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Required Coverage of Home Test Kits for Sexually Transmitted Diseases

Maryland Health Care Commission

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Section 1: Executive Summary

Introduction

Senate Bill 634 (S.B. 634), "Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage", was introduced in the Maryland legislature on February 3, 2022, by Senator Clarence Lam[1]. The stated purpose of the bill was to "require certain health insurance policies and contracts to provide coverage for the purchase of home test kits for sexually transmitted diseases and related laboratory costs" under certain circumstances.

The Maryland Health Care Commission (MHCC) has retained Axene Health Partners, LLC (AHP) to deliver health care related actuarial services to assist the Commission in completing its legislative requirement under the Insurance Article §15–1501 regarding S.B. 634, including the appropriate fiscal, medical, and social analyses. Since S.B. 634 did not pass, AHP has completed its work assuming that a similar legislation is introduced and passed in the current legislative session.

Background

Jonathan Mermin, M.D., M.P.H, the director of the CDC's National Center for HIV/AIDS, Viral Hepatitis, STI, and TB Prevention describes the burden of STIs in the US as "staggering." He also reports in a 2021 press release that sexually transmitted disease rates are at an all-time high[2]. To add to the already difficult task of assessing the risks of untreated sexually transmitted diseases, not only is there a large cohort of asymptomatic patients there are also many patients unwilling to get tested because of other factors related to the stigma associated with sexually transmitted diseases. The realities of a large untested population suffering from highly preventable and treatable diseases has driven healthcare leaders to action. In fact, Department of Health and Human Services has developed a 5-year plan to address key issues, including devoting more resources to STI home test kit development and implementation[3]. One of the recommendations in that report is for states to review their laws and policies to see if there are any unnecessary barriers.

Sexually transmitted infections (STIs) are behavior-driven diseases that fall into 4 primary categories:

- Infections, like gonorrhea and syphilis, which are inexpensive to treat when caught early, but can lead to costly complications if they are not caught early.
- Infections, like herpes, which have no cure at the moment but with treatments to ameliorate symptoms.
- Infections, like HIV, with expensive treatments, but lead to lower costs if caught early.
- Undiscovered infections and newly discovered infections, like monkeypox.

In recent years, STI incidence and prevalence rates have grown rapidly because of increased substance abuse, increased poverty, decreased condom use among vulnerable populations, and shrinking public health resources[4]. While an STI home test kits mandate is not designed to address some of these issues, like poverty, it is expected to remove key barriers an individual may face, like privacy, costs, and convenience. The success of a mandate will depend in part on the ability of the carriers to set up delivery options to ensure that the appropriate test is selected to ensure proper diagnosis and that there is adequate follow-up in the form of counseling and education, regardless of the results of the

test. There will likely be a trade-off between meeting these goals in a cost-efficient manner and consumer flexibility in choosing the delivery option that best meets consumers' needs.

Key Findings

AHP estimates that if an STI home test kit mandate is enacted, then the cost of testing alone could result in an increase in premiums for the first year after the effective date between 0.05% and 0.20%. As more tests are performed, there will be a one-time surge in the cost of treatment. When those costs are taken into consideration, AHP projects that the financial impact of such legislation will range from no impact to 0.50%. AHP projects that over time, treatment costs will decrease and, at some point, may even offset the cost of tests. The decrease in treatment costs will be attributable to:

- Transmission Rates. With proper follow-up, consumers are more likely to change behavior, resulting in fewer cases of STIs.
- Lower Cost Per Disease. Increased testing will likely mean that more diseases will be detected in the early stages, which, of course, will be easier and less expensive to treat than if detected after complications have developed.

The medical community is somewhat divided on STI home test kits. On one hand, reputable organizations, including The Johns Hopkins University School of Medicine , have successfully developed a home test kit provider organization. On the other hand, carriers, presumably with input from their medical staff, deem home test kits to be experimental and investigative. Since the definition of investigative and experimental varies by carrier, a definitive response to this is not possible. That said, based on our research, some STI test kits, like the HIV test OraQuick, have been FDA-approved or FDA-cleared and have shown favorable sensitivity and specificity rates. Other tests do not meet those criteria.

Since carriers do not currently cover STI home health kits, an implementation period will be necessary to set up the systems, revise forms, file rates, etc. In this analysis, AHP has assumed effective date for any legislation will be on the first of the year following the date the legislation passes. This timing is procedurally ideal as most insurance contracts are on a calendar year basis. Since other types of home test kits, like food allergy test kits, are entering the market, carriers may want to set up their systems to handle test kits on a robust basis. This process may be costly, especially for smaller carriers.

It is worth noting that the results of our carrier survey suggest carriers do not believe STI home test kits qualify as either essential health benefits or preventive services as defined in the Affordable Care Act (ACA). Future legislation or regulatory clarity may change this interpretation.

About This Report

In preparing this report, AHP was cognizant of two primary goals. First, the principal intended users of this report is the Maryland General Assembly. With that in mind, AHP has addressed the key issues the intended users need to consider as they draft the legislation and consider passage. The second goal is to address issues carriers need to consider while complying with the legislation. To meet these two goals, AHP has structured the report as follows:

- Section 2. Financial Analysis. In this section, AHP describes the financial impact of an STI home test kit mandate on premiums, including the underlying methods and assumptions. The

projections used in the report represent the average impact over all Maryland carriers. The impact for a specific carrier will depend on the circumstances of the carrier, the final language of the bill, and current conditions at the time the projection is made. This section is also designed to provide a roadmap for carriers to use in making their final projections.

- Section 3. About STIs. This section provides background information on each of the STIs considered in this report and describes the steps recommended by the Centers for Disease Control and Prevention (CDC) for treatment, prevention, screening, risk assessment, and follow-up. Although this section is primarily for context, carriers can use this information as a starting point for revising their medical policy and implementing systems.
- Section 4. STI Home Test Kits. Passage of an STI home test kit mandate could provide another valuable tool in stemming the STI public health crisis. That impact, however, has to be measured against resources available today. This section describes those resources, including the availability of STI home test kits.
- Section 5. Administrative Considerations. The success of a mandate will depend in part on the carriers' ability to set up the appropriate systems and to administer the process on a day-to-day basis. This section addresses the key issues carriers are expected to face.

Terminology

The term "sexually transmitted infection" (STI) has largely replaced the term "sexually transmitted disease" (STD) in medical literature. We have used the term STI throughout this report.

Section 2. Financial Analysis

AHP projects that the cost of providing STI home test kits will increase premiums by 0.05% to 0.20% just for testing. AHP also projects that the net impact of future test kit legislation will range from no increase in premium to a 0.50% increase after considering additional treatment costs and potential savings from lower transmission rates and reduced complications. The numbers presented here represent the average overall impact to the carriers in Maryland. Each carrier will have to estimate their own financial impact based on the specific circumstances of the carrier and the conditions at the time the projection is made. For simplicity, AHP has assumed an effective date of January 1, 2024 for purposes of the financial projections described below.

The Technology Curve

In today's environment, new drugs, new medical procedures, and new medical devices are being introduced constantly. Each introduction will likely increase costs. The two big questions are "How quickly will we see the cost increases?" and "What will the cost be once the growth in costs reaches a steady state?" There is no one-size-fits-all answer to those questions, but based on our experience pricing benefits, AHP predicts that STI home test kits will follow a technology curve[5]. There are usually four phases to a technology curve:

- The Hesitancy Phase. When new technology is introduced, there is some initial hesitancy by both patients and providers to use the new technology. For new drugs, that period usually lasts only a few months since clinical trials provide valuable background information and drug companies promote their products heavily. This period can last many years for a complex surgical procedure since surgeons need time to perfect the surgery to minimize complications. This acceptance period for STI home test kits will likely be between these two extremes.
- The Rapid Growth Phase. At some point, patients and providers overcome the initial hesitancy and the technology enters the next phase. Once providers and consumers become comfortable with the technology, there tends to be a rapid growth phase as patients and providers "join the bandwagon." At this point there is also a release of pent-up demand.
- The Cool-Down Phase. At some point, utilization reaches its peak. After that there is a "cool-down" period after pent-up demands are met.
- Steady State. The final stage is the "steady state" phase. During this period, utilization and costs tend to increase in pace with overall premiums.

AHP projects that STI home test kits are entering the rapid growth phase now. This is based on the observation that STI home test kits are being adopted by some well-known organizations, like the Alabama Department of Public Health[6]. Other states, specifically California, have implemented legislation similar to S.B. 634[7]. AHP projects that STI home test kits will enter the cool-down phase sometime in 2024. AHP projects that the financial impact will begin to level off in 2025 or 2026.

Mandate Parameters

Since S.B. 634 has not passed, it is reasonable to assume that future legislation will undergo some modifications. After reading the current bill, AHP has grouped the potential modifications into two scenarios for discussion purposes, which we are calling "in-network only" and "out-of-network

available" options where the term "options" refers to the types of options that may be under the mandate.

The estimates underlying the in-network only scenario include assumptions that the final bill allows carriers to apply the same techniques they use for other benefits to control costs while still meeting the clinical needs of consumers. Specifically, it is assumed that the requirements of the bill include:

- Each applicable insurance plan must cover at least one in-network delivery option to conveniently obtain a home test kit for each STI for which there is one available.
- The test will be considered in-network if it is requested online or prescribed by an in-network doctor.
- The option complies with all public health reporting requirements.

Under Scenario 1, the in-network only scenario, it is likely that carriers will only cover STI home kits obtained through the carrier's on-line system and/or directly from an in-network provider. Of course, carriers could develop other options if they so desired. Under Scenario 2, the out-of-network available option, carriers would be required to cover STI home test kits purchased from on-line retailers, like Amazon, and from brick-and-mortar retailers, like Walmart; paper claim submission to carriers would be required for reimbursement. AHP has assumed that the non-preferred options would be treated as out-of-network for reimbursement purposes, which means that STI Home Test Kits might not be covered under in-network only plans.

The advantage of Scenario 2 is that consumers have more flexibility in meeting their needs. The disadvantages of this option are:

- Costs. Since carriers will not be able to negotiate prices for STI Home Test Kits, carrier cost per test will likely be higher than under Scenario 1. From a consumer perspective, the cost per test will be more expensive, and higher cost-sharing will apply with potential exposure to balance-billing.
- Test Selection. Without appropriate medical guidance, there is a good chance that consumers will select the wrong test kits. There are currently over 10 STI home test kits on the market, as displayed in Appendix A. Some test for just one or two STIs, while others cover a broad range of STIs. If the wrong test is chosen, then a second test may be needed. Worse yet, consumers may develop complications that would not have developed had the right tests been chosen initially. Under the in-network option scenario, carriers will be able to evaluate the effectiveness of the risk assessment and test selection process.
- Follow-up. The Centers for Disease Control and Prevention (CDC) recommends that once a test comes back positive, consumers receive immediate treatment for the disease and education to prevent a recurrence. Again, carriers are better able to evaluate follow-up procedures under the out-of-network option.

AHP considered a third scenario under which any STI kit would be covered as in-network regardless of the delivery option. We did not attempt to price this option for two reasons. First, STI on-site tests are considered preventive benefits. Under the ACA, free preventive benefits are only available in-network[8]. Arguably, the same language could apply to STI home test kits. Second, this structure could result in an unprecedented increase in demand due to direct-to-consumer advertising, fraud, waste, abuse, and administrative costs. There is no reasonable basis to estimate this type of increase in demand.

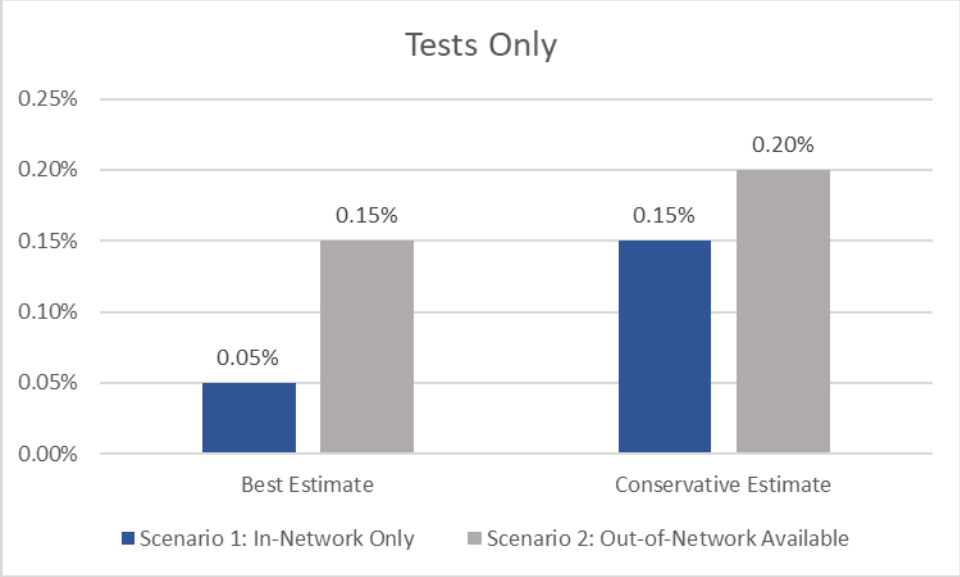
Financial Impact of Testing

In developing the financial projections related to mandating coverage of STI Home Test Kits, AHP presents a range of values. The low end of the range represents AHP's best estimate of the financial impact; the high end of the range provides a conservative view, and includes the contingencies discussed below. The conservative estimate is not a worst-case scenario. That said, the probability that costs will exceed the conservative estimate is in the 10% to 20% range.

The starting point for estimating the cost of testing was to determine the total 2021 cost of only the tests and the related visits. To do that, we leveraged national data from the MarketScan[9] database as well as extracts from the Maryland All-Payer Claims Database[10]. We developed a range of 0.15% - 0.45% in our analysis. Based on that analysis, AHP assumed that on average carriers spent 0.30% for testing in 2021. AHP projects that this number will be 0.40% in 2024, assuming similar trends in STI incidence rates as seen in recent years. This estimate is based on the assumption STI test legislation will pass in early 2023.

As Figure 1 shows, the expected increase in 2024 premium ranges from 0.05% to 0.15% for Scenario 1 and 0.15% to 0.20 for Scenario 2. To interpret these numbers, a 0.05% increase in test costs will mean that the expected cost for just testing in 2025 will be 0.45% (0.40% + 0.05%) or a 12.5% increase over what would have happened had the bill not passed ((0.45% ÷ 0.40%) – 1).

Figure 1. Projected Increase 2024 STI Test Impact on Premium



The key assumption for Scenario 1 in this analysis are:

- Best Estimate. For the best estimate view, AHP assumed that on average the cost of test kits and related visits will keep pace with general cost trends. It is likely that the cost of STI home test kits per se will increase faster than general medical inflation, but that increase will be offset by lower medical costs. Specifically, it was assumed that the reduction in emergency

department visits would offset the increase in cost of the tests. As a result, the entire 0.05% increase is attributable to utilization, which reflects both an increase in the number of utilizers and an increase in the average number of tests per utilizer. A 0.05% increase in premium corresponds to a 12.5% increase in the total number of tests attributable to passage of STI test kit legislation.

- The Conservative Estimate. For the conservative estimate, AHP assumed that not all the increase in the cost of the test kits would be offset by lower visit cost. The 0.15% increase in premium for this view is 0.025% attributable to costs. A 0.025% increase in costs means the average cost per test rose 6.25% higher than general medical inflation. The remaining 0.125% attributable to utilization, which corresponds to a 31.25% increase in the number of tests.

For Scenario 2, the key assumptions are:

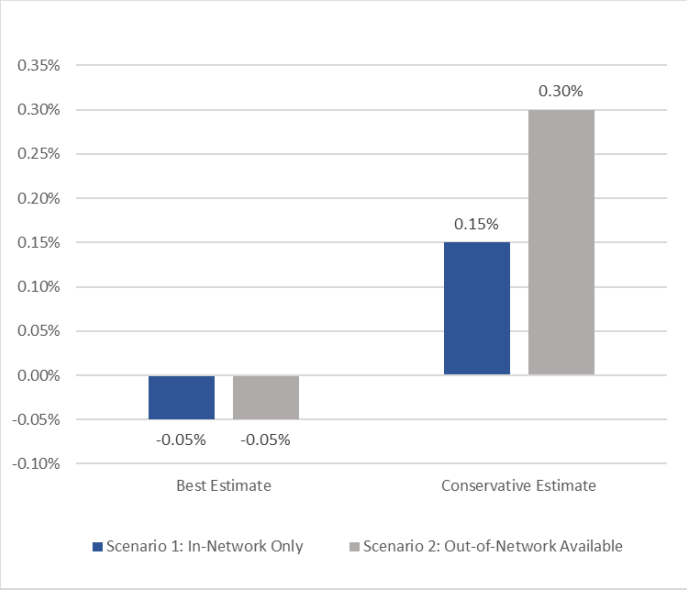
- Best Estimate. in the best estimate view are also 0.025% costs, which means that the cost of test kits is expected to increase 6.25% higher than general medical inflation. AHP assumes that the cost per visit will be the same under both scenarios, but the costs of the tests themselves will be higher under Scenario 2 since carriers will not be able to negotiate the price on all test kits. The remaining 0.125% is attributable to utilization, which corresponds to a 31.25% increase in the number of tests.
- The Conservative View. The logic for the conservative view is similar to the logic for the best estimate view. The cost utilization split is 0.05% costs, which corresponds to a 12.50% increase over general medical inflation, and 0.15% for utilization, which corresponds to a 37.50% increase in tests due to the bill.

One note of clarification is that the utilization projections described above include the anticipated increase due to Monkeypox or other STIs not discovered at this time. It appears at the time of this writing that Monkeypox has been contained, so there should be little or no material financial impact[11].

Treatment Costs

Like tests, treatment costs follow a technology curve. The treatment technology curve lags the test curve. Should STI test kit legislation pass, , carriers can expect to see an increase in the number of people taking tests and an increase in the average number of tests per utilizer. As the number of tests increase, there will be an increase in treatment costs. Treatment costs in this context includes the cost of curing the disease when a cure is available and ameliorating symptoms when a cure is not available. The financial impact of increased testing will depend on what percent of tests are positive and the mix of diagnoses. Many STIs can be easily treated with a relatively low-cost, one-time treatment, while others, like HIV, are not curable and require lifetime care to ameliorate the symptoms. As a result, AHP projects an increase in treatment costs during the rapid expansion and cool-down phases of the utilization technology curve. Over time, however, treatment costs are expected to be lower than they would be without the passage STI home test kit legislation. The potential for lower treatment costs depends on whether the follow-up process affects behavior as discussed in the next section. AHP's projections of the impact of treatment costs on premiums is shown in Figure 2.

Figure 2. Projected Increase 2024 STI Treatment Impact on Premium



The analysis described above showed that the cost of STI testing and treatment of the disease and complications for 2021 was 1.4%. This number excludes non-health related costs like productivity. Trending to 2021 using the same trend factors used above, the baseline cost for STI testing, treatment, and complications is 2.0%

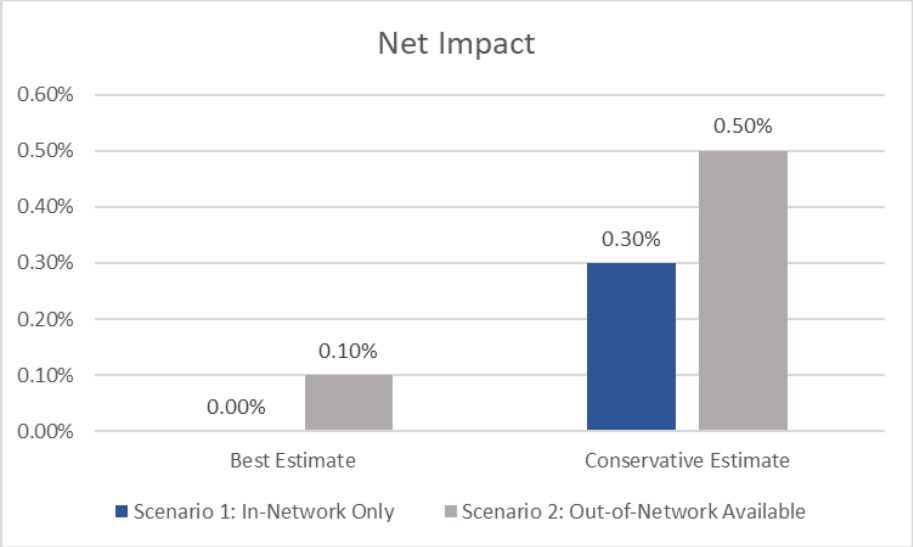
Net Impact of STI Test Kit Legislation

The net financial impact of STI test kit legislation includes the cost of the tests, treatment costs, and administrative costs. AHP has considered administrative costs to be immaterial with two disclaimers:

- Implementation Costs. Most carriers will incur a one-time cost to implement the changes needed to implement STI test kit legislation. That expense may be material to the carrier, but it will be incurred before the effective date of the legislation. Implementation costs are carrier-specific, so AHP did not attempt to estimate.
- Paper claims. In Scenario 2, the out-of-network available option, it is possible for a person to purchase a test kit on-line or at a brick-and-mortar store. In that case, the person would submit a paper claim for submission. Paper claims are more expensive to adjudicate than electronically submitted claims, especially for STI claims since there is currently no billing code to indicate an STI test kit at this time. In doing this analysis, AHP assumed such claims would be out-of-network or not covered depending on the type of coverage. In that case, the expectation is that there may be a short one-time surge in paper claims in 2024, eventually there would be very few paper claims. As a result, AHP deemed them to be immaterial for the purpose of this report. That said, the administrative costs could be material if the non-preferred options are treated as in-network.

Based on the analysis above, AHP's projection of the net impact of an STI home test kit mandate on premiums is shown in Figure 3.

Figure 3. Projected Increase 2024 STI Net Impact on Premium



The state of California performed a similar analysis in March of 2021 regarding the financial impact of California S.B. 306. The authors of that report concluded that the net impact of S.B. 306 would be between 0.02% and 0.12% depending on the organization in question. The low end of this range, the 0.02% number, applied to employer group insurance. The high end of the range, the 0.12% number, applied to Medi-Cal (the California Medicaid program) managed care. Presumably, this difference is because the Medi-Cal population is younger and more vulnerable[12]. This analysis is basically consistent with our findings with three major exceptions. The primary difference is that California numbers compared cost and utilization on a service-by-service basis. AHP's estimates were done on an all-in approach, including services not included in the California analysis. Second, AHP trended the costs to 2024, the first year the legislation is assumed to be in effect. Finally, AHP results reflect changes in utilization due to the technology curve.

Carrier-Specific Estimates

Each carrier will have to estimate their specific financial impact taking into consideration their current experience and updated information available at the time the analysis is completed. Carriers may want to use the analytical techniques described above as a roadmap for their analysis. The following appendices are included to assist carriers in that effort:

- Appendix B: CPT-4 codes for STI tests
- Appendix C: Bill codes for STI test kits
- Appendix D. Diagnosis Codes for STIs

Section 3. STI Background

STIs are behaviorally-driven and they are increasing rapidly. In Maryland, the rate of primary and secondary syphilis cases increased 253% from 2010 to 2019[13]. STIs are a growing public health burden as many go untreated and lead to complications (infertility, pelvic inflammatory disease, cervical cancer, etc.)[14]. One of the major reasons so many cases go untreated is that most STIs are asymptomatic in early stages, though when symptoms develop there may be complicating conditions which are more complex and expensive to treat. Given the nature of STIs, medical treatment alone is not sufficient to solve the public health crisis. Screening, prevention, risk assessment, and counseling also play key roles.

Types of STIs

Sexually transmitted diseases (STIs) involve the transmission of bacteria, parasites, and/or viruses between sexual partners through sexual contact (oral, anal, or vaginal). For purposes of this report, AHP has grouped STIs into four major categories. The first category is STIs that are inexpensive to treat went caught early, but often lead to complications with significant costs. These STIs include:

- Chlamydia. Chlamydia is one of the most common STIs in the United States. Chlamydia spreads easily because it is often asymptomatic, though if left untreated can cause serious complications including pelvic inflammatory disease, preterm delivery, and infertility in women, and urethritis and epididymitis in men. Chlamydia is easily cured with an antibiotic regimen[15].
- Gonorrhea. Gonorrhea is a common STI caused by the bacteria *Neisseria gonorrhoeae*. Gonorrhea is often asymptomatic and can be spread unknowingly. If left untreated Gonorrhea can cause serious complications in both men and women, including infection in reproductive organs and other areas of the body. Gonorrhea is easily cured with an antibiotic regimen[16].
- Trichomoniasis. Trichomoniasis is a common STI caused by a parasitic infection. A minority of infected individuals are likely to develop symptoms. Trichomoniasis is associated with increased risk of cervical or prostate cancer and HIV infection. Trichomoniasis is easily treated with oral medication[17].
- Syphilis. Syphilis is characterized by staged development, with each stage (primary, secondary, latent, and tertiary) having different symptoms and complications. Without treatment, tertiary syphilis can damage internal organs and even result in death. Syphilis can also be spread through childbirth, in addition to increasing the likelihood of a low-birth-weight-baby and stillbirth. Syphilis is easily cured with antibiotics[18].

The second category includes STIs with no cure at the moment, but with treatments to ameliorate symptoms. These STIs include:

- Hepatitis B (HBV). HBV is a serious liver infection caused by a virus. HBV infection is typically short term, though it can increase the risk of developing liver failure, liver cancer, and cirrhosis in cases which last longer than six months. There is not currently a cure for HBV, however a vaccine can prevent the disease[19].
- Herpes Simplex Virus (HSV). Herpes is an STI caused by two viruses: HSV Type 1, which causes oral herpes and HSV Type 2, the main cause of genital herpes. Infection by both viruses causes lifelong symptoms and are not curable, however symptoms can be controlled through antiviral medication[20].

- Human Papillomavirus (HPV). HPV is the most common STI and is usually asymptomatic and eliminated from the body without treatment. There are many types of HPV, and some cause genital warts, while others lead to certain types of cancer. There is no cure for HPV, however there is a vaccination to prevent HPV infection, and high-risk HPV types can be treated to prevent the development of cancer[21].

The third category includes STIs with expensive treatments. Early detection is particularly important for these STIs. They include:

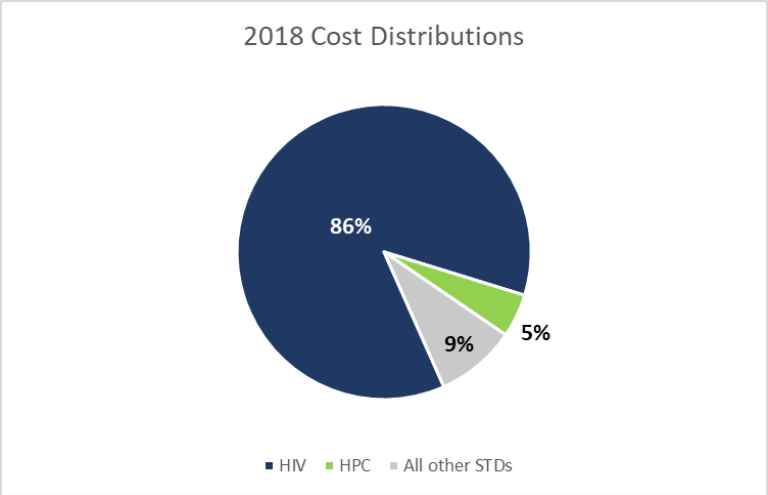
- Human Immunodeficiency Virus (HIV). As the name implies, HIV is a virus that attacks the body's immune system and if not treated can lead to AIDS (acquired immunodeficiency syndrome). There is currently no effective cure for HIV, however HIV can be controlled with proper medical care. HIV patients who develop AIDS have badly damaged immune systems and develop opportunistic infections and other serious illnesses and are likely to die prematurely[22].
- Hepatitis C (HCV). HCV is a viral infection that causes liver inflammation, sometimes leading to serious liver damage. It can take decades for symptoms to occur, and in a minority of cases Hepatitis C infection is cleared from the body without treatment. HCV is curable with oral medication[23].

The fourth and final category are STIs that have not yet been discovered or are in the early stages of the technology curve. The most notable STI in this category currently is monkeypox. To date, there have been less than 30,000 cases reported in the U.S., most of which were reported in July and August of 2022. Since then, only about 1,000 cases are reported monthly. A low-transmission rate vaccine is available[24].

Key Statistics

Based on the financial impact analysis described above, the STI disease burden for these health plans ranged from 0.8% to 2.0%. Nationally, HIV was the largest cost contributor by far as shown in Figure 4.

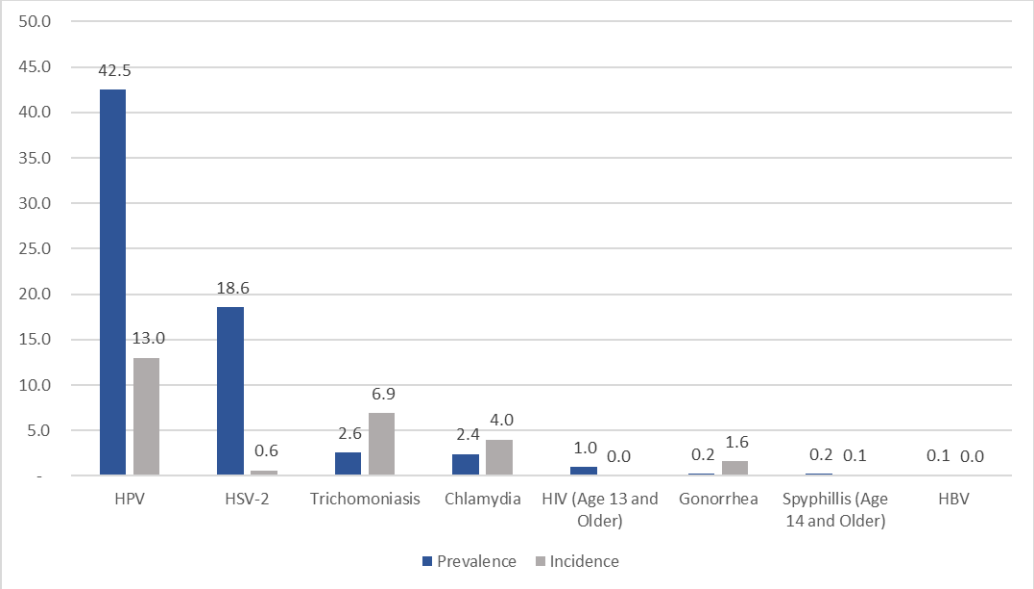
Figure 4. 2018 Lifetime Cost Distribution by STI



Source: Centers for Disease Control and Prevention, STI Fact Sheet Incidence, Prevalence, and Cost of Sexually Transmitted Infections in the United States (cdc.gov)

As Figure 5 shows, although HIV is the largest cost contributor, it is not the most common STI.

Figure 5. 2018 Incidence and Prevalence Rates



The prevalence rate is defined as the average number of unique individuals with the disease at any point in time during the year, regardless of the year the disease was first diagnosed. So, for STIs like HIV, which is basically a life-long disease, the prevalence on any given day in the year will include people diagnosed in 2018, 2017, etc. The incidence rate, on the other hand, represents the total new cases during the year. Chlamydia, on the other hand, is a short-term disease. Most cases are cured in less than a year, so the incidence rate is higher than the prevalence rate.

According to the Maryland Department of Health Center for STI prevention, some of the reasons for the recent increase in STIs include[25]:

- Social Determinants of Health. Social determinants of health, like poverty, substance abuse, stigma, and housing can reduce access to prevention and care.
- Condom Use. Decreased condom use or incorrect condom use among vulnerable groups can lead to spread of STIs.
- Public Health Resources. Fewer public health resources, especially staff and clinics, have reduced patient access to education and counseling.

Guidelines

There are a number of organizations promulgating STI clinical and public health guidelines, including the CDC and the United States Preventive Task Force[26]. In this report, AHP relied on "Sexually Transmitted Infections Treatment Guidelines, 2021[27]" published by the CDC since it is the most detailed. The emphasis in these sources is on who should be screened and how often. There are generally no references as to the specific tests to be administered.

Prevention Guidelines

The CDC recommends five major strategies for the prevention of STIs:

- Risk assessment, education, and counseling. This strategy focuses on individuals at risk for an STI. The focus is on avoiding STIs by changes in sexual behavior and use of recommended preventive actions, like wearing a condom.
- Vaccines. Pre-exposure vaccines are recommended for STIs for which a vaccine is available.
- Identification. This strategy focuses on identifying persons with an asymptomatic disease and persons with symptoms associated with an STI.
- Post-diagnosis care. Once a person has been identified as infected, then treatment, counseling, and follow-up are needed to avoid further complications and minimize further transmission.
- Partners. Given the nature of STIs, once a person has been identified as infected or at risk, there is a good chance that their sexual partners will also be at risk. To minimize that exposure, this strategy focuses on identifying partners and providing them with the appropriate evaluation, treatment, and counseling.

State and local public health departments play a key role in prevention. Maryland, as well as other states, require laboratories, doctors, and other medical providers to report all confirmed cases of chlamydia, gonorrhea, or syphilis within one working day.[28] Once a case is reported, the case may be referred to Partner Services, an agency that provides free, voluntary, and confidential sexual health services to individuals and their partners[29]. The CDC also requires reporting of all designated infectious diseases on an annual basis.

Risk Assessment

Given the nature of STIs, risk assessments focus on the person's behavior and social circumstances. Specifically, many risk assessments focus on the "five Ps":

- Partners. The number and gender of partners plays a key role in assessing risk.
- Practices. Sexual practices also play a key role in assessing risk. Many risk assessment include specific questions about whether the person has anal, oral, or vaginal sex. The assessment may also include questions about drug use, especially for people at risk of HIV or hepatitis.
- Protection. These questions tend to focus on condom use and testing frequency.
- Past history. These questions focus on past testing and diagnosis of the person and their partners.
- Pregnancy. Since some diseases can be transmitted through childbirth, pregnancy questions are key to a risk assessment.

Of course, as with any medical risk assessment, the effectiveness of the assessment will vary by the questions asked and the experience, knowledge, and due diligence of the assessor.

Screening Guidelines

Screening guidelines vary by population with the following populations identified as particularly at risk:

- Pregnant women
- Adolescents
- Children

- Men having sex with other men
- Women having sex with other women or with both men and women
- Transgender and gender diverse people
- Inmates within a correctional facility

The specific guidelines within each of these populations vary by STI, the person's age, and the results of the risk assessment.

Education and Counseling

According to the CDC Guidelines, prevention counseling is most effective if provided "in a nonjudgmental and empathetic manner appropriate to the patient's culture, language, sex and gender identification, sexual orientation, age, and developmental level[30]." Counseling methods may include videos, large group sessions, on-line learning modules, or intensive one-on-one sessions. Topics covered as part of counseling include information on reducing risky behavior and proper condom use. If substance abuse is part of the problem, then the counseling may include a referral to an appropriate specialist.

Section 4. STI Home Test Kits

The concept of home test kits is not new. Home pregnancy tests were introduced in the 1970s, almost 50 years ago[31]. Today, a consumer can purchase many types of home tests kits, such as food allergy tests, diabetes test supplies, and cholesterol screening tests. Each test kit is designed to provide the consumer with valuable information about the presence or severity of a disease. Some test kits, like diabetes testing, colorectal cancer screening, and COVID tests, are covered by many insurance plans. In the absence of a mandate, factors a carrier may consider in determining whether or not to cover a home test kit include clinical effectiveness, the availability of alternate resources, the availability of an effective delivery system, administrative simplicity, and cost-benefit, which was discussed in Section 2., Financial Impact. Carriers routinely exclude technology that is considered "experimental or investigative" and services not considered "medically necessary."

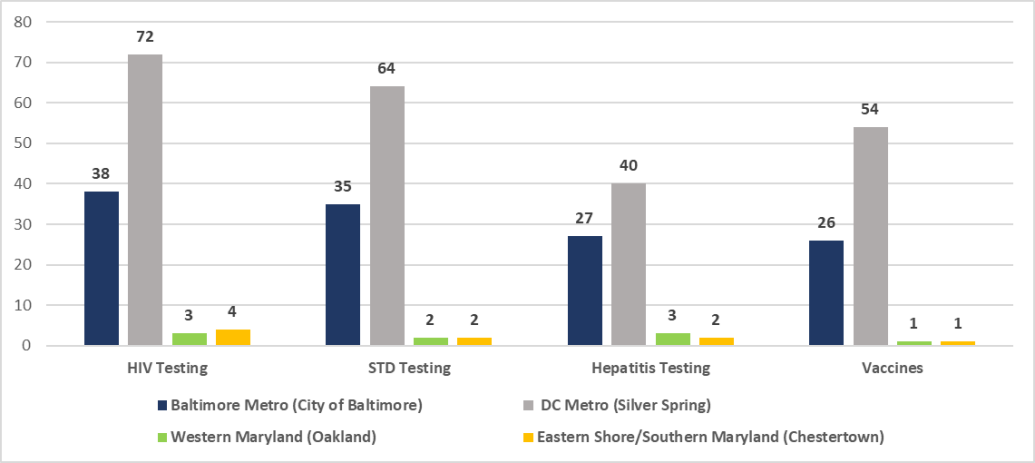
Resources Availability Today

In Maryland, individuals have several options for obtaining on-site STI testing, including:

- One of Maryland's Public Health Service locations. There is at least one location in each county and in Baltimore City[32]
- Planned Parenthood[33]
- A doctor's office
- A certified lab service like Quest or LabCorp
- An emergency department
- A walk-in clinic, like a MinuteClinic at CVS

These services vary widely in terms of convenience, costs, privacy, and available counseling, all of which can pose barriers to better health. Arguably, however, the biggest barrier is simply wading through all the options to determine the best one given an individual's circumstances. Marylanders may also use the website Get Tested | National HIV, STI, and Hepatitis Testing (cdc.gov). At this site, users can input a zip code or a city/state and filter by distance (less than 10 miles, less than 25 miles, or less than 50 miles). Users can also indicate if they only want to see low or no cost locations and if they only want to see mail-in sites. A sample of the findings is shown in Figure 6.

Figure 6. Number of Testing Sites by Location



Source: IWTK, Get Tested | National HIV, STI, and Hepatitis Testing (cdc.gov) (Filters: low or no cost available, within 10 miles)

Marylanders also have three options for STI home health kits. Inova Juniper[34], a non-profit organization based in Northern Virginia, provides home test kits, but requires individuals to travel to a designated location, which may or may not be convenient. Under this option, consumers can collect the specimen in private, but there is a loss of privacy at the point of pick-up. The second option, IWantTheKit (IWTK), provides an online option that is both convenient and private. IWTK is an organization founded in 2004 by the Johns Hopkins University School of Medicine. Their laboratory is licensed by the State of Maryland and certified by the College of American Pathologists. IWTK partners with several organizations including the Baltimore City Health Department, the Howard County Health Department, and the Maryland Department of Health. Marylanders also have the option of buying an STI home test kit in a brick-and-mortar retail store or on-line through an on-line retailer like Amazon. Consumers using this last path face a "paradox of choice," which states that at some point too many options mean it is more difficult to a make a choice.

Delivery System Examples

In choosing an STI testing option, consumers may consider:

- Privacy. Since there is a stigma attached to STIs, a consumer may want privacy during the entire process including receiving the test, taking the specimen, and actual results. There is an additional privacy issue for enrollees on a family health insurance contract. Other members of the family can see that the test was taken and potentially see the results of the tests[35]. Based on our analysis, about 25% of all STI test takers are dependents.
- Convenience. Most testing options available today require a visit of some kind. That visit may be a visit to an ED, a lab, or a telemedicine visit. Consumers may delay or forgo a test if it is inconvenient to physically go to the provider's location or schedule time for a telemedicine visit.
- Costs. At some point, STI home test kits may be considered a preventive benefit, which would mean that the entire costs for the test would be covered at 100% as long as the enrollee uses only in-network providers. For now, however, it appears that enrollees using only in-network providers will be responsible for the cost for the applicable copay, deductible, or coinsurance. If enrollees have a high-deductible health plan, then there is a good chance that they will pay the entire cost of the test, albeit at a discounted price. If the visit portion of the test is in-network

but the lab is out-of-network, under the No Surprises Act the enrollee must be notified in advance. The enrollee, however, may find that process cumbersome and may not seek follow-up treatment as a result.

Of course, carriers will also consider costs, which has already been discussed in Section 2. In addition, a carrier may consider enrollee satisfaction, which has just been discussed, and enrollee well-being, which includes ensuring that the enrollee selects the right test and receives the appropriate follow-up.

Based on the carrier surveys and our research, the two most common delivery systems include an on-line option and a hand-delivered option. The on-line option is used by IWTK, Binx[36], the system used by the Alabama Department of Health, and some on-line retailers. Typically, the key steps in the process include:

- Risk analysis. Once enrollees have signed into a secure website, verified their credentials, and requested a kit, enrollees fill out a risk assessment to determine which kit, if any, is needed. Kits are then mailed to enrollees.
- Specimen. Enrollees follow the instructions to take the necessary specimens. The specimens are mailed back to labs for analysis.
- Results and Follow-up. Once results are back from the lab, enrollees are notified, usually on-line.

The hand-delivered option is used by staff model HMOs and some clinics. The process works similarly to the on-line option, except providers are used to doing risk assessments, results notifications, and follow-ups.

Covered Services

In order for a mandate to be effective, a mandate must clearly specify which services are mandated and which are not. Another key consideration is consistency with regulatory requirements. STI home test kits currently require laboratory testing, which is regulated under the Clinical Laboratory Improvement Amendments ("CLIA"), which requires clinical laboratories to be certified by the Center for Medicare and Medicaid Services ("CMS"). Three federal agencies are responsible for the CLIA[37]:

- The Food and Drug Administration ("FDA"). The FDA categorizes tests by complexity and reviews requests for application by waiver.
- CMS. CMS conducts inspections and enforces regulatory compliance.
- The Centers for Disease Control and Prevention ("CDC"). The CDC provides analysis, research, and technical assistance.

The FDA does not perform any tests per se on a device. Instead, the agency reviews information provided by manufacturers about devices before they can be marketed. The intensity of such review depends on the nature of the device. The FDA classifies medical devices into three categories based on complexity:

- Class III. Class III represents the most complex devices, including devices that are implanted into the body or have the potential to harm the body, like pacemakers and breast implants, and require FDA approval. The FDA approval process is the most rigorous process and almost always includes clinical data.

- Class II. Class II medical devices are designed to be used outside the body. Home pregnancy kits fall into Class II. These devices must be cleared by the FDA, which means that the product is "substantially equivalent to a similar device that already has FDA clearance or approval." The similar device is known as a "predicate." Clinical data may or may not be required.
- Class I. Class I medical devices include very low-risk devices like tongue depressors and non-electrical hospital beds. Class I devices must be registered with the FDA, but there is little or no oversight provided.

A list of all devices approved or cleared by the FDA for home use can be found at Find All FDA-Approved Home and Lab Tests | FDA. Only one STI home health kit, the OraQuick HIV home test kit, is currently listed on this website. A manufacturer of a Class II test may apply for a waiver. A list of tests covered under a waiver can be found at CPT CODE(S) (cdc.gov). There are several STI home test kits listed on this site. The criteria for a waiver include[38]:

- Simplicity. The test must employ methods that are so simple and accurate that the probability of an erroneous result is negligible.
- Safety. The test poses no unreasonable risk of harm to the patient if performed incorrectly.
- CLIA-Certified Laboratory. The test must be performed in a laboratory with a CLIA certificate of waiver.

Perhaps, the clearest way to define covered services is in terms of tests that are FDA-approved or FDA-cleared. In other words, tests included in one of the two data bases cited above. One note for clarity. STI home test kit providers often advertise that they use certified labs. Defining covered services in terms of certification is redundant and, possibly, misleading. All cleared and approved tests must be processed in a certified lab, but the lab may also process tests that do not meet those criteria.

It may also be prudent to include language relating to emergency use authorizations. A manufacturer may also apply for an Emergency Use Authorization ("EUA"), which was enhanced during the pandemic. At this point, there is no clear evidence that this is being used for STI home health kits, but that is a future possibility given the rapid increase in utilization. The key provisions of an EUA are:

- Public Emergency. Unapproved tests, vaccines, and treatments can be used with some limitations during a declared public emergency and cannot be used after the public health emergency is over.
- Effectiveness. Based on the totality of the evidence, it is reasonable to believe that the product may be effective.
- Risk-Benefit. Based on the best available evidence, the benefit is deemed to outweigh the risks.
- No Alternatives. There is no adequate supply of approved alternatives.

All devices must be registered annually with the FDA. This is just a notice to the FDA that the device is being marketed, even if the test has not gone through a review process. As a result, a device that is described as FDA-registered or FDA-listed may or may not have been approved or cleared[39].

This process is not without its critics. Some of the criticism focuses on recent device failures like surgical mesh, hip replacements and saline breast implants. As a result of these failures, there have been calls for more oversight after a device is put on the market. Similarly, there are concerns that a predicate

device used to meet the “substantially equivalent" requirement may have been recalled for safety reasons.

Acceptance by the Medical Community

There is a difference of opinion regarding the clinical effectiveness of STI home test kits. Both sides agree, however, that sensitivity and specificity are key measures of clinical effectiveness.

Measures of Clinical Effectiveness

Sensitivity and specificity are two key measures of test effectiveness. Sensitivity measures reflect how well a test correctly identifies people who have the disease in question. A 90% sensitivity level means that the test will correctly identify 90 out of every 100 people known to have the disease. The other 10 people will show a false-negative. That is, the test will show they do not have the disease, but they really do. This means that the people with a false negative will not receive the needed treatment, counseling, and education. This could lead to the person minimizing regard for the impact of the risky behavior which led to the disease in the first place. Specificity measures the ability of a test to correctly exclude patients who do not have the disease. A 90% specificity level means that the test will correctly identify 90 people who do not have the disease. The remaining 10 people will show a false positive. The false positives will most likely seek follow-up care. Although treatment may not be necessary, there is an opportunity for education and counseling.

Sensitivity and specificity rates vary considerably by test within a disease type. For example, a 2017 review of gonorrhea home test kits showed the sensitivity rates varied from 12.5% to 95% when compared to laboratory tests. The specificity rates ranged from 89% to 99.8%. Another 2017 study showed similar results for chlamydia home test kits[40].

Acceptance by the Medical Community

The medical community is somewhat divided on STI home health kits. On one hand, Johns Hopkins University School of Medicine developed and operated an STI home health kit provider, IWTK. On the other hand, carriers, presumably in consultation with their medical staff, still consider STI home kits to be experimental and investigative. Each carrier has its own definition of experimental and investigative, so AHP cannot provide a direct point-by-point commentary. That said, we have the following observations:

- Clinical Trials. Most carriers exclude devices still in a clinical trial. The approved or cleared language would automatically exclude any tests still in clinical trials.
- Treatment Standards. Most carriers only cover benefits where there are acceptable standards regarding the appropriate treatments, including the frequency of testing. Both the CDC Guidelines and the USPSTF guidelines provide this information.
- Clinical Effectiveness. As noted above, sensitivity and specificity rates vary by test. In theory, the approved/cleared language should be sufficient. If that becomes a sticking point, one way to deal with this is to allow carriers to determine which of the available tests for a disease state are considered in-network. Presumably, they would only use tests with the highest sensitivity and specificity rates.

Section 5. Administrative Considerations

In order to implement and administer the provision of a mandate, the final language needs to be clear, especially when it involves the degree of flexibility the carriers' have in designing options. Some carriers may want the flexibility to design systems to accommodate not just STI test kits, but test kits for other issues like food allergies.

Methodology

As part of this research, AHP, at the behest of the MHCC, asked carriers to complete a survey on their current coverage of STI home test kits and anticipated problems if a mandate passes. The survey instrument is shown in Appendix D and the results are summarized in Appendices E – H. Three carriers covering 3.2 million Maryland enrollees responded to the survey. This section addresses the issues identified in the survey as well as a few issues identified by AHP.

Definition of Health Insurance Policies

If a mandate passes, it is assumed that it would apply to each individual, group, or blanket health insurance policy or contract that is issued or delivered in the state by an insurer or a non-profit health insurance plan. Presumably, this means that the bill will apply to any insurance contract regulated by the State of Maryland, including HMOs. In that case, an estimated 1.1 million to 1.6 million[41] lives will be impacted, including:

- Individual insurance contracts (165k to 225k)
- Small group insurance contracts (250k to 265k)
- Large group insurance contracts, including the State of Maryland employee benefit plan (640k to 765k)

These numbers exclude the limited number of Grandfathered plans still in effect. Similarly, the bill would not apply to plans regulated by Federal law including self-insured plans regulated under ERISA, Medicare, and Medicaid, which are regulated by the Centers for Medicare and Medicaid Services (CMS).

Implementation

Whenever there is a change in benefits or medical policy, carriers must go through an implementation process which includes revising claims and other administrative systems and notifying policyholders, providers, and enrollees. For example, in order to assure a January 1, 2024, effective date, the legislation would need to be passed in early 2023 to allow carriers to reflect the change in their policy forms and rate filings. The implementation process for home test kits may be more complicated than for other technologies, especially if the carrier decides to set up an online system.

Medical Policy

Although the literature supports the notion that STI home test kits are clinically appropriate and medically necessary, survey responses indicate that carriers still consider them "experimental and investigative." This is not surprising given that STI home test kits are still in the hesitancy phase of the technology curve. Should legislation pass, carriers may want to perform their own literature reviews, including an in-depth review of the effectiveness of each specific test.

Many carriers already cover home test kits for diabetes, colon cancer, and COVID, but they do not cover STI home test kits and other home test kits like A1C, etc. If a mandate passes, then a carrier may want to review the medical policy not only the test kits currently covered, but also the criteria for adding other kits over time.

Essential Health Benefits and Preventive Services

Under the Affordable Care Act (ACA), health plans must cover 10 essential health benefits[42]. In Maryland, this includes[43]:

- Outpatient hospital services. A "service" is defined as a health care diagnosis, procedure, treatment, or item.
- Outpatient laboratory and diagnosis services. A "service" means a health care diagnosis, procedure, treatment, or item.
- Preventive services. Preventive services are to be covered with no cost-sharing (deductibles, copayment amounts, coinsurance). Preventive services are defined in part as evidence-based items or services that have in effect of a rating of A or B in the current recommendations of the United States Preventive Services Task Force. The ACA has listed out the screenings to be considered preventive[44].

At this point, none of the carriers surveyed consider STI home test kits to be essential health benefits. If that changes, then STI home test kits would be required regardless of whether or not a mandate is enacted. To the extent they are implicitly or explicitly included in the list of ACA preventive services, an ACA enrollee would receive the test without any cost-sharing.

Section 6. Actuarial Considerations

This report has been prepared by Gregory G. Fann, FSA, FCA, MAAA, who is also the primary contact. The report has been peer-reviewed by:

- Erik D. Axene, MD, FACEP, M.Ed.
- Joan C. Barrett, FSA, MAAA
- Tony Pistilli, FSA, CERA, MAAA, CPC
- John Price, FCA, MAAA

Except for our clinical expert, Dr. Axene, all members of the team members of the American Academy of Actuaries (MAAA) in good standing and are qualified to perform this work. This report was prepared in accordance with the following Standards of Practice as promulgated by the Actuarial Standards Board of the American Academy of Actuaries:

- Actuarial Standards of Practice No. 1, "Introductory Standard of Practice"
- Actuarial Standards of Practice No. 5, "Incurred Health and Disability Claims"
- Actuarial Standards of Practice No. 23, "Data Quality"
- Actuarial Standards of Practice No. 25, "Credibility Procedures Applicable to Accident and Health, Group Term Life, and Property/Casualty Coverages"
- Actuarial Standards of Practice No. 41, "Actuarial Communication"
- Actuarial Standards of Practice No. 56, "Modeling"

Although AHP has performed due diligence in researching the legal implications of this analysis, this report does not constitute a legal opinion and the reader should consult their own legal counsel about specific legal issues.

Appendix A. Available STI Home Test Kits

Company	Test	Cost	Chlamydia	Gonorrhea	Hepatitis B	Hepatitis C	Herpes	HIV	HPV	Syphilis	Trichomoniasis
Let's Get Checked	Simple 2	$ 99	x	x							
	Standard 5	$ 149	x	x				x		x	x
	Complete 8	$ 249	x	x						x	x
MyLabBox	Uber Box	$ 199	x	x		x	x	x		x	x
	Safe Box	$ 169	x	x				x			x
	Total Box	$ 399	x	x		x	x	x	x	x	x
PrioritySTD	Twin STD	$ 119	x	x							
	10-Panel STD	$ 198	x	x	x	x	x		x	x	
EverlyWell	Chlamydia & Gonorrhea	$ 69	x	x							
	STD Test Package	$ 127	x	x		x		x		x	x
CVS Health	STI & HIV Test Kit	$ 100	x	x			x	x		x	x

Sources (accessed 11/7/2022):

- Priority STI Testing (https://www.prioritySTItesting.com/get-tested-now/)
- LetsGetChecked (https://www.letsgetchecked.com/home-STI-test/)
- Everlywell (https://www.everlywell.com/products/?category=8)
- myLAB Box (https://www.mylabbox.com/at-home-tests/)
- CVS Health At Home (https://www.cvs.com/shop/cvs-health-at-home-sti-hiv-test-kit-1-ct-prodid-401987)

Appendix B. CPT/HCPCS Codes for STI Tests

The list below is a comprehensive list of CPT/HCPCS codes used to bill for STI testing.

CPTs 80055 and 80081 are obstetric lab panels, meaning these codes are billed in place of a defined list of CPT codes for individual tests, when all those defined tests were performed. These codes were not included in the financial analysis due to the nature of obstetric lab testing and the other tests included in the panel which are not STI-related, however the codes are included here for completeness.

CPTs 87800 and 87801 are for detection of un-specified infectious organisms and can be used to bill for Gonorrhea and Chlamydia testing, however each test has more specific codes that are more appropriate to use (namely 87490 – 87491 for Chlamydia, and 87590 – 87592 for Gonorrhea). These codes were similarly not included in the financial analysis because only a portion of utilization of these codes will be for STIs, and general utilization of the codes is very small.

Note that there are currently no CPT or HCPCs codes for home test kits – all codes in the list below are for facility-based testing (either in the office, ER, or other outpatient or inpatient facility).

CPT/HCPCS Code	STI Type	Type of Test	For STI Only
80055	Hepatitis B	Immunoassay	No - OB Panel (87340)
80055	Syphilis	Antigen	No - OB Panel (86592)
80081	Hepatitis B	Immunoassay	No - OB Panel (87340)
80081	Syphilis	Antigen	No - OB Panel (86592)
80081	HIV	Immunoassay	No - OB Panel (87389)
86592	Syphilis	Antigen	Yes
86593	Syphilis	Antigen	Yes
86631	Chlamydia	Antigen	Yes
86632	Chlamydia	Antigen	Yes
86689	HIV	Antigen	Yes
86694	Herpes	Antigen	Yes
86695	Herpes	Antigen	Yes
86696	Herpes	Antigen	Yes
86701	HIV	Antigen	Yes
86702	HIV	Antigen	Yes
86703	HIV	Antigen	Yes
86704	Hepatitis B	Antigen	Yes
86705	Hepatitis B	Antigen	Yes
86706	Hepatitis B	Antigen	Yes
86707	Hepatitis B	Antigen	Yes
86780	Syphilis	Antigen	Yes
86803	Hepatitis C	Antigen	Yes
86804	Hepatitis C	Antigen	Yes
87110	Chlamydia	Culture Method	Yes

CPT/HCPCS Code	STI Type	Type of Test	For STI Only
87270	Chlamydia	Immunoassay	Yes
87320	Chlamydia	Immunoassay	Yes
87340	Hepatitis B	Immunoassay	Yes
87341	Hepatitis B	Immunoassay	Yes
87350	Hepatitis B	Immunoassay	Yes
87389	HIV	Immunoassay	Yes
87390	HIV	Immunoassay	Yes
87391	HIV	Immunoassay	Yes
87490	Chlamydia	Probe Technique	Yes
87491	Chlamydia	Probe Technique	Yes
87492	Chlamydia	Probe Technique	Yes
87515	Hepatitis B	Probe Technique	Yes
87516	Hepatitis B	Probe Technique	Yes
87517	Hepatitis B	Probe Technique	Yes
87520	Hepatitis C	Probe Technique	Yes
87521	Hepatitis C	Probe Technique	Yes
87522	Hepatitis C	Probe Technique	Yes
87528	Herpes	Probe Technique	Yes
87529	Herpes	Probe Technique	Yes
87530	Herpes	Probe Technique	Yes
87534	HIV	Probe Technique	Yes
87535	HIV	Probe Technique	Yes
87536	HIV	Probe Technique	Yes
87537	HIV	Probe Technique	Yes
87538	HIV	Probe Technique	Yes
87539	HIV	Probe Technique	Yes
87590	Gonorrhea	Probe Technique	Yes
87591	Gonorrhea	Probe Technique	Yes
87592	Gonorrhea	Probe Technique	Yes
87623	HPV	Probe Technique	Yes
87624	HPV	Probe Technique	Yes
87625	HPV	Probe Technique	Yes
87660	Trichomoniasis	Probe Technique	Yes
87661	Trichomoniasis	Probe Technique	Yes
87800	Gonorrhea	Probe Technique	No - Generic Test
87801	Chlamydia	Probe Technique	No - Generic Test
87806	HIV	Immunoassay	Yes
87808	Trichomoniasis	Immunoassay	Yes
87810	Chlamydia	Immunoassay	Yes
87850	Gonorrhea	Immunoassay	Yes
G0432	HIV	Immunoassay	Yes
G0433	HIV	Immunoassay	Yes

CPT/HCPCS Code	STI Type	Type of Test	For STI Only
G0435	HIV	Antigen	Yes
G0472	Hepatitis C	Antigen	Yes
G0475	HIV	Antigen	Yes
G0476	HPV	Probe Technique	Yes
G0499	Hepatitis B	Antigen	Yes
S3645	HIV	Antigen	Yes

Appendix C. Diagnosis Codes

ICD-10 Diagnosis Code	Description
A50.*	Congenital Syphilis
A51.*	Early Syphilis
A52.*	Late Syphilis
A53.*	Other and unspecified syphilis
A54.*	Gonococcal Infection
A55.*	Chlamydial Lymphogranuloma
A56.*	Other sexually transmitted chlamydial diseases
A59.*	Trichomoniasis
A60.*	Anogenital Herpesviral infections
A63.0	Anogenital warts
B07.8	Other viral warts
B16.*	Acute Hepatitis B
B17.0	Acute Hepatitis B
B18.0	Chronic Heptatitis B
B18.1	Chronic Heptatitis B
B18.2	Chronic Hepatitis C
B19.1	Unspecified Heptatitis B
B19.2	Unspecified Hepatitis C
B20	HIV
Z00.*	Encounter for general examination without complaint
Z01.4*	Encounter for gynocological examination
Z11.3	STD Screening
Z11.4	HIV Screening
Z11.51	HPV Screening
Z11.8	Other Infectious/Parasitic Screening
Z11.9	Other Infectious/Parasitic Screening
Z20.2	Contact w/ STD
Z20.5	Contact w/ Hepatitis
Z20.6	Contact w/ HIV
Z22.4	Carrier of STI
Z22.6	Carrier of HLTV
Z72.5*	High risk sexual behavior

Appendix D. Survey Language

MARYLAND HEALTH CARE COMMISSION

Procurement ID MHCC 23-006: SB-634 STD Home Test Kits Mandate

Survey questionnaire: Please respond in blue cells

Please complete and return by September 30, 2022 to john.price@axenehp.com

Insurer:	Current Health Plan Coverage for STD Tests									
STD Test Types and Lines of Business	Covered Lives	Physician Order Required?		Specimen Collection			Processing/Results		
		In Network	OON	Office	Lab	Home	Office	Lab	Home
		Response Legend **Yes** = Required **No** = Not Required **N/C** = Not Covered		**Response Legend** **C** = Covered **N/C** = Not Covered			**Response Legend** **C** = Covered **N/C** = Not Covered		
All STD Tests									
Current Large Groups									
Current ACA Small Groups									
Current ASO Groups									
All Commercial LOBs									
Medicaid									
Please note any exceptions to the above responses									

If there are variations to the above responses for specific STD tests, please respond in the following list:

Chlamydia
Gonorrhea
Hepatitis B
Hepatitis C
Herpes
HIV
HPV
Syphilis
Trichomoniasis

Health Plan Survey Questions

1	Which STD home tests are currently covered by major lines of business (large group, ACA small group, ACA individual, self-funded, FEHBP, Medicaid, etc.)
2	What percentage of enrollees by major LOB are covered for STD home tests?
3	What are the applicable benefit requirements and limitations for STD home tests? (e.g. physician ordered, in/out of network, type of test/test kit, place of service, etc.)
4	What are the applicable exclusions for STD home tests?
5	What are the coverage/benefit differences, if any, by major LOB for STD home tests?
6	If STD home test kits are mandated for coverage (Maryland SB 634): a. what are the issues needing to be addressed for successful implementation?
	b. what are the major challenges, if any, to manage costs and utilization while providing appropriate access to STD home tests?
	c. what are new major issues, if any, to minimize the potential for fraud, waste and abuse of STD home test kit benefits?
7	Please provide your company's websites/URLs containing current detailed information regarding coverage requirements or exclusions for STD tests and STD home tests if covered
8	Please provide any additional coverage provisions or exclusions applicable to STD tests if not noted above

Appendix E. Survey Results Summary

Insurer:	Current Health Plan Coverage for STD Tests								
STD Test Types and Lines of Business	Covered Lives	Physician Order Required?		Specimen Collection			Processing/Results		
		In Network	OON	Office	Lab	Home	Office	Lab	Home
		Response Legend **Yes** = Required **No** = Not Required **N/C** = Not Covered		**Response Legend** **C** = Covered **N/C** = Not Covered			**Response Legend** **C** = Covered **N/C** = Not Covered		
All STD Tests									
Payor A									
Current Large Groups	118,112	Yes	Yes	C	C	N/C	C	C	N/C
Current ACA Small Groups	195,338	Yes	Yes	C	C	N/C	C	C	N/C
Current ASO Groups	1,484,089	Yes	Yes	C	C	N/C	C	C	N/C
All Commercial LOBs	223,016	Yes	Yes	C	C	N/C	C	C	N/C
Medicaid	79,756	Yes	Yes	C	C	N/C	C	C	N/C
Payor B									
Current Large Groups	0	C	N/C	C	C	N/C	C	C	N/C
Current ACA Small Groups	0	C	N/C	C	C	N/C	C	C	N/C
Current ASO Groups	0	C	N/C	C	C	N/C	C	C	N/C
All Commercial LOBs	0	C	N/C	C	C	N/C	C	C	N/C
Medicaid	0	C	N/C	C	C	N/C	C	C	N/C
Payor C									
Current Large Groups	9,003	Traditional plans – no HMO-based plans – varies	Varies based on plan's OON coverage	N/C	N/C	N/C	C	C	N/C
Current ACA Small Groups	7,525	Traditional plans – no HMO-based plans – varies	Varies based on plan's OON coverage	N/C	N/C	N/C	C	C	N/C
Current ASO Groups	222,038	No-optional coverage based plan benefits	Varies based on plan's OON coverage	N/C	N/C	N/C	C	C	N/C unless per plan benefits
All Commercial LOBs	238,566								
Medicaid	57,477	No	No	N/C	N/C	N/C	C	C	N/C
Please note any exceptions to the above responses				A charge for specimen handling is incidental to the primary service performed and does not warrant separate payment.					

Appendix F. Payer A Questions

	Health Plan Survey Questions
1	Which STD home tests are currently covered by major lines of business (large group, ACA small group, ACA individual, self-funded, FEHBP, Medicaid, etc.)
	No STD home tests are currently covered by major lines of business.
2	What percentage of enrollees by major LOB are covered for STD home tests?
	0
3	What are the applicable benefit requirements and limitations for STD home tests? (e.g. physician ordered, in/out of network, type of test/test kit, place of service, etc.)
	Not applicable.
4	What are the applicable exclusions for STD home tests?
	Any service, supply, or procedure that is not specifically listed in the Member's Evidence of
5	What are the coverage/benefit differences, if any, by major LOB for STD home tests?
	Not applicable.
6	If STD home test kits are mandated for coverage (Maryland SB 634): a. what are the issues needing to be addressed for successful implementation?
	If STD home test kits are mandated for coverage the major issues that will need to be addressed for successful
	b. what are the major challenges, if any, to manage costs and utilization while providing appropriate access to STD home tests?
	The major challenges to manage costs and utilization while providing appropriate access to STD home tests include
	c. what are new major issues, if any, to minimize the potential for fraud, waste and abuse of STD home test kit benefits?
	Thoughts to consider to minimize the potential for fraud,waste and abuse of STD home test kit benefits include,
7	Please provide your company's websites/URLs containing current detailed information regarding coverage requirements or exclusions for STD tests and STD home tests if covered
	Not applicable. No STD home tests are covered at this time. See section 10.1 (D) Contract Exclusions.
8	Please provide any additional coverage provisions or exclusions applicable to STD tests if not noted above
	Not applicable.

Appendix G. Payer B Responses

	Health Plan Survey Questions
1	Which STD home tests are currently covered by major lines of business (large group, ACA small group, ACA individual, self-funded, FEHBP, Medicaid, etc.)
	None.
2	What percentage of enrollees by major LOB are covered for STD home tests?
	None.
3	What are the applicable benefit requirements and limitations for STD home tests? (e.g. physician ordered, in/out of network, type of test/test kit, place of service, etc.)
	N/A
4	What are the applicable exclusions for STD home tests?
	N/A
5	What are the coverage/benefit differences, if any, by major LOB for STD home tests?
	N/A
6	If STD home test kits are mandated for coverage (Maryland SB 634): a. what are the issues needing to be addressed for successful implementation?
	1) One implementation challenge relates to labs that are associated with the tests. If the test kit is covered but the kit is sent to a lab that's out-of-network for the patient, the patient could be balance billed. 2) KP and other carriers don't regularly cover over-the-counter products, so it will be an implementation challenge to do so. 3) KP supports the requirement in the legisation to require coverage only if a home test kit is ordered by an in-network physician.
	b. what are the major challenges, if any, to manage costs and utilization while providing appropriate access to STD home tests?
	Some home tests kits may not be reliable. If that is the case, and individual may need to come in for a more reliable test or may miss the opportunity to have treatment at an early stage in the disease, increasing health care system utilization.
	c. what are new major issues, if any, to minimize the potential for fraud, waste and abuse of STD home test kit benefits?
7	Please provide your company's websites/URLs containing current detailed information regarding coverage requirements or exclusions for STD tests and STD home tests if covered
	A patient can complete an e-visit at their online portal and have a test ordered for them.
8	Please provide any additional coverage provisions or exclusions applicable to STD tests if not noted above

Appendix H. Payer C Responses

	Health Plan Survey Questions
1	Which STD home tests are currently covered by major lines of business (large group, ACA small group, ACA individual, self-funded, FEHBP, Medicaid, etc.)
	STD Home Tests are not currently covered, unless per self-funded plan benefits.
2	What percentage of enrollees by major LOB are covered for STD home tests?
	0
3	What are the applicable benefit requirements and limitations for STD home tests? (e.g. physician ordered, in/out of network, type of test/test kit, place of service, etc.)
	At this time there are not billable codes for STD home tests so there is not a specific payment policy.
4	What are the applicable exclusions for STD home tests?
	Home test kits are generally a plan exclusion, unless related to diabetic testing. STD home kits are generally considered experimental and/or investigational at this time.
5	What are the coverage/benefit differences, if any, by major LOB for STD home tests?
	no differences
6	If STD home test kits are mandated for coverage (Maryland SB 634): a. what are the issues needing to be addressed for successful implementation?
	The primary issues are distribution to members and reimbursing members since there are no billable codes.
	b. what are the major challenges, if any, to manage costs and utilization while providing appropriate access to STD home tests?
	Home tests kits are not on a pharmacy formulary or have billable codes. If coverage were to be mandated, we would have little control over utilization and cost control.
	c. what are new major issues, if any, to minimize the potential for fraud, waste and abuse of STD home test kit benefits?
	It would appear easiest to prevent fraud by handling it via pharmacy distribution to members
7	Please provide your company's websites/URLs containing current detailed information regarding coverage requirements or exclusions for STD tests and STD home tests if covered
	See Clinical Policy Guidelines for respective diagnosis/ screenings: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/medical-clinical-policy-bulletins.html
8	Please provide any additional coverage provisions or exclusions applicable to STD tests if not noted above

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