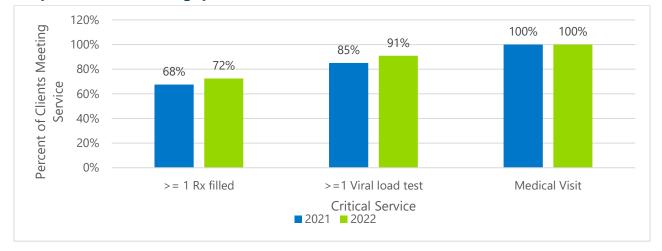
Since HCA is forbidden from sharing the net cost of individual drugs due to federal Medicaid Drug Rebate Program restrictions, we cannot share the fiscal impacts for PrEP. HCA can, however, share relative cost differences. Based on cost projections for these two options, HCA expects Descovy to be twice as expensive as Truvada and its generics. This means, on average, each client using Descovy costs the state twice as much as a client using Truvada and its generics.

Health outcomes findings

HCA analyzed health outcomes data available from the Department of Health (DOH). This analysis aimed to identify any changes in reported health outcomes for HIV patients during this period.

Graph 8 shows three key metrics in HIV treatment in 2021 and 2022. In 2021, HCA identified 5,697 clients diagnosed with HIV who had at least one doctor visit. In 2022, this decreased to 4,306 clients diagnosed with HIV who had at least one doctor visit. Of the 2021 clients, 15 percent did not have a viral load measurement despite professional guidelines and best practices recommending viral load checks roughly once every six months. In 2022, this metric improved where only nine percent did not have a viral load test.

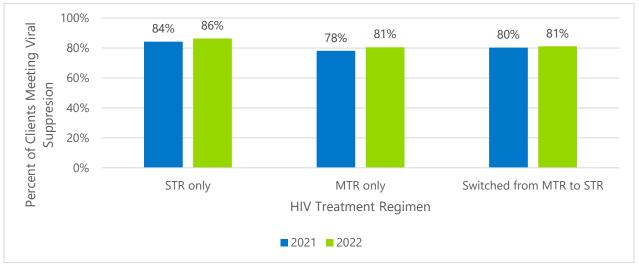
Of the 5,697 clients in 2021 with HIV, 32 percent did not fill any prescriptions for HIV through Apple Health. Patients who are Ryan White supplement recipients or who are dual eligibles (meaning the client has both Medicare and Medicaid) may choose not to fill prescriptions through Apple Health, so the actual number of clients with HIV in Apple Health who are taking prescriptions for HIV may be higher than observed. In 2022, the observed rate was lower, with only 28 percent not filling any prescriptions for HIV through Apple Health.



Graph 8: Performance gaps in critical HIV services, 2021–2022

Graph 9 shows viral suppression levels by STR or MTR in calendar years 2021 and 2022. **This data only includes 3,120 clients (42 percent) out of 7,429 clients on Apple Health using medications for treatment of HIV in 2022**. Since this data includes less than half of clients, it is challenging to draw meaningful conclusions about how well patients are managed on these medications without more complete data on patient outcomes.

This graph only includes clients who were diagnosed with HIV, had at least one prescription drug claim, and had at least one viral load test during the calendar year. In 2021, 3,848 clients were included in the analysis. In 2022, 3,120 clients were included in the analysis.



Graph 9: Viral suppression levels by drug regimen, 2021–2022

Of clients who received at least one viral load test during the year, the percentages of clients who meet viral suppression are similar. In 2022, the percentage of patients that meet viral suppression and who started on an STR were slightly higher (86 percent) than patients who either started on MTR (81 percent) or who switched from MTR to STR (81 percent).

Conclusion

This report analyzes pharmacy claims data for the four-year period before and 18-month period after removing prior authorization for HIV medications for Apple Health. Some key findings in this report are as follows.

Overall financial findings

- Net cost for HIV medications rose from \$86.35 million in 2022 to \$92.66 million in 2023. Net costs are projected to be \$94.05 million in 2024.
- Utilization of HIV medications rose from 5,874 clients in 2019 to 8,057 in 2023, with a projected decline in 2024 to 7,758.
- The net cost per client-month (NCPCM) in 2022 was \$1,887.30. After removing prior authorizations in 2023, the NCPCM rose to \$1,964.52, and the observed cost in the first half of 2024 is \$2,151.40.
- The data suggests Apple Health is paying more for HIV medications following the removal of prior authorization in 2023.

HIV treatment financial findings

- Since 2023, STR have overtaken MTR as the most-used regimen for the treatment of HIV, going from 49.5 percent of regimens in 2022 to 58.1 percent of regimens in 2024.
- In 2022, the average cost per year for a client on an MTR was \$11,789.46 whereas the average cost per year for a client on STR was \$18,698.60. This aligns with the conclusion in the Institute for Clinical and Economic Review (ICER) report that the Biktarvy had an unsupported price increase from 2022 to 2023.
- For 2024, the average cost per year for a client on an MTR is projected to be \$11,589.24 whereas the average cost per year for a client on STR is projected to be \$19,448.52. MTR in this analysis grouped both once-daily and twice-daily dosing regimens.
- The increase in patients switching from MTR to STR and the number of clients starting on STR are the primary drivers of increasing costs to Apple Health.

PrEP financial findings

- Shifts in utilization for PrEP are not as strong since the removal of prior authorization in 2023.
- Utilization trends are beginning to favor Descovy over Truvada and its generics.
- The average daily cost of Descovy is twice that of Truvada and its generics.

Health outcomes findings

- HCA and DOH lack robust health outcomes data to properly measure the impact the removal of prior authorization will have on viral suppression.
- HCA was able to analyze about 42 percent of its 2022 population using medications for the treatment of HIV.
- Of the data available, patients who started on STR had a higher percentage of being virally suppressed (86 percent) compared to those who started on MTR (81 percent) or those who switched from MTR to STR (81 percent). This analysis only included 3,120 clients (42 percent) out of 7,429 clients on Apple Health, so it is challenging to draw meaningful conclusions about how well patients are managed on these medications without more complete data on patient outcomes.