Health Impact Review of SB 5551
Concerning Medicaid coverage for HIV antiviral drugs (2022 Legislative Session)

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WASHINGTON STATE BOARD OF HEALTH

HEALTH EQUITY
Governor's Interagency Council on Health Disparities

Full review
The full Health Impact Review report is available at:
https://sboh.wa.gov/Portals/7/Doc/HealthImpactReviews/HIR-2022-02-SB5551.pdf

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Contents

Executive Summary
SB 5551, Concerning Medicaid coverage for HIV antiviral drugs
(2022 Legislative Session)

Evidence indicates that SB 5551 would likely improve availability of certain HIV antiviral drugs by removing prior authorization barriers, which may increase availability of, use of, and adherence to antiretroviral therapy (ART); improve health outcomes; and reduce inequities for people living with HIV enrolled in Apple Health.

BILL INFORMATION

Sponsors: Randall, Liias, Billig, Das, Dhingra, Frockt, Keiser, Lovelett, Lovick, Mullet, Nguyen, Pedersen, Saldaña, Stanford, Trudeau, Wilson, C.

Summary of Bill:

- Requires Washington State Health Care Authority (HCA) to provide Apple Health coverage for all U.S. Food and Drug Administration (FDA)-approved HIV antiviral drugs without prior authorization beginning January 1, 2023.
- Requires managed care health systems initiating or renewing a contract with HCA to administer a Medicaid Managed Care Plan to provide this coverage.

HEALTH IMPACT REVIEW

Summary of Findings:
This Health Impact Review found the following evidence for provisions in SB 5551:

- **Informed assumption** that requiring HCA to provide Apple Health coverage for all FDA-approved HIV antiviral drugs without prior authorization would improve availability of certain HIV antiviral drugs by removing prior authorization barriers. This assumption is based on information from the New York State Department of Health AIDS Institute, the HIV Medication Access Workgroup, and key informants.
- **A fair amount of evidence** that improving availability of certain HIV antiviral drugs, specifically single-tablet regimens (STRs), by removing prior authorization barriers would likely increase availability of, use of, and adherence to ART for some people enrolled in Apple Health.
- **Very strong evidence** that adherent use of ART would improve health outcomes for people living with HIV and prevent transmission to others.
- **A fair amount of evidence** that improving health outcomes would decrease inequities for people living with HIV by insurance status.

Introduction and Methods

A Health Impact Review is an analysis of how a proposed legislative or budgetary change will likely impact health and health disparities in Washington State (RCW 43.20.285). For the purpose of this review 'health disparities' have been defined as differences in disease, death, and other adverse health conditions that exist between populations (RCW 43.20.270). Differences in health conditions are not intrinsic to a population; rather, inequities are related to social determinants (e.g. access to healthcare, economic stability, racism, etc.). This document provides summaries of the evidence analyzed by State Board of Health staff during the Health Impact Review of Senate Bill 5551 (SB 5551).

Staff analyzed the content of SB 5551 and created a logic model depicting possible pathways leading from the provisions of the bill to health outcomes. We consulted with experts and contacted key informants about the provisions and potential impacts of the bill. We conducted an objective review of published literature for each pathway using databases including PubMed, Google Scholar, and University of Washington Libraries. We evaluated evidence using set criteria and determined a strength-of-evidence for each step in the pathway. More information about key informants and detailed methods are available upon request.

The following pages provide a detailed analysis of the bill, including the logic model, summaries of evidence, and annotated references. The logic model is presented both in text and through a flowchart (Figure 1). The logic model includes information on the strength-of-evidence for each pathway. The strength-of-evidence has been established using set criteria and summarized as:

- **Very strong evidence:** There is a very large body of robust, published evidence and some qualitative primary research with all or almost all evidence supporting the association. There is consensus between all data sources and types, indicating that the premise is well accepted by the scientific community.
- **Strong evidence:** There is a large body of published evidence and some qualitative primary research with the majority of evidence supporting the association, though some sources may have less robust study design or execution. There is consensus between data sources and types.
- **A fair amount of evidence:** There is some published evidence and some qualitative primary research with the majority of evidence supporting the association. The body of evidence may include sources with less robust design and execution and there may be some level of disagreement between data sources and types.
- **Expert opinion:** There is limited or no published evidence; however, rigorous qualitative primary research is available supporting the association, with an attempt to include viewpoints from multiple types of informants. There is consensus among the majority of informants.
- **Informed assumption:** There is limited or no published evidence; however, some qualitative primary research is available. Rigorous qualitative primary research was not possible due to time or other constraints. There is consensus among the majority of informants.

- **No association:** There is some published evidence and some qualitative primary research with the majority of evidence supporting no association or no relationship. The body of evidence may include sources with less robust design and execution and there may be some level of disagreement between data sources and types.
- **Not well researched:** There is limited or no published evidence and limited or no qualitative primary research and the body of evidence has inconsistent or mixed findings, with some supporting the association, some disagreeing, and some finding no connection. There is a lack of consensus between data sources and types.
- **Unclear:** There is a lack of consensus between data sources and types, and the directionality of the association is ambiguous due to potential unintended consequences or other variables.

This review was completed during Legislative Session and was subject to the 10-day turnaround required in statute. This review was subject to time constraints, which influenced the scope of work for this review. The annotated references are only a representation of the evidence and provide examples of current research. In some cases, only a few review articles or meta-analyses are referenced. One article may cite or provide analysis of dozens of other articles. Therefore, the number of references included in the bibliography does not necessarily reflect the strength-of-evidence. In addition, some articles provide evidence for more than one research question, so are referenced multiple times.

Analysis of SB 5551 and the Scientific Evidence

Summary of relevant background information

- HIV antiviral medications are used to treat and prevent HIV. They are a large class of drugs, including antiretrovirals and pre-exposure prophylaxis (PrEP) (personal communication, Department of Health [DOH], January 2022).
- In 1996, trials using triple drug combinations showed positive results with sustained decrease in plasma HIV viral load.[1] Shortly thereafter, highly active antiretroviral therapy (ART) became widely available in North America, and HIV/AIDS morbidity and mortality fell drastically.[1,2]
- The Undetectable = Untransmissible (U = U) concept came from the Swiss National AIDS 2008 statement signifying that "[people living] with HIV who receive [ART] and have achieved and maintained an undetectable viral load cannot sexually transmit the virus to others."[3] In 2011, ART was demonstrated as a way to significantly reduce HIV transmission.[1]
- A 2012 study estimated half (49%) of HIV transmissions were from the 20% of people living with HIV who were unaware of their infection.[4]
- Scientific advancements have allowed HIV, with testing and treatment, to be a manageable chronic disease.[5]
- Estimates indicate only 55% of people living with HIV are virally suppressed due to poor linkage to care and retention in care.[6]
- In 2019, the U.S. Department of Health and Human Services (HHS) announced the "Ending the HIV Epidemic in the U.S." initiative, which aims to reduce the number of new HIV infections by 90% by 2030.[7] The use of ART is one of the four pillars of ending the HIV epidemic.[6]
- Single-tablet regimens (STRs), commonly known as one-pill regimens, "combine a complete [HIV] treatment regimen into a single fixed-dose tablet."[5] Not all drugs and classes are available as STR.[6]
- HHS in collaboration with the National Institutes of Health (NIH) publishes federally approved medical practice guidelines for HIV/AIDS. The Panel on Antiretroviral Guidelines for Adults and Adolescents updated the "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV" (The Guidelines) in August 2021.[6]
    - The Guidelines state that "[a]chieving viral suppression currently requires the use of combination [antiretroviral] regimens that generally include three active drugs from two or more drug classes" and "[t]he increasing number of [antiretroviral] drugs and drug classes makes viral suppression below detection limits an achievable goal in most patients."[6]
    - The Guidelines acknowledge that "[t]reatment adherence includes initiating care with an HIV provider (linkage to care), regularly attending appointments (retention in care), and adherence to [ART]. The concept of 'continuum of care' has been used to describe the process of HIV testing, linkage to HIV care, initiation of ART, adherence to treatment, retention in care, and virologic

suppression."[6] Adherence to each step along the continuum of care is necessary for people living with HIV to achieve optimal clinical outcomes and to realize the potential public health benefits of treatment as a tool to prevent transmission.[6]

- ART is costly, with total annual undiscounted spending on antiretroviral drugs reaching $22.5 billion nationally in 2018.[6]
- The Medicaid prescription drug benefit is optional for state Medicaid programs under federal law; all 50 states provide this benefit.[8]
    - The Omnibus Budget Reconciliation Act of 1990 established the Medicaid Drug Rebate Program under which states receive "the best price offered by [drug] manufacturers as a condition of coverage".[8]
    - Under federal law, state Medicaid programs are required to provide coverage for all U.S. Food and Drug Administration (FDA)-approved medications from manufacturers in the Medicaid Drug Rebate Program, including all HIV antiretroviral medications.[9] However, states may use utilization controls (e.g., preauthorization, step therapy, preferred drug lists, quantity limits, etc.) to control costs of or limit access to prescription drugs.[9]
        - Twenty-eight states have HIV medications on a Preferred Drug List, and 21 states do not prefer all HIV medications.[10]
        - Twelve states have legislation prohibiting management of HIV drugs.[10]
    - Federal law allows state Medicaid programs to require people to pay "nominal" cost sharing for medical and pharmacy benefits.[6] Many states, including Washington State, do not require cost sharing (personal communication, Washington State Health Care Authority [HCA], January 2022).[6]
- The Washington State Medicaid program (Apple Health)* provides coverage for HIV antiviral medications, and the Apple Health Preferred Drug List (PDL) includes a long list of HIV antiviral medications.[11] Treatment regimens on the PDL are clinically effective at suppressing viral load and are more cost effective.[10]
    - The Pharmacy and Therapeutics Committee evaluates available evidence about the safety, efficacy, and effectiveness of prescription medications in a drug class, and makes recommendations to HCA about which drugs should be classified as preferred.[12]
    - HCA requires that "in the absence of certain clinical or psycho-social conditions […] patients […] begin treatment on [an] equally effective, less costly alternative prior to starting the more costly HIV drugs" that are not on the PDL.[10]
    - Prior authorization is required for drugs not listed on the PDL. Generally, "a client must have tried and failed, or is intolerant to, a designated number of preferred drugs within the drug class unless contraindicated or not clinically appropriate."[11] However, people do not need to meet the requirement for "tried and failed" to potentially qualify for HIV antiviral drugs not on the PDL (personal communication, HCA, January 2022).[13] Certain drugs must also meet other

*Apple Health is the Washington State Medicaid program. In this report, the use of Medicaid will be retained to refer to the federal Medicaid program or to research related to national or other state Medicaid programs.

criteria, and HCA Medical policy number 12.10.99-3, Antivirals – HIV Combinations, specifies that "new-to-market [HIV antiviral drugs]…are non-preferred and subject to…prior authorization (PA) criteria. If a drug within this policy receives a new indication approved by the [FDA], medical necessity for the new indication will be determined on a case-by-case basis."[14]
    - HCA medical policy also states that requests for medications not on the PDL may be approved if there "are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer" on a case-by-case basis.[14]
    - In 2021, the number of requests for prior authorization increased by 22% compared to 2020.[10]
    - People who become Medicaid eligible and are on a treatment regimen not on the PDL may remain on their current treatment regimen without going through the prior authorization process (personal communication, HCA, January 2022).
- In 2021, ESSB 5092 (Chapter 334, Laws of 2021) required two workgroups examining access to HIV medications. The Washington State Legislature:
    - Requested the Washington State LGBTQ Commission to seek input from stakeholders and provide recommendations on three topics: 1) access to HIV antiviral drugs on the PDL; 2) impact of drug access on public health and the statewide goal of reducing HIV transmission; and 3) maximizing pharmaceutical drug rebates for HIV antiretroviral drugs.[13] The LGBTQ Commission convened the HIV Medication Access Workgroup, which provided recommendations in October 2021.[13]
    - Requested DOH to convene a workgroup to make recommendations on funding and policy initiatives that address the spread of sexually transmitted infections (STIs). Among other topics, the workgroup is required to make recommendations related to expanding access to PrEP and to HIV post-exposure prophylaxis (PEP). The recommendations are due to the Legislature in December 2022 (personal communication, DOH, January 2022).

Summary of SB 5551

- Requires HCA to provide Apple Health coverage for all FDA-approved HIV antiviral drugs without prior authorization beginning January 1, 2023.
- Requires managed care health systems initiating or renewing a contract with HCA to administer a Medicaid Managed Care Plan to provide this coverage.

Health impact of SB 5551

Evidence indicates that SB 5551 would likely improve availability of certain HIV antiviral drugs by removing prior authorization barriers, which may increase availability of, use of, and adherence to antiretroviral therapy (ART); improve health outcomes; and reduce inequities for people living with HIV enrolled in Apple Health.

Pathway to health impacts
The potential pathway leading from the provisions of SB 5551 to decreased health inequities are depicted in Figure 1. We have made the informed assumption that requiring HCA to provide Apple Health coverage for all FDA-approved HIV antiviral drugs without prior authorization would improve availability of certain HIV antiviral drugs by removing prior authorization barriers. This informed assumption is based on information from the New York State Department of Health AIDS Institute, the HIV Medication Access Workgroup, and key informants. There is a fair amount of evidence that improving availability of certain HIV antiviral drugs, specifically STRs, by removing prior authorization barriers would likely increase availability of, use of, and adherence to ART for some people enrolled in Apple Health.[5,6,15] There is very strong evidence that adherent use of ART would improve health outcomes for people living with HIV and prevent transmission to others.[2,3,5,6,16-23] There is a fair amount of evidence that improving health outcomes would decrease inequities for people living with HIV by insurance status.[18,24,25]

Scope
Due to time limitations, we only researched the most direct connections between provisions of the bill and health inequities and did not explore the evidence for all possible pathways. For example, we did not evaluate potential impacts related to:

- Apple Health funding. While a fiscal note from HCA for SB 5551 was not available at the time this report was completed, key informants stated that removing the prior authorization system would likely increase costs for Apple Health, with a potential cost of $6,000 more per year for each patient on a non-preferred drug (personal communication, HCA, January 2022). Evidence from states with open access policies (i.e., without prior authorization systems) suggested that costs may increase as much as $40-60 million per year if more people begin using STRs (personal communication, HCA, January 2022). STRs currently make up a smaller proportion of claims (27%) but account for 46% of total expenditures on HIV antiviral drugs.[10]
- Other medications on the PDL. The PDL includes many medications used to treat many chronic diseases, such as multiple sclerosis, diabetes, and rheumatoid arthritis (personal communication, HCA, January 2022). Key informants stated that removing prior authorization for one drug class may also impact other classes of medications (personal communication, HCA, January 2022).

Magnitude of impact
SB 5551 would impact people living with HIV in Washington State enrolled in Apple Health or who could become eligible for Apple Health.

In 2019, there were more than 14,000 people living with HIV in Washington State.[16] The number of new cases of HIV in Washington State remained stable from 2015 to 2019, with an average rate of 5.4 new cases of HIV per 100,000 people.[16] King and Mason counties had new HIV case rates above the state rate (9.2 and 7.3 cases per 100,000 people, respectively).[16] In 2019, 48% of new HIV cases in Washington State occurred in King County.[16]

Approximately 89% of people living with HIV in Washington State are engaged in care (i.e., have access to and are using HIV healthcare services), and 82% of people living with HIV have a suppressed viral load.[16]

HCA does not have an exact estimate of the number of people living with HIV who are currently enrolled in Apple Health (personal communication, HCA, January 2022). National research has found that Medicaid is the single largest payer for people living with HIV,[18] and estimates suggest that 40% of all people living with HIV are enrolled in Medicaid.[19] Data from a representative, random sample of people living with HIV in Washington State in 2018 found that approximately 43% of people living with HIV reported using Medicaid coverage for their medical care.[26] While an exact estimate is not available, data suggest that approximately 6,000 people living with HIV may be enrolled in Apple Health.

Lastly, it is not possible to estimate how many people living with HIV enrolled in Apple Health may change or switch treatment regimens as a result of SB 5551. Research has indicated that people "may switch their ART [regimens] for various reasons, including tolerability, suboptimal adherence, long-term toxicities, simplifying the regimen, the regimen performing poorly, or modification resulting from comorbid conditions that may lead to drug-drug interactions."[27] A national study with 5,744 people living with HIV enrolled in Medicaid found that 14% of people switched ART regimens from 2006 to 2011.[27] Research has documented adverse outcomes related to switching ART treatments,[27] and key informants shared that people living with HIV may be hesitant to change drug regimens that work for them (personal communication, January 2022). Moreover, in 2020, HCA reported that, based on an informal survey sent to all Medicaid pharmacy directors, 26.9% of HIV claims were for STRs,[10] and evidence has shown that the use of STRs has increased over time (personal communication, HCA, January 2022).

Overall, it is not possible to estimate how many people living with HIV enrolled in Apple Health may be impacted by SB 5551. However, the bill has the potential to impact all people living with HIV in Washington State enrolled in Apple Health or who could become eligible for Apple Health.

Logic Model

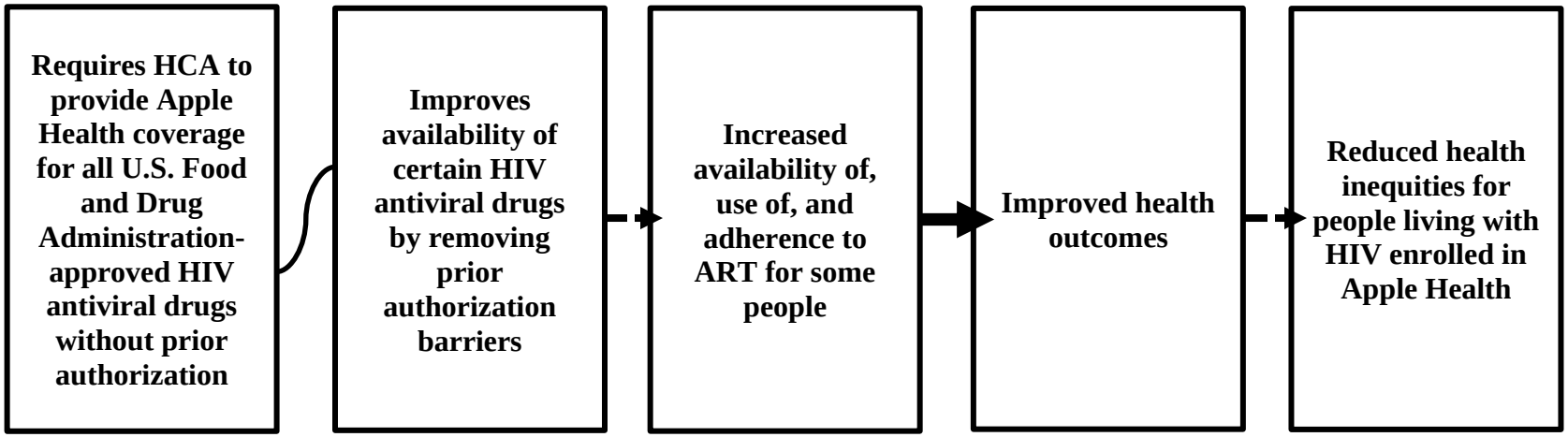

Figure 1:

Concerning Medicaid coverage for HIV antiviral drugs

SB 5551

Summaries of Findings

Would requiring HCA to provide Apple Health coverage for all U.S. Food and Drug Administration-approved HIV antiviral drugs without prior authorization improve availability of certain HIV antiviral drugs by removing prior authorization barriers?
We have made the informed assumption that requiring Washington State Health Care Authority (HCA) to provide Apple Health coverage for all U.S. Food and Drug Administration (FDA)-approved HIV antiviral drugs without prior authorization would improve availability of certain HIV antiviral drugs by removing prior authorization barriers. This informed assumption is based on information from the New York State Department of Health AIDS Institute, the HIV Medication Access Workgroup (convened by the Washington State LGBTQ Commission), and key informants.

Washington State Apple Health provides coverage for HIV antiviral medications.[11] In 2018, HCA implemented a prior authorization system for certain HIV antiviral medications not on the Apple Health Preferred Drug List (PDL) or new-to-market.[11,13,14] Under this prior authorization system, a provider must proactively petition for a medication not included on the PDL or new-to-market for their patient.[13] The petition must explain why the PDL drugs are not suitable for the patient or demonstrate why the PDL regimen would not be effective for the patient.[13] HCA medical policy states that requests for medications not on the PDL may be approved if there "are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer" on a case-by-case basis.[14]

SB 5551 would remove the prior authorization requirements for all FDA-approved HIV antiviral drugs, which would remove prior authorization as a barrier to certain HIV antiviral drugs. There is limited empirical evidence evaluating barriers due to prior authorization for HIV antiviral drugs. The American Academy of HIV Medicine has stated that prior authorization for HIV drugs restricts access to medication, delays treatment (which increase healthcare costs), and creates administrative burdens for healthcare providers.[28] In 2014, New York State Department of Health AIDS Institute completed a survey with people living with HIV and healthcare providers to identify barriers to acquiring and prescribing HIV medications.[29] Approximately 9% of respondents reported prior authorization as a barrier.[29] Respondents reported that prior authorization resulted in delays of medication and treatment interruptions for people living with HIV and created time burdens for providers.[29]

Key informants in Washington State also discussed potential barriers to prior authorization, including denials, physician prescribing practices, delay of care, and foregoing care (personal communications, January 2022). HCA began tracking prior authorization denials in 2020. Data from 2020 and 2021 showed that approximately 75% of prior authorization requests for HIV antiviral drugs were approved and 25% were denied in both 2020 and 2021.[10] Claims may be denied if they do not meet certain medically-necessary or situational circumstances[10] (e.g., "behavioral health condition which impairs the patient's ability to manage multiple medications"[14]). Key informants stated that denials were a barrier for some people to initiate individualized, effective treatment regimens (personal communications, January 2022). By removing potential barriers due to the prior authorization system, key informants felt that people

living with HIV enrolled in Apple Health would have more timely access to all HIV antiviral drugs without the risk of denial (personal communications, January 2022).

Healthcare providers or case managers typically work with patients to request drugs not on the PDL (personal communications, January 2022). The HIV Medication Access Workgroup found that some healthcare providers face the potential burden of preparing justifications and materials for a prior authorization request.[13] One key informant shared that some providers will prescribe a treatment regimen from the PDL rather than initiate the prior authorization process in order to provide medication as quickly as possible (personal communication, January 2022). Similarly, some healthcare providers may perceive it as easier to try a drug regimen that can be immediately prescribed, rather than investing time in the prior authorization process (personal communication, January 2022). The HIV Medication Access Workgroup and key informants suggested that the prior authorization system may influence provider prescribing practices (personal communication, January 2022) and may interfere with the patient-provider relationship.[13]

Lastly, key informants also stated that the prior authorization process can take time and may delay care for some people (personal communications, January 2022). Similarly, the prior authorization system may result in a patient falling out of care or foregoing care (personal communication, January 2022). For example, a person may have limited access to transportation, which could impact their ability to return to a healthcare provider for additional visits if prior authorization is required to receive medication (personal communication, January 2022).

The HIV Medication Access Workgroup stated that there are significant barriers to effective HIV prevention and treatment for people enrolled in Apple Health or who may become eligible for Apple Health and "the removal of the prior authorization system is not a panacea for addressing the complex issues that create barriers to effective HIV treatment."[13] Many studies have documented the systematic barriers to accessing and using healthcare for people enrolled in Medicaid.[18,24,25] One researcher explained that, "[m]any studies demonstrate more advanced disease and greater co-morbidities among persons with public or no insurance, accounting at least in part for the differences in [various health] outcomes, but some studies demonstrate a persistently worse outcome for those with public or no insurance even after adjustment, suggesting access to care or process of care issues."[25]

Therefore, we have made the informed assumption that requiring HCA to provide Apple Health coverage for all FDA-approved HIV antiviral drugs without prior authorization would likely remove prior authorization as a specific barrier to certain HIV antiviral drugs.

Would improving availability of certain HIV antiviral drugs by removing prior authorization barriers increase availability of, use of, and adherence to ART for some people enrolled in Apple Health?

There is a fair amount of evidence that improving availability of certain HIV antiviral drugs, specifically single-tablet regimens (STRs), by removing prior authorization barriers would likely increase availability of, use of, and adherence to ART for some people enrolled in Apple Health.

Key informants stated that increasing availability of certain HIV antiviral drugs may increase a person's ability to initiate an individualized treatment regimen in a timely manner (personal communications, January 2022). HIV treatment regimens must be individualized for each patient based on a person's medical history, HIV treatment history, and life circumstances in order to maximize drug efficacy (i.e., ability to achieve viral suppression) and adherence (personal communications, January 2022). NIH's "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV" (The Guidelines) state that "the first principle of successful treatment is to design a plan to which the patient can commit."[6] This involves individualizing a plan (with the person living with HIV's input) that considers their daily schedule; tolerance of pill number, size, and frequency; and issues affecting absorption (e.g., use of acid-reducing therapy and food requirements).[6] Moreover, research has found that switching ART treatments may result in increased hospitalizations, nonpharmacy costs, pharmacy costs, and adverse treatment outcomes.[27] Consequently, "[e]fforts to put patients on an optimal ART regimen initially, therefore reducing the need for subsequent switching, may have a positive effect on patients…"[27]

A patient's adherence to ART can be influenced by a variety of factors, including their social situation and clinical condition, the prescribed regimen, and the patient-provider relationship.[6] Evidence indicates that poor adherence is often a consequence of one or more behavioral, structural, and psychosocial barriers (e.g., depression and other mental illness, low levels of social support, busy or unstructured daily routines, inconsistent access to medication due to financial and insurance status).[6] Changes in life events, insurance status, comorbid conditions, health systems, etc. can affect retention in care and adherence and may change over time.[6] As such, "[t]o improve treatment adherence […] it is critical to take multiple approaches, such as minimizing socio-structural barriers, improving management of health systems, strengthening patient–provider relationships, and working with patients to ensure that regimens are acceptable, feasible, and have minimal side-effects."[5] Healthcare providers should work with each person's needs (or barriers to care) to identify an approach that works for them to improve adherence.[6]

SB 5551 would primarily impact availability of STRs as an option for ART, though provisions of the bill would also apply to the availability of other drugs and ART regimens in the future (personal communication, DOH, January 2022). Researchers have noted that newer ART regimens, including STRs, "offer improvements in dosing convenience, tolerability, and treatment resistance" compared to older regimens.[27] Certain people may especially benefit from increased access to STRs, including those facing situational barriers to more complex drug regimens (e.g., communities of color, people engaging in transactional sex, and/or people experiencing mental health concerns, substance use, or housing instability [personal communications, January 2022]) as well as people facing structural barriers to medication access (e.g., limited access to healthcare providers or pharmacies).[15] Key informants also noted that rapid/same day start for STRs and ART initiation is important for people who are pregnant, are over 50 years of age, have an acute HIV infection, or have an advanced stage of HIV (i.e., AIDS) (personal communication, DOH, January 2022). In these cases, "every effort should be made to initiate ART immediately, and ideally, on the same day as diagnosis" (personal communication, DOH, January 2022).

STRS can also affect adherence. For example, "[o]nce-daily regimens, including those with low pill burden (even if not one pill once daily), without a food requirement, and few side effects or toxicities, are associated with higher levels of adherence."[6] A 2019 systematic review, including 29 studies, examined the relationships between (1) STRs versus multi-tablet regimens (MTRs) use and adherence, (2) levels of treatment adherence and viral suppression, and (3) STR/MTR use and viral suppression.[5] Results specific to objective 1 showed that STRs were associated with statistically significantly higher treatment adherence than MTRs in 9 of 11 observational studies.[5] Authors also conducted a meta-analysis which found that "STRs [were] associated with significantly higher ART adherence at 95% and 90% thresholds."[5] Similarly, a study among people living with HIV enrolled in Medicaid found that 22.7% of people on STRs were adherent over a six month time period compared to 11.7% of people on MTRs.[15] People were also less likely to discontinue use of STRs compared to MTRs over the two-year study period.[15] While evidence suggests that STRs are easier for people to use, "data to support or refute the superiority of a STR versus a once-daily multi-tablet regimen (MTR) […] are limited."[6] The Guidelines note that comparison of STRs to MTRs is also hampered as not all drugs and classes are available as STR.[6]

The Guidelines also state that "[t]reatment adherence includes initiating care with an HIV provider (linkage to care), regularly attending appointments (retention in care), and adherence to [ART]."[6] Access to and use of HIV testing and linkage to HIV healthcare services are pre-requisites to a person living with HIV's adherence to ART and SB 5551 does not impact other structural barriers to accessing, using, and adhering to ART. However, there is a fair amount of evidence that improving availability of certain HIV antiviral drugs, specifically STRs, would likely increase availability of, use of, and adherence to ART for some people enrolled in Apple Health.

Would increased availability of, use of, and adherence to ART for some people enrolled in Apple Health improve health outcomes?

There is very strong evidence that adherent use of ART improves health outcomes for people living with HIV and prevents transmission to others. Healthy People 2030 states that access to health services improves health outcomes and reduce health inequities, and can be improved by increasing health insurance coverage, increasing availability of health care resources (e.g., people enrolled in Medicaid may experience limited access to providers depending on where they live), and considering economic, social, cultural, and geographic barriers to increase the efficiency and timeliness of healthcare delivery.[30] There is a large body of evidence supporting the positive association between use of health services for the early detection and treatment of physical and mental health disorders[31] and improved health outcomes, including for HIV treatment and prevention. Since there is strong consensus in the scientific literature supporting this association, less time was spent researching this connection.

Successful ART treatment (which suppresses the amount of HIV in the body) allows people living with HIV to achieve viral suppression, which prevents negative health effects of HIV infection and prevents transmission to others.[3,6,16,17,21,22] Earlier initiation of ART is associated with better health outcomes, including lower morbidity and mortality.[18] Results of a 2019 systematic review showed "higher adherence rates were associated with higher levels of viral suppression" in 13 of 18 studies (72%).[5] Meanwhile, the review found mixed results among five

studies assessing the association between STR versus MTR use and viral suppression.[5] Authors concluded further research is necessary to determine whether adherence to STRs versus MTRs results in improved virologic and clinical outcomes.[5] These mixed findings align with evidence cited in The Guidelines.[6]

When an appropriate ART regimen is followed with optimal adherence, HIV is transformed from being potentially fatal to a manageable chronic disease.[5,32] One researcher explained that, "[a]s people with HIV live longer, they appear to develop diseases and conditions that are characteristic of middle-aged and older populations, including rising obesity and weight gain, diabetes, cardiovascular disease, and other chronic conditions. Additionally, HIV and its treatment may themselves increase the prevalence of some conditions."[19] Evidence suggests that adherent use of ART may reduce HIV-related comorbidities. A 10-year, multistate, longitudinal evaluation of Medicaid administrative claims data found that "[a]lthough rates of comorbid conditions increased over time, the percentage of [people] having any HIV-related condition declined; this was also true of HIV-related cancers. This is likely due to dramatic improvements in ART. The most consequential improvement was widespread implementation of [STRs], but there is also evidence that ART adherence improved over [the study] time period."[19] Similarly, the U.S. Preventive Services Task Force (USPSTF) concluded that, "HIV suppression with ART may also decrease inflammation and immune activation thought to contribute to higher rates of cardiovascular disease and other end-organ damage."[6] Conversely, "[s]uboptimal adherence reduces the likelihood of viral suppression which in turn increases the risk of transmission and the development of drug resistance, thereby limiting future treatment options. Suboptimal adherence has both clinical and economic consequences, including accelerated disease progression and mortality, decreased [health-related quality of life], and higher healthcare costs."[5]

Lastly, adherent use of ART has also been shown to reduce sexual transmission of HIV.[3,6,17,22] In absence of a vaccine or cure, the Health Resource & Services Administration, an agency of the U.S. Department of Health and Human Services (HHS), strongly supports increased prevention efforts.[2] For example, "Test and Treat" is an approach that relies on HIV treatment as prevention. Widespread testing and swift connections of those who are HIV seropositive to ART treatment significantly reduces the risk of transmission.[2] For people living with HIV who use ART daily as prescribed and achieve and maintain viral suppression, there is effectively no risk of sexually transmitting HIV to an HIV-negative partner (100% effectiveness estimate).[3,20] This concept is known as U=U (Undetectable = Untransmissible).[3]

Overall, there is very strong evidence that adherent use of ART improves health outcomes for people living with HIV and prevents transmission to others.

Will improving health outcomes reduce health inequities for people living with HIV enrolled in Apple Health?

There is a fair amount of evidence that improving health outcomes would decrease inequities for people living with HIV by insurance status.

National research has indicated that people living with HIV enrolled in Medicaid experience worse health outcomes than people living with HIV enrolled in other types of health insurance.[18]

Prior to the implementation of the Patient Protection and Affordable Care Act (ACA) (2010), a body of evidence showed that people living with HIV enrolled in Medicaid had worse health outcomes than people with private insurance, including later initiation of ART, higher incidence of comorbidities (e.g., cardiovascular diseases, renal impairment, chronic hepatitis), less sustained viral suppression, and higher mortality rates.[24] For example, a retrospective study of 1,885 people living with HIV found that the odds of initiating ART at less severe stages of HIV was significantly greater for people enrolled in private insurance, self-pay, and other/unknown insurance status, compared to people enrolled in Medicaid,[18] potentially indicating a delay of care. People enrolled in private insurance were 1.5 times more likely to start ART at less severe stages of HIV than people enrolled in Medicaid.[18] While the study did not evaluate the reasons for the delay of care, the authors stated that people enrolled in Medicaid may face a number of systematic barriers to accessing healthcare, including barriers related to geography, transportation, language, and health literacy.[18]

The ACA expanded Medicaid coverage, and evidence has indicated that increased Medicaid enrollment is associated with increased use of healthcare services and higher rates of diagnosis of chronic health conditions, particularly among low-income adults.[24,33,34] However, studies since implementation of the ACA have shown that inequities for people living with HIV enrolled in Medicaid persist.[24,25] A cohort study with 3,908 people living with HIV receiving care at 12 clinics in Washington D.C. found that, while people living with HIV enrolled in public insurance were more likely to meet laboratory monitoring standards, people living with HIV enrolled in private insurance were statistically significantly more likely to have greater durable viral suppression than people living with HIV enrolled in public insurance.[24] Specifically, 80% of people living with HIV enrolled in private insurance and using ART had durable viral suppression compared to 69% of people living with HIV enrolled in public insurance and using ART.[24] The study concluded that some of the differences in outcomes may be due to structural barriers experienced by people enrolled in public health insurance (e.g., transportation).[24]

A longitudinal study (spanning the time period before and after the implementation of the ACA) with 2,363 people diagnosed with late-stage HIV (i.e., AIDS) found that people enrolled in Medicaid who were virally suppressed had 1.36 times higher risk of mortality compared to people with private insurance who were virally suppressed.[25] The authors concluded "compared to persons with AIDS and private insurance, persons with public insurance have increased mortality, possibly due to a greater burden of non-infectious, age-related diseases [i.e., comorbidities]."[25]

Key informants stated that Medicare does not require prior authorization for any HIV antiviral medications and that coverage of HIV antiviral medications likely varies by private health insurance plans (personal communication, HCA, January 2022). There is the potential that removing prior authorization for HIV antiviral drugs not on the PDL could place Medicaid in parity with other types of insurance coverage, which could further improve health outcomes and reduce inequities experienced by people living with HIV enrolled in Apple Health.

It is well-documented that people living with HIV experience health inequities, including inequities due to racism, and by sex, sexual orientation, and gender identity.[16,24,25] In 2020 in Washington State, approximately 84% of individuals living with HIV were male, and the

majority (59%) of new cases were among men who have sex with men.[16] In 2019, 47% of Asian Washingtonians received late HIV diagnosis compared to 22% of white Washingtonians.[16] Non-Hispanic Black and Hispanic Washingtonians are disproportionately represented among the state's new cases of HIV. In 2019, non-Hispanic Blacks comprised 4% of the state's total population (2020 population estimate)[35] but accounted for 17% of new HIV cases.[16] Hispanics comprised 14% of the state population[35] and accounted for 24% of new HIV cases.[16] Inequities in HIV-related health outcomes also exist by age and level of education and for people experiencing violence (e.g., intimate partner violence), those working in transactional sex, those with co-occurring mental health conditions, those with disabilities (e.g., cognitive delays), those with substance use disorders, those experiencing houselessness, and those living in rural areas (personal communications, January 2022).[24,25]

Researchers have also noted that intersectionality for people experiencing multiple types of stigma (e.g., HIV-related stigma, sexual stigma, racism, gender discrimination) may worsen health outcomes.[36-38] A meta-analysis of 64 studies examining the association between HIV-related stigma and various health outcomes found significant associations between stigma and high rates of depression, low levels of social support, low treatment adherence, and lower access to and use of healthcare and social services.[36] The analysis also found positive, but weaker relationships between stigma and anxiety, quality of life, physical health, emotional and mental distress, and sexual risk practices.[36] Experiences of stigma have also been associated with depression, anxiety, hopelessness, negative social interactions, loss of social support, and decreases in self-esteem and self-efficacy.[39] Approximately 79% of respondents to the People Living with HIV Stigma Index Project reported a reduction in psychological, physical, and material well-being as a result of stigma experiences, including depression, anxiety, social isolation, and decreased sleep and physical activity.[40]

Overall, there is limited data about people living with HIV enrolled in Apple Health. However, since evidence suggests that people living with HIV who are enrolled in Medicaid experience worse HIV-related health outcomes than people living with HIV enrolled in other types of health insurance, there is a fair amount of evidence that improving health outcomes for people living with HIV who are enrolled in Apple Health would improve health equity.

Annotated References

1. **Vella Stefano, Schwartlander Bernard , Sow Salif Papa , et al. The history of antiretroviral therapy and of its implementation in resource-limited areas of the world. *AIDS.* 2012;2012(26):1231-1241.**
Vella et al. provided a history of antiretroviral therapy (1987 to 2011) as well as its implementation in resource-limited areas of the world.

2. **U.S. Department of Health and Human Services A Living History | Timeline. Available at: https://hab.hrsa.gov/livinghistory/timeline/toward_passage.htm. Accessed October, 2019.**
This Health Resources & Services Administration page outlines the history of the HIV/AIDS epidemic and the scientific advancements and policy efforts to treat people living with HIV and to prevent transmission of the disease. Information cited was included in the following timeline discussions: 1995 - First Protease Inhibitor Becomes Available and 2013 - High-Impact Prevention.

3. **Eisinger R. W., Dieffenbach C. W., Fauci A. S. HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable. *JAMA.* 2019;321(5):451-452.**
The authors examined the science-based evidence behind the concept of Undetectable = Untransmissible (U =U), which signifies that "individuals with HIV who receive antiretroviral therapy (ART) and have achieved and maintained an undetectable viral load cannot sexually transmit the virus to others." The first declaration of the U = U concept came from the Swiss National AIDS 2008 statement. The HIV Prevention Trials Network (HPTN) conducted the first randomized clinical trial in 2011 that compared the effect of early initiation with delayed initiation of ART among 1,763 couples. This trial found a 96.4% reduction in HIV transmission in the early ART group compared with the delayed ART group. The effect of maintaining viral suppression and preventing HIV transmission proved durable in a 5-year follow-up, with no linked transmissions when viral load was suppressed by ART. Other subsequent studies confirmed these findings, including the PARTNER 1 study, finding that in 58,000 condomless sexual acts, there were no linked HIV transmissions. PARTNER 1 did not have statistical evidence to determine transmission risk for receptive anal sex, however the Opposites Attract study with 323 couples (men who have sex with men) documented 16,800 acts of condomless sex, with no linked HIV transmission. PARTNER 2 evaluated 77,000 condomless sexual acts, where one partner had achieved viral suppression and the other uninfected partner was not receiving antivirals and there were no resulting linked HIV transmissions. The authors describe three principles that are required to be met to realize the U = U concept. (1) Taking ART as prescribed is "essential for achieving and maintaining an undetectable viral load." The authors cite a 2015 CDC report that stated that 20% of people with HIV are not clinically suppressed and that 40% in the same year did not maintain viral suppression for more than 12 months. Adherence can be impacted by access to care and access to stable care. (2) People must adhere to the time frame of reaching viral suppression. There is existing guidance that viral suppression measured at 6 months after starting therapy is required for U =U. The authors cite studies that indicate there is residual HIV transmission risk during the first 6 months of initiating ART. (3) People should follow the recommended schedule for viral load testing. The schedule includes testing at entry into care; at the initiation of ART or treatment modification; and 2 to 8 weeks

after initiating ART, with repeated testing every 4 to 8 weeks until viral loads are suppressed, followed by subsequent testing every 3 to 4 months. After stable status for more than 2 years, people can be monitored in 6-month intervals. The authors explained that when ART is stopped, a person has a viral rebound in 2 to 3 weeks. The authors cite a systematic review by LeMessurier et. al. comprised of 12 clinical studies that concluded that "there is negligible risk (0.00 transmissions/100 person-years, 95% CI, 0.00-0.28) of HIV sexual transmission among HIV-discordant partners when the partner with HIV adheres to ART and maintains a suppressed viral load (<200 HIV-1 RNA copies/mL) measured routinely every 4 to 6 months." The authors concluded that the body of evidence studied for over a decade can and should be considered scientifically sound; that concept of U = U provides an incentive for people living with HIV to seek, initiate and adhere to ART; and that U = U is a critical tool to preventing HIV transmission.

4. **Hall H. Irene, Holtgrave David R., Maulsby Catherine. HIV transmission rates from persons living with HIV who are aware and unaware of their infection. *AIDS.* 2012;2012(26):887-896.**

This research letter from Hall et al. provides HIV transmission rate modeling estimates of secondary infections from those aware and unaware of their HIV infection. "An estimated 49% of transmissions were from the 20% of persons living with HIV unaware of their infection." Additionally, "About eight transmissions would be averted per 100 persons newly aware of their infection; with more infections averted the higher the percentage of persons with viral suppression who can be linked to care. Improving all stages of HIV care would substantially reduce transmission rates." Authors noted several limitations to the analysis: 1) the percentage of persons with viral suppression may vary based on the definition used; 2) little new information was available for some of the parameters in the model (e.g., magnitude of reduction in risk behavior or number of partners); and 3) other factors may contribute to HIV transmission not considered in the model.

5. **Altice F. , Evuarherhe O., Shina S. , et al. Adherence to HIV treatment regimens: systematic literature review and meta-analysis. *Dove Medical Press.* 2019;13:475-490.**

This systematic literature review and meta-analysis by Altice et al. examined the relationship between single-tablet antiretroviral therapy regimens (STRs) (versus multiple-tablet regimens [MTRs]), treatment adherence, and viral suppression. Authors cited evidence that "ART regimens differ in dosing complexity, toxicity, and tolerability – factors that influence adherence to treatment and outcomes." As suboptimal adherence reduces the likelihood of viral suppression, it can result in increased risk of transmission and of developing drug resistance, which limits future treatment options. Authors cited a study published in 2000 which found that high adherence (taking 95% or more of prescribed doses) was associated with greater viral suppression, avoidance of drug resistance, and HIV-associated complications. They also cited results of a 2016 meta-analysis which suggest that adherence of 80-90% may adequately achieve viral suppression, "suggesting that some types of regimens may be more forgiving than others". Researchers conducted a systematic review to "identify studies investigating at least one of the following: (1) STR/MTR use and adherence; (2) levels of adherence and viral suppression; and (3) STR/MTR use and viral suppression." An initial literature search was completed September 6, 2013 (studies published between 2006 and 2013), and a subsequent search was conducted September 14, 2016, to identify research published since the first literature pull (2013-2016). One reviewer manually screened identified titles and abstracts against pre-specified eligibility

criteria for each objective. Inclusion criteria included: available full text original research published in English, conducted in North America or the European Union, and involving adults diagnosed with HIV; studies in which patients received once-daily ART and those with a one-pill regimen arm with no confirmation that treatment was administered once daily were included, those in which all patients received more-than-once-daily regimens were excluded. A total of 2,117 publications were initially identified, and 29 studies met inclusion criteria across the three objectives (11 for objective 1 [9 conducted in the USA, 2 conducted in the EU]; 18 for objective 2; and 4 for objective 3), two of which were relevant for all three objectives. They then performed a meta-analysis to assess the relationship between STR vs MTR use and adherence in observational settings (i.e., at equal to or greater than 95% and equal to or greater than 90% adherence thresholds). For objective 1, results of the meta-analysis showed that STRs were associated with higher treatment adherence than MTRs in 10/11 observational studies, and the differences were statistically significant in 9 studies. Meta-regression analyses did not find a significant effect of sex, age, or race on association between STR or MTR use and treatment adherence. Specifically, STRs were associated with "63% greater likelihood of achieving [greater than or equal to] 95% adherence (95% CI=1.52–1.74; P,0.001) and a 43% increase in the likelihood of achieving [greater than or equal to] 90% adherence (95% CI=1.21–1.69; P,0.001)" compared to MTRs. For objective 2, 13 of 18 studies found "higher adherence rates were associated with higher levels of viral suppression". Researchers did not conduct a meta-analysis addressing this objective due to "high variation in adherence thresholds and viral outcomes reported in identified studies". However, one study found that "patients optimally adherent to ART were [3] times more likely than non-adherent patients to be virally suppressed." Of the other 5 studies, 2 had mixed outcomes and 3 did not find an effect of adherence on virologic outcomes. Results were mixed in five studies investigating the association between STR or MTR use and viral suppression. For objective 3, researchers found mixed results among the 5 studies investigating the association between STR versus MTR use and viral suppression. Authors stated, "despite several studies showing that STRs are associated with greater adherence than MTRs, the impact of this improvement on virologic suppression has yet to be clearly demonstrated." They concluded further research is required to determine whether adherence to STRs results in improved virologic and clinical outcomes. Authors noted study limitations included: studies use real-world adherence and were non-randomized; studies results may be confounded by patient differences; most studies calculated adherence according to pharmacy records and reimbursement claims data, which may not reflect true adherence; only a small number of studies directly evaluated the association between STR use and clinical outcomes; limited data on INSTI regimens (now recommended). Disclosure: The employer of three authors is funded by Gilead Sciences, and one author was an employee of Gilead Sciences at the time of publishing. Authors reported no other conflicts of interest in this work.

6. **Adolescents Panel on Antiretroviral Guidelines for Adults and. HIV Clinical Guidelines: Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. U.S. Department of Health and Human Services National Institutes of Health;2021.**

The U.S. Department of Health and Human Services (HHS), in collaboration with the National Institutes of Health (NIH) publishes federally-approved medical practice guidelines for HIV/AIDS. The Panel on Antiretroviral Guidelines for Adults and Adolescents updated the "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV" in

August 2021. The Guidelines summarize available research, assign a strength of evidence, and provide recommendations on treatment goals, initiation of antiretroviral therapy (ART), and use of ART to prevent sexual transmission (i.e., treatment as prevention) among other topics.

7. **What is *Ending the HIV Epidemic in the U.S.*? 2022; Available at. Accessed 1/10/2022.**

In 2019, the U.S. Department of Health and Human Services (HHS) announced the "Ending the HIV Epidemic in the U.S." initiative, which aims to reduce the number of new HIV infections by 90% by 2030. The use of ART is one of the four pillars of ending the HIV epidemic.

8. **Medicaid Prescription Drug Laws and Strategies. 2021; Available at: https://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx. Accessed.**

The National Conference of State Legislatures (NCSL) provides an overview of Medicaid prescription drug coverage and strategies implemented by state governments to administer coverage. They explain that the Medicaid prescription drug benefit is an option for state Medicaid programs, and all 50 states provide this benefit. According to NCSL, "The Omnibus Budget Reconciliation Act of 1990 established the Medicaid Drug Rebate Program (MDRP), which requires participating drug manufacturers to provide significant rebates to the federal government and states as a condition of having their outpatient drugs covered by Medicaid." Under the Medicaid Drug Rebate Program, states receive "the best price offered by manufacturers as a condition of coverage" and have a range of strategies they may implement to modify how the Medicaid pharmacy benefit is administered.

9. **Dawson L., Dolan R. State Medicaid Management of Prescription Drugs for HIV Treatment and Prevention. Kaiser Family Foundation;2020.**

Kaiser Family Foundation completed a survey of Medicaid officials in all 50 states and the District of Columbia about Medicaid pharmacy practices in place or implemented in 2019. This report by Kaiser Family Foundation provides a summary of state Medicaid coverage for HIV antiretroviral drugs. They stated that "[s]pending on antiretrovirals (ARVs), the drugs used to treat and prevent HIV, has an outsized impact on state Medicaid programs." Kaiser Family Foundation stated that, "[s]ince state Medicaid programs are required by law to cover all FDA-approved medications from manufacturers that have entered into federal rebate agreements, all [antiretrovirals] are covered." However, states may choose to use utilization management to limit or control use of prescription drugs. Since antiretrovirals are high cost drugs, state Medicaid programs use utilization controls, including preauthorization, to control costs. They state that utilization controls may reduce costs, but may result in access barriers, reduced use of essential medications, worse health outcomes, and new HIV infections. Fourteen states have passed legislation prohibiting utilization controls (e.g., preauthorization) for antiretroviral medications. Forty-six states (including Washington State) do not require preauthorization for PrEP.

10. **Authority Washington State Health Care. HIV: How HCA Uses Evidence to Inform Decision Making. 2021.**

The Health Care Authority (HCA) prepared a presentation for the Drug Utilization Review Board, presented on December 15, 2021 focused on HIV drug regimens and how HCA uses evidence to inform decision making. The presentation included slides that covered how clinical

criteria are developed, how (if needed) a budget analysis would be performed, information on single tablet versus multi tablet regimens, data on HIV use and cost of single tablet and multi tablet utilization and authorization requests, and an overview of related practices in other states.

11. **Apple Health Preferred Drug List (PDL). 2022; Available at: https://www.hca.wa.gov/billers-providers-partners/programs-and-services/apple-health-preferred-drug-list-pdl. Accessed 1/9/2022.**
This Washington State Health Care Authority webpage includes information about the Apple Health Preferred Drug List.

12. **Merrick LeighBeth. Senate Bill Report: SB 5551, Concerning Medicaid coverage for HIV antiviral drugs.2022.**
The Senate Bill Report for SB 5551, Concerning Medicaid coverage for HIV antiviral drugs provides a summary of the provisions of the bill and a background on the policy topic.

13. **Commission Washington State LGBTQ. Input from the HIV Medication Access Workgroup: Provided to the LGBTQ Commission as they prepare a Brief Report to the Washington State Legislature in accordance with Budget Proviso SB 5092 Sec.18.6.a.Olympia, WA2021.**
The LGBTQ Commission was directed by the Legislature through SB 5092 (2021) to convene stakeholders on topics related to (1) access to HIV antiretroviral drugs on the Medicaid drug formulary, (2) impact of drug access on public health and statewide HIV reduced transmission goals, and (3) maximizing pharmaceutical drug rebates for HIV antiretroviral drugs. The proviso required collaboration with the Health Care Authority (HCA), Department of Health (DOH), advocates, consumers, and medical professionals to provide recommendations on the topic areas. Workgroups convened between August and October 2021. The report contextualized that the workgroup considered the issue of moving towards an open access system from a prior-authorization system was a "false dichotomy," and that there were significant barriers beyond the prior-authorization system. The report delineated the framework for both an open access system and a prior-authorization system. Consistent workgroup participants agreed on six key issues: (1) access to HIV treatment is an equity issue; (2) there are disputed consequences of moving from a prior-authorization system to an open access system; (3) actual costs need to be understood; (4) the prior-authorization system creatives obstacles with implications for individual and public health; (5) drug pricing, drug costs, and the role of rebates is unclear; and (6) goals of the 2016 "End AIDS 2020" report have not been met. The report provided options to address the six issues. Finally, the report offered additional considerations, including new single-tablet regimens; little data exists on the impact and costs of these drugs.

14. **Authority Washington State Health Care. Antivirals -- HIV Combinations, Medical policy no. 12.10.99-3. 2020.**
Washington State Health Care Authority Medical policy no. 12.10.99-3 outlines medical necessity criteria for HIV antiviral drug combinations. The policy refers to three policies addressing coverage of HIV antivirals, including rilpivirine (Edurant) (12.10.90.AA), emtricitabine alafenamide-tenofovir (Descovy) (approved for use as PrEP) (12.10.99.AA), and cabotegravir/rilpivirine (Cabenuva) (12.10.99.AB). The policy also states instances where prior authorization is required.

15. **Cohen J., Beaubrun A., Bashyal R., et al. Real-world adherence and persistence for newly-prescribed HIV treatment: single versus multiple tablet regimen comparison among US Medicaid beneficiaries. *AIDS Res Ther.* 2020;17(1):12.**
Cole et al. conducted a multi-state, longitudinal evaluation of Medicaid administrative claims data from 2001 to 2012 from 14 states (accounting for approximately 75% of HIV prevalence; not including Washington State) to identify changes over time in the 10 most common HIV-related comorbidities among people living with HIV. They found that 9 out of 10 comorbid conditions increased over time, though the greatest increases occurred among chronic conditions associated with older age (e.g., hyperlipidema, hypertension, diabetes), but not specifically associated with HIV. In 2012, 31% of people living with HIV enrolled in Medicaid exhibited evidence of hypertension, 26% of psychiatric disease, 25% liver disease, and 23% of pulmonary disorder. The authors found that, "[a]lthough rates of comorbid conditions increased over time, the percentage of enrollees having any HIV-related condition declined; this was also true of HIV-related cancers. This is likely due to dramatic improvements in ART. The most consequential improvement was widespread implementation of [STRs], but there is also evidence that ART adherence improved over [the study] time period."

16. **Washington State Department of Health Office of Infectious Disease. Washington State HIV Surveillance Report 2020 Edition.Tumwater, WA2020.**
In 2019, there were more than 14,000 individuals living with HIV in Washington State. The number of new cases of HIV in Washington State remained stable from 2015 to 2019, with an average rate of 5.4 new cases of HIV per 100,000 people. King and Mason counties had new HIV case rates above the state rate (9.2 and 7.3 cases per 100,000 people, respectivey). Clark, Columbia, Pierce, and Spokane counties had rates similar to the state rate (4.6, 4.9, 5.8, and 4.4 cases per 100,000 people, respectively). In 2019, approximately 89% of people living with HIV were engaged in care, and 82% of people living with HIV have a suppressed viral load. In 2018, there were 205 deaths among cases of HIV infection. In 2019, there were 410 new cases of HIV. In 2019, approximately 83% of new cases were among cis-gender males, 15% among cis-gender females, 2% among transgender females, and 0% among transgender males. Most cases (41%) were among individuals aged 25-34. The majority of new cases (59%) were among men having sex with men. By race/ethnicity, 49% of new cases were among Whites, 17% were among Blacks, and 24% were among Hispanics. Between 2015-2019, foreign-born Blacks had the highest rate of new HIV cases, with 52.6 cases per 100,000 individuals. The rates for Blacks (both foreign-born and U.S. born), Hispanics (foreign-born), and Native Hawaiian/Pacific Islanders were higher than the state rate. From 2015 to 2019, 50% of new HIV cases occurred in King County.

17. **R Chou, S Selph, T Dana, et al. Screening for HIV: systematic review to update the U.S. Preventive Services Task Force recommendation. Evidence synthesis No. 95. *Agency for Healthcare Research and Quality.* 2012.**
The U.S. Preventive Services Task Force (USPSTF) is an independent panel of experts that systematically reviews the evidence and provides recommendations intended to help clinicians, employers, policymakers, and others make informed decisions about healthcare services. This review, which focused on HIV screening for adolescents and adults, included evidence from randomized clinical trials and observational studies. Findings indicated that screening for HIV is

accurate, screening only targeted groups misses a large number of cases, and that antiretroviral therapy (ART) reduces the risk of death and sexual transmission of HIV.

18. **Schneider G., Juday T., Wentworth C., 3rd, et al. Impact of health care payer type on HIV stage of illness at time of initiation of antiretroviral therapy in the USA. *AIDS Care.* 2013;25(11):1470-1476.**
Schneider et al. completed a retrospective analysis of GE Centricity Outpatient Electronic Medical Records data from 1885 adults living with HIV from January 1, 1997 to September 30, 2009 to determine the effect of payer type on HIV stage at time of antiretroviral therapy (ART) initiation. The authors hypothesized that people with Medicaid would have worse HIV severity at ART initiation than people with other types of insurance (i.e., Medicare, private insurance, self-pay, other/unknown). They cite prior evidence suggesting that Medicaid is the largest payer for people living with HIV. Their analysis controlled for age, gender, race, smoking status, physician visit frequency, and comorbidities. Approximately 12% (218 people) of the sample group had Medicaid, and people with Medicaid had more severe HIV than patients with other insurance types. Overall, the authors found that the odds of initiating ART at less severe stages of HIV was statistically significantly greater for people with private insurance, self-pay, and other/unknown, compared to people with Medicaid. For example, people with private insurance were 1.5 times more likely to start ART at less severe stages of HIV than people with Medicaid. Initiation was similar for people with Medicare. Since evidence indicates that earlier initiation of ART is associated with better health outcomes, including lower morbidity and mortality, the authors stated that these findings "underscore the need for mitigating barriers, particularly in the Medicaid population, that may delay treatment initiation." They stated that people with Medicaid may face a number of systematic barriers to accessing healthcare, including barriers related to geography, transportation, language, and health literacy.

19. **Cole M. B., Galarraga O., Rahman M., et al. Trends in Comorbid Conditions Among Medicaid Enrollees With HIV. *Open Forum Infect Dis.* 2019;6(4):ofz124.**
Cole et al. conducted a multi-state, longitudinal evaluation of Medicaid administrative claims data from 2001 to 2012 from 14 states (accounting for approximately 75% of HIV prevalence; not including Washington State) to identify changes over time in the 10 most common HIV-related comorbidities among people living with HIV. They found that 9 out of 10 comorbid conditions increased over time, though the greatest increases occurred among chronic conditions associated with older age, but not specifically associated with HIV (e.g., hyperlipidema, hypertension, diabetes). In 2012, 31% of people living with HIV enrolled in Medicaid exhibited evidence of hypertension, 26% of psychiatric disease, 25% liver disease, and 23% of pulmonary disorder. The authors found that, "[a]lthough rates of comorbid conditions increased over time, the percentage of enrollees having any HIV-related condition declined; this was also true of HIV-related cancers. This is likely due to dramatic improvements in ART. The most consequential improvement was widespread implementation of [STRs], but there is also evidence that ART adherence improved over [the study] time period."

20. **Centers for Disease Control and Prevention. Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV. 2019; Available at:**

https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html. Accessed September, 2019.
This Centers for Disease Control and Prevention (CDC) website provides "the best estimates of effectiveness for various strategies to prevent HIV acquisition or transmission. Each estimate was identified from the published scientific literature and represents the effectiveness of each strategy when used optimally." Additionally, "combining prevention strategies may be even more effective." However, strategies must be used correctly and consistently in order to work. This page includes effectiveness estimates for antiretroviral therapy (ART), oral daily pre-exposure prophylaxis (PrEP), male condom use, and circumcision of adult males.

21. **Eshleman S. H., Wilson E. A., Zhang X. C., et al. Virologic outcomes in early antiretroviral treatment: HPTN 052. *HIV Clin Trials.* 2017;18(3):100-109.**
This study evaluated time to viral suppression and virologic failure among index participants who started ART in the 2011 HIV Prevention Trials Network (HPTN) clinical trial of 1,763 couples from 12 low- and middle-income countries. HPTN's full enrollment ran from 2007 to 2010 and participants were counseled on the individual and public health benefits of ART. The couples were enrolled in two study arms: the first initiated ART treatment immediately after enrollment, the second after a CD4 cell count fell below 250 cells/mm3. Researchers documented participant viral load testing protocol and parameters for viral suppression and virologic failure. Researchers examined the potential ascertainment bias in determining the timing of a viral suppression due to variation in the timing of viral load measurements, characteristics of study participants in different groups, and the association of demographic and other factors with time to viral suppression and virologic failure. The HPTN trial identified two periods of risk for HIV transmission when a person in on ART therapy: at the time of ART initiation, before suppressed viral loads, and after virologic failure. Eshleman et al. found a similar time to viral suppression for both study arms (p=0.06). The researchers found three factors independently associated with a longer time to viral suppression. The first association was a higher viral load at ART initiation in studies where ART was initiated at lower CD4 cell counts. The second association associated with a longer time to viral suppression was a person's age (less than 25 years old). This population through previous research has also been associated with having lower adherence to treatment regimens. Third, there were regional differences that were associated with a longer time to viral suppression. Eshleman et al. also found an association between lower educational attainment and virologic failure, though they state that further studies are needed whether the association they observed was due to low adherence or other factors. The authors conclude that the HPTN study, along with others, provide strong support for universal early-start of HIV treatment regardless of CD4 cell count. The HPTN trial, along with other studies indicate that "sexual transmission of HIV is very unlikely when the infected individual is virally suppressed" and that "linked partner infections were not observed when index participants were stably suppressed on ART." It is accepted that "achieving and maintaining viral suppression after ART initiation directly benefits those on ART and has public health benefits by reducing HIV transmission."

22. **Davari M., Giwa H. B., Nabizade A., et al. Antiretroviral therapy and the risk of sexual transmission of HIV: a systematic review and meta-analysis. *HIV Med.* 2020;21(6):349-357.**

Davari et al. discussed of the effectiveness of ART in minimizing the sexual transmission of HIV. The authors quoted the Swiss National AIDS 2008 statement that outlined when people living with HIV are considered non-infectious, noting that since this statement, more systematic reviews and meta-analyses have been performed. Davari et. al. conducted this systematic review to examine the "the effect of ART on the risk of sexual transmission of HIV" and to "evaluate the effect of ART with or without condom use on the risk of sexual transmission of HIV." Authors searched Cochrane, Web of Science, EMBASE, SCOPUS and PubMed Central databases for articles published between 2007 and 2019 and filtered for English language reviews, systematic reviews, meta-analysis and human species. Studies were included if they were a systematic review or meta-analysis and included intervention of ART with or without condom use, and when a study's outcomes of interest included HIV transmission events. Study participants included those 18 years old or older and who were members of hetero- or homosexual serodiscordant couples. Searches yielded 1,424 articles references and the authors ultimately included 10 eligible studies, half from the United States (n=5). The studies were classified as either stratified or unstratified to separate studies with clinical heterogeneity and clinical homogeneity. The researchers conducted a meta-analysis of four studies that considered the risk of transmission associated with versus without ART, with a point estimate of relative risk. A second meta-analysis consisted of two cohorts that considered the risk of transmission associated with versus without ART, with a point estimate of incidence rate. A third meta-analysis consisted of a cohort where people on ART had suppressed viral loads and was a subgroup analysis of two studies. All 10 studies found that "there was a reduction in the risk of sexual transmission of HIV with the use of ART in both heterosexual serodiscordant couples and [men who have sex with men (MSM)] serodiscordant couples." The review also showed that consistent condom use led to further reduced transmission. When considering early versus delayed treatment, "risk was found to be lower for early treatment than for late treatment." Through their meta-analysis, the researchers concluded that ART compared with no ART was associated with a lower risk of transmission with significantly lower relative risk (rr=0.48, 95% CI, 0.439–0.525, Q = 0.524; I2 = 0.0%; overall effect Z = 15.99, P < 0.0001) for cohorts with effect sizes as relative risks. There was a 52% reduction risk of transmission in groups on ART compared to those not on ART. ART vs. no ART was associated with a reduction in the time at risk from 5.6 person-years (95% CI 3.26–9.62 person-years, Q = 0.771; I2 = 0.0%; overall effect Z = 6.25, P < 0.0001) in the untreated groups to 0.85 person-years (95% CI 0.28–2.99 person-years, Q = 0.038; I2 = 76.7%; overall effect Z = 0.11, P = 0.772) in the treated groups. This implied an 84% reduction of risk of transmission in people in the treated group. People on ART with suppressed viral loads had a very low risk of transmission (95% CI 0.00–0.00); Q = 1.00; I2 = 0.0%; overall effect Z = 6.8, P < 0.0001].

23. **Chou R. , Evans C. , Hoverman A. , et al. Preexposure Prophylaxis for the Prevention of HIV Infection: Evidence Report and Systematic Review for the US Preventive Services Task Force. *US Preventive Services Task Force.* 2019.**

Chou et. al. completed a systematic review to support the United States Preventative Services Task Force's (USPSTF) development of new recommendations for the use of PrEP to prevent HIV infection. The review was to "synthesize the evidence on effects of PrEP on HIV acquisition risk, mortality, harms, and other clinical outcomes; effects of adherence on PrEP-associated outcomes; and accuracy of methods for identifying potential candidates for PrEP" through five key questions (KQ). Authors searched Ovid MEDLINE, the Cochrane Library, and

EMBASE data based for English-language articles for articles published since "inception" through June 2018, with supplemental review of reference lists and on-going surveillance through article alerts and targeted search between June 2018 and January 2019. The systematic review included 14 RCTs in 37 articles (n=18,837), 8 observational studies (n=3,884), and seven studies of diagnostic accuracy of HIV risk prediction instruments (n=32,279). KQ1 considered the benefits of PrEP in individuals without preexisting HIV infections versus placebo versus no PrEP on the prevention of HIV infection and quality of life and considered how the benefits differ by population subgroup or by dosing strategy or regimen. KQ1 included 12 randomized clinical trials. Participant mean age was younger than 40 (n=18,244) and all enrolled were at an increased risk of infection. Trials were conducted in Africa, Thailand, the United States, Canada, and Europe. Trials conducted in the United States, Canada, and Europe enrolled men who have sex with men. KQ2 considered the diagnostic accuracy of provider or patient risk assessment tools in identifying people with increased risk of HIV acquisition who were PrEP candidates. Seven studies were evaluated (n=32,311). The seven trials "evaluated instruments developed and validated in US cohorts for predicting incident HIV infection." Six of the studies were of men who have sex with men and one evaluated people who inject drugs (PWID). The authors note the studies for this question had methodological shortcomings. KQ3 examined the rate of adherence to PrEP in US primary care-applicable settings and evaluated 10 studies (n=3,177). The duration of PrEP use ranged from 6 months to 2 years. Nine studies were rated as fair quality, one was rated as good quality. KQ4 examined the association between adherence to PrEP and effectiveness in preventing HIV acquisition. Three RCTs (n=5,591) found "PrEP associated with greater effectiveness compared with placebo for reducing risk of HIV infection among participants having higher adherence to daily PrEP based on daily pill counts or daily diaries, compared with participants having lower adherence." KQ5 examined the harms of PrEP versus the placebo or no PrEP when used for the prevention of HIV infection through examining 12 trials (n=18,282). The examination found "no significant difference between PrEP versus placebo in risk of serious adverse events" (RR, 0.93 [95% CI, 0.77-1.12]; I2 = 56%). There was associated risk of renal and gastrointestinal events for people who used PrEP, though most events were mild and reversable. There was no association found between PrEP users versus non-PrEP users for considered sexually transmitted infections. The authors concluded that their findings show that in populations that are at an increased HIV infection risk, PrEP was associated with decreased risk of acquiring HIV infection. This risk varied based on the level of adherence to the PrEP regimen. For trials conducted in the United States, adherence varied widely. Adherence was generally lower in men ages 16-20 who have sex with men.

24. **Goldstein D., Hardy W. D., Monroe A., et al. Despite early Medicaid expansion, decreased durable virologic suppression among publicly insured people with HIV in Washington, DC: a retrospective analysis. *BMC Public Health.* 2020;20(1):509.**
Goldstein et al. evaluated data from 2011 to 2015 (after implementation of the Affordable Care Act) from the Washington D.C. Cohort Study. Their study included 3,908 people living with HIV receiving care at 12 clinics (including community and hospital clinics) in Washington D.C.. The authors compared HIV outcomes among people living with HIV enrolled in private insurance versus public insurance (i.e., Medicaid and Medicare). They examined a number of HIV monitoring outcomes (e.g., greater than or equal to 2 lab measures/year) and durable viral suppression outcomes (e.g., receiving ART for greater than or equal to 12 months). They controlled for a number of demographic and clinical factors (e.g., age, gender, race/ethnicity,

housing status, employment status, year since HIV diagnosis, HIV transmission risk categories, AIDS diagnosis, comorbidities [i.e., substance use, depression, psychotic disorder, hypertension, hepatitis C]). The primary research question assessed the impact of insurance type on durable viral suppression among ART-naïve and ART-experienced people. Overall, they found that, while people living with HIV enrolled in public insurance were more likely to meet laboratory monitoring standards, people living with HIV enrolled in private insurance were statistically significantly more likely to have greater durable viral suppression measures than people living with HIV enrolled in public insurance. For example, 80% of people living with HIV enrolled in private insurance and using ART had durable viral suppression compared to 69% of people living with HIV enrolled in public insurance and using ART. They also found that likelihood of durable viral suppression increased with age, for whites and Hispanics, and for people without an AIDS diagnosis. They found no significant relationship with housing status or mode of HIV transmission. They stated that some of the differences in outcomes may be due to structural barriers experienced by people enrolled in public health insurance (e.g., transportation to pharmacies). The authors also presented prior research showing that, prior to the Affordable Care Act, people living with HIV enrolled in Medicaid had worse health outcomes than people with private insurance, including later initiation of ART, higher incidence of comorbidities (e.g., cardiovascular diseases, renal impairment, chronic hepatitis), less sustained viral suppression, and higher mortality rates.

25. **Jabs A. W., Jabs D. A., Van Natta M. L., et al. Insurance status and mortality among patients with AIDS. *HIV Med.* 2018;19(1):7-17.**

Jabs et al. conducted the Longitudinal Study of the Ocular Complications of AIDS study, which is a prospective, observational study with 2,363 people diagnosed with late-stage HIV (i.e., AIDS), to determine the impact of insurance status on mortality risk factors. The study population experienced a mortality rate of 4.0/100 person-years, and mortality was greatest among people with public insurance compared to people with private insurance. The authors calculated a hazard ratio of 1.36 for people enrolled in Medicaid compared to people with private insurance. People enrolled in Medicaid who were also virally suppressed also had higher risk of mortality compared to people with private insurance who were virally suppressed. The authors concluded "compared to persons with AIDS and private insurance, persons with public insurance have increased mortality, possibly due to a greater burden of non-infectious, age-related diseases [i.e., HIV-related comorbidities]." They also cited prior research suggesting that "public insurance may be a marker for chronic non-infectious, age-related co-morbidities." Risk factors of mortality were also more likely for Hispanics, older people, lower levels of education, among other clinical factors. The authors explained that, in a larger body of research not specific to HIV-related health outcomes, "[m]any studies demonstrate more advanced disease and greater co-morbidities among persons with public or no insurance, accounting at least in part for the differences in outcomes, but some studies demonstrate a persistently worse outcome for those with public or no insurance even after adjustment, suggesting access to care or process of care issues."

26. **Project Medical Monitoring. Improving the Lives of People Living with HIV in Washington. Washington State Department of Health, Office of Infectious Disease;2019.**

The Medical Monitoring Project is a surveillance system designed to combine clinical, behavioral, and contextual information about the experiences of people living with HIV in

Washington State. A random, representative sample of approximately 200 people living with HIV in Washington State are interviewed every year. This report provides information from 2019.

27. **Korsnes J. S., Goodwin B. B., Murray M., et al. Antiretroviral Treatment Switching and Its Association With Economic Outcomes and Adverse Treatment Effects Among Commercially Insured and Medicaid-Enrolled Patients With HIV in the United States. *Ann Pharmacother.* 2016;50(12):989-1000.**

Korsnes et al. completed a retrospective analysis of commercial and Medicaid administrative healthcare claims (available from the Truven MarketScan databases) for 14,590 people living with HIV in the U.S. from 2006 to 2011 to determine whether switching ART regimens was associated with increased healthcare costs, resource use, and adverse treatment outcomes. The study sample included 5,744 people living with HIV enrolled in Medicaid. Fourteen percent of people living with HIV enrolled in Medicaid switched ART treatment. Controlling for a number of demographic and clinical characteristics, the authors found that switching ART treatments resulted in a 36% increase in hospitalizations, 25% increase in nonpharmacy costs, 18% increase in pharmacy costs, and increased risk of adverse treatment effects (e.g., hyperlipidemia, gastrointestinal intolerance, skin rash). The authors concluded that, "[e]fforts to put patients on an optimal ART regimen initially, therefore reducing the need for subsequent switching, may have a positive effect on patients…" The authors explained that new ART regimens "offer improvements in dosing convenience, tolerability, and treatment resistance." People "may switch their ART [regimens] for various reasons, including tolerability, suboptimal adherence, long-term toxicities, simplifying the regimen, the regimen performing poorly, or modification resulting from comorbid conditions that may lead to drug-drug interactions."

28. **Medicine American Academy of HIV. Prior Authorization: Policy brief.Washington D.C.no date.**

The American Academy of HIV Medicine represents HIV physicians, physician assistants, nurse practitioners, and pharmacists. This policy brief provides information about the impact of prior authorization on accessing HIV medication.

29. **Institute New York State Department of Health AIDS. Barriers to HIV Medication Access.2014.**

In 2014, the New York State Department of Health AIDS Institute conducted the Access to HIV Medications Survey with 42 people living with HIV and 64 healthcare providers to identify barriers to acquiring and prescribing HIV medications. The AIDS Institute stated that, "[t]he survey, while limited, helped the AIDS Institute begin to quantify barriers to medications that had previously only been reported anecdotally." They identified a number of barriers to accessing HIV medications including: mail order medications (37% of respondents), coverage (20%), prior authorization (9%), Medicaid spenddown (6%), access to medication (5%), co-payments (5%), and other problems (19%) (e.g., communication, deductible cost, language barriers, pharmacy complaints, pharmacy delays, pharmacy errors, refills, and service complaints). Specific to prior authorization, the authors stated that prior authorization resulted in delays of medication and treatment interruptions for people living with HIV and in time burdens for providers. They concluded that, "[b]alancing out the positive effects of prior authorization

policy, to control costs and assure appropriate coverage, is an important next step in breaking down barriers to HIV medications."

30. **Healthy People 2030: Access to health services. 2020; Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health/literature-summaries/access-health-services. Accessed.**
Healthy People 2030 includes a goal to improve access to health services as a key issue in improving healthcare access and quality as a social determinant of health.

31. **American Psychological Association. Evidence-Based Practice in Psychology: APA Presidential Task Force on Evidence-Based Practice. 2006;61(4):271-285.**
The American Psychological Association (APA) created a policy indicating that the evidence-base for a psychological intervention should be evaluated using both efficacy and clinical utility as criteria. The Association President appointed the APA Presidential Task Force on Evidence-Based Practice and the task force published this document with the primary intent of describing psychology's commitment to evidence-based psychological practices. This document, though, also references many research articles providing evidence for the efficacy of a number of psychological treatments and interventions. The reference list for this document highlights the growing body of evidence of treatment efficacy from the 1970s through 2006. Note that this does not indicate that all treatments are effective, but rather than there is a very large body of evidence supporting that evidence-based treatments are available.

32. **Hill L. , Ballard C. , Cachay C. . The Role of the Clinical Pharmacist in the Management of People Living with HIV in the Modern Antiretroviral Era. *AIDS Review.* 2019;21:195-210.**
The authors examined the role of a clinical pharmacist in the medical management for people living with HIV (PLWH) through a review of literature focused on clinical pharmacist (CP) involvement in the care of PLWH. Authors noted a limited number of applicable studies, and as such, search requirements were limited. The review pulled literature from 2006 onward that was written in English. The results yielded 12 studies related to HIV related interventions and impact on virologic outcomes; 2 studies on aging and vulnerable populations; 2 studies on the pharmacist role in comorbidities; 9 studies in medication reconciliation and transitions of care; and 5 studies on HIV prevention including PrEP. The majority of the studies were conducted in the United States. The researchers discussed ART treatment and the movement towards rapid initiation of ART for faster viral suppression. The authors discussed the role CPs have in scaling up rapid initiation and adherence. The authors discussed that the success of ART "depends on the regimen optimization to reduce pill burden and dosing frequency, reduce side effects, and address drug interactions" and that CPs can impact drug adjustment recommendations (i.e., decreased numbers of pills or frequency) that may also increase adherence. A change in ART therapy may be recommended due to virologic failure, toxicities, regimen complexity, non-adherence, and prevention of toxicities. The authors contextualized that PLWH are living longer and that in 2015 in the United States, 45% PLWH were 50 years old or greater. As the population of PLWH increases and ages, the presence of comorbidities is also increasing (i.e. cardiovascular renal, bone, diabetes, obesity, and hyperlipidemia) and these comorbidities also require a respective drug regimen. Specific to PLWH, "polypharmacy" has been identified as a significant predictor of non-adherence to ART." Additionally, comorbidities may compound

medical management and adherence for PLWH who may experience additional barriers to medical management such as social isolation, mental health concerns, unstable housing, and substance abuse. The researchers discussed the significant amount of resources involved with prior authorization processes and the role CPs could play to advocate for their patients' optimal coverage.

33. **Van Der Wees Philip J., Zaslavsky Alan M., Ayanian John Z. Improvements in health status after Massachusetts health care reform.** ***The Milbank Quarterly.*** **2013;91(4):663-689.**
Van Der Wees et al. aimed to compare trends in the use of ambulatory health services and overall health status before and after health reform in Massachusetts. In 2006, Massachusetts underwent a health care reform that, among other provisions, established, "...an individual mandate to obtain health insurance if affordable, expanded Medicaid coverage for children and long-term unemployed adults, subsidized health insurance for low and middle-income residents, and a health insurance exchange to help higher-income residents obtain unsubsidized insurance." This study utilized data from the Behavioral Risk Factor Surveillance System (BRFSS) from 2001-2011 for Massachusetts as well as surrounding states that did not undergo reform (Connecticut, Maine, New Hampshire, Rhode Island, and Vermont). A total 345,211 survey participants aged 18-64 were included in this study. The authors found that, compared to residents in neighboring states, Massachusetts residents reported better general, physical, and mental health; increased use of screening tests for cervical and colorectal cancer and cholesterol; a higher likelihood of having insurance and a personal doctor. These differences remained significant after adjusting for sex, age, race/ethnicity, income, employment, marital status, and education, and the annual unemployment rates in each state. In a subgroup analysis, the authors found that Massachusetts residents with an income less than 300% of the federal poverty level had the greatest increase in health status outcomes. The authors conclude that although health care reform in Massachusetts was associated with meaningful gains, health inequities still exist for low-income residents and further innovations, as well as federal health reform, may be necessary.

34. **Wherry L. R., Miller S. Early coverage, access, utilization, and health effects associated with the Affordable Care Act Medicaid expansions: a quasi-experimental study.** ***Annals of internal medicine.*** **2016;164(12):795-803.**
Wherry et al. used data from the National Health Interview Survey (NHIS) from 2010 to 2014 to evaluate whether state Medicaid expansion was associated with changes in insurance coverage, access to and utilization of care, and self-reported health. The authors used data for adults aged 19-64 with incomes below 138% of the federal poverty level in states that did and did not expand Medicaid. Compared with nonexpansion states, respondents in expansion states reported significant increases in diagnoses of diabetes and high cholesterol but no differences in diagnoses of hypertension, access to care, health status, or mental health. Medicaid expansions were also associated with significant increases in visits to a general physician. The authors conclude that these data provide evidence that the Affordable Care Act Medicaid expansions are associated with an increase in insurance coverage and health care utilization and that fully understanding the impacts of the expansion are crucial to future policy debates.

35. **Small Area Demographic Estimates by Age, Sex, Race and Hispanic Origin (2011-2020). In: Management WSOoF, ed. Olympia, Washington2021.**
This Washington State dataset from the Office of Financial Management presents estimates of April 1, 2021 population by age, sex, race, and Hispanic origin.

36. **Rueda S., Mitra S., Chen S., et al. Examining the associations between HIV-related stigma and health outcomes in people living with HIV/AIDS: a series of meta-analyses. *BMJ Open.* 2016;6(7):e011453.**
Rueda et al. completed a meta-analysis of 64 studies published between 1996 and 2013 that examined the association of HIV-related stigma and health outcomes for people living with HIV. The majority of studies (42) were conducted in the U.S. and used a cross-sectional study design (53). The authors defined HIV-related stigma as "discounting, discrediting, and discriminating against people perceived to have HIV" and includes enacted, anticipated, and internalized experiences of stigma. They looked at health outcomes associated with HIV-related stigma, including mental health (e.g. depression), quality of life, physical health, social support, adherence to treatment, access to and use of health care services, and risk behaviors. They found significant associations between HIV-related stigma and high rates of depression, low levels of social support, low treatment adherence, and lower access to and use of health care and social services. They also found weaker relationships between stigma and anxiety, quality of life, physical health, emotional and mental distress, and sexual risk practices. Access to health care services was measured by the "degree that people living with HIV have access to and use healthcare units, clinics, and social services." The authors' meta-analysis of 9 studies that evaluated access to care and controlled for other potential confounders showed that individuals that experienced HIV-related stigma were 21% less likely to access or use health and social services. The authors stated, "despite a few studies that do not support the association between HIV-related stigma and access to and usage of health and social services, other studies support the notion that perceived stigma of people living with HIV was associated with low access to care, or delayed presentation in care, possibility stemming from perceived discrimination by healthcare providers." The authors also note that intersectionality for individuals experiencing multiple types of stigma (e.g. HIV-related stigma, sexual stigma, racism, gender discrimination) may worsen health outcomes. The authors concluded, "HIV-related stigma has a detrimental impact on a variety of health-related outcomes in people [living] with HIV."

37. **Stockton M. A., Giger K., Nyblade L. A scoping review of the role of HIV-related stigma and discrimination in noncommunicable disease care. *PLoS One.* 2018;13(6):e0199602.**
Stockton et al. completed a scoping review of literature to identify the potential role of HIV-related stigma in accessing care for noncommunicable diseases. Individuals living with HIV are more susceptible to noncommunicable diseases (e.g. cancer, cardiovascular disease, chronic pulmonary disease, diabetes, anxiety, depression), especially as individuals experience longer life expectancy outcomes and as the global burden of noncommunicable diseases increases. HIV-related stigma may serve as a barrier to accessing prevention, diagnosis, and treatment services for non-communicable diseases. The authors noted that, "as [people living with HIV] seek care outside their regular HIV-care settings, there is some evidence that suggests the risk of encountering stigma related to HIV within the health system may rise." Their review included 16 articles published between 2007 and 2017, including 5 that took place in the U.S. One study

"among Asian Americans living with HIV found HIV stigma was negatively correlated with self-efficacy in recognizing and seeking medical attention for a heart attack (r= -0.43, p, .0005)." The authors also discuss that individuals may experience stigma related to noncommunicable diseases in addition to experiencing HIV-related stigma. In addition, "individuals may also face discrimination that influences their health for reasons unrelated to their health status and belonging to multiple stigmatized groups has been shown to compound the negative effects of stigma." HIV-stigma may also impact access to care for noncommunicable diseases for individuals that are HIV-negative, either due to beliefs that certain noncommunicable diseases are associated with HIV (e.g. cervical cancer) or due to integrated care models that provide care for both HIV and noncommunicable diseases. Overall, the authors found that fear of disclosure of HIV status, internalized shame and embarrassment, and actual or perceived negative perceptions of health care providers negatively impact access to care for noncommunicable diseases for individuals living with HIV. The authors also concluded that HIV-related stigma and noncommunicable disease-related stigma impacted access to care for patients regardless of HIV status.

38. **Katz I. T., Ryu A. E., Onuegbu A. G., et al. Impact of HIV-related stigma on treatment adherence: systematic review and meta-synthesis. *J Int AIDS Soc.* 2013;16(3 Suppl 2):18640.**

Katz et al. conducted a systematic review to determine the impact of HIV-related stigma on adherence to HIV antiretroviral therapy (ART). They reviewed 75 articles published between 1997 and 2013, including 34 qualitative studies and 41 quantitative studies. The authors did not identify how many studies were conducted in the U.S. However, they noted that the largest proportion (37%) of quantitative studies were conducted in the U.S. They conducted a meta-synthesis of qualitative studies to identify emerging themes across studies. The qualitative research showed that social support was important for ART adherence and helped to overcome HIV-related stigma to access care and treatment. In addition, "in many settings, study participants described HIV-related stigma as being layered on top of pre-existing inequalities, such as those related to gender, race, or sexual minority status." In many instances, this stigma led to individuals opting not to take medication for fear of disclosure. The authors also identified a common theme of poverty and explained the reciprocal relationship between stigma and poverty: "HIV-associated illness reinforces the perceived economic inadequacy of HIV-positive persons, who are excluded from networks of mutual aid. Stigmatized persons are excluded from the community, undermining their social support and worsening economic insecurity." Among the 41 quantitative studies included in the review, 61% found that stigma was associated with reduced ART adherence or that disclosure was associated with improved adherence. Thirty-nine percent of studies found no association. Overall, both enacted and internalized stigma undermine ART adherence by undermining social support and adaptive coping.

39. **Sweeney S. M., Vanable P. A. The Association of HIV-Related Stigma to HIV Medication Adherence: A Systematic Review and Synthesis of the Literature. *AIDS Behav.* 2016;20(1):29-50.**

In this systematic review, Sweeney et al. examine the relationship between HIV-related stigma and medication adherence, specifically antiretroviral therapies (ART). They included 38 studies published between 1997 and 2014 in their review. The authors did not note how many studies were conducted in the U.S. The authors considered 3 main types of HIV-related stigma:

anticipated, enacted, and internalized stigma. They define each type as, "anticipated stigma involves expectations of discrimination, stereotyping, and/or prejudice from others in the future due to one's serostatus…enacted stigma involves experiences…that have already occurred…internalized stigma refers to self-endorsing negative feelings and beliefs about having HIV." Experiences of stigma have been associated with depression, anxiety, hopelessness, negative social interactions, loss of social support, and decreases in self-esteem and self-efficacy. HIV-related stigma may also impact HIV testing, access to care, medication adherence, and disclosure. The authors provide an example that since medication adherence may require individuals to take medication at inopportune times or in public environments, fear or anxiety about inadvertent disclosure may result in delayed or skipped doses. Of 15 studies that combined multiple dimensions of stigma, six found that stigma was significantly associated with poor self-reported medication adherence. Four studies examining the impact of internalized stigma and three studies examining the impact of anticipated stigma on medication adherence found mixed results, with most associations disappearing in multivariate analysis models. All three studies focused on enacted stigma found an association between stigma and poor medication adherence. However, the authors found that, overall, "the majority of studies using single measures of stigma (n= 25/29) found an association between increased stigma and adherence difficulties, while every study assessing multiple indicators (n= 8/8) found an association between at least one type of stigma and nonadherence." The authors noted that the mediator between stigma and adherence is unknown, though they propose that the relationship may be impacted by mental health concerns, self-efficacy, and concerns about disclosure.

40. **Arnold M. P., Benton A., Loveluck J., et al. The People Living with HIV Stigma Index: Michigan, Wave I Findings, 2014-2016. UNIFIED-HIV Health and Beyond;2016.** The People Living with HIV Stigma Index Project documented experiences of internalized, social, and institutional stigma among individuals living with HIV in Detroit, Michigan. This report provides findings from Wave 1 of the study (2013-2016), which included a community survey and questionnaire with 70 people living with HIV in Detroit. Overall, 80% of individuals experienced negative feelings of self-blame and guilt about their positive serostatus; 73% experienced at least one form of social discrimination (e.g. rejection from potential partners); 20% experienced at least one form of institutionalized discrimination (e.g. healthcare, housing, insurance access); and 20% felt their rights as a person living with HIV had been violated or abused. In addition, "79% of individuals living with HIV reported a reduction in psychological, physical, and material well-being, particularly with respect to depression and anxiety, social engagement and support, and physical self-care (e.g., sleep, physical activity)" as a result of experiences of stigma and discrimination. Findings suggested that experiences of stigma differed for some communities, with people with lower socioeconomic status, people engaged in sex work, and people with a history of incarceration experiencing more consequences as a result of HIV-related stigma. Some differences also existed by age and race/ethnicity. The report also details where people living with HIV and experiencing stigma turn for support. In addition, stigma contributes to depression, anxiety, loss of income, isolation, suicide ideation and attempts, and substance use.