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Paying for Prevention: Challenges to Health Insurance Coverage for Biomedical HIV Prevention in the United States

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Abstract

Reducing the incidence of HIV infection continues to be a crucial public health priority in the United States, especially among populations at elevated risk such as men who have sex with men, transgender women, people who inject drugs, and racial and ethnic minority communities. Although most HIV prevention efforts to date have focused on changing risky behaviors, the past decade has yielded efficacious new biomedical technologies designed to prevent infection, such as the prophylactic use of antiretroviral drugs and the first indications of an efficacious vaccine. Access to prevention technologies will be a significant part of the next decade's response to HIV, and advocates are mobilizing to achieve more widespread use of these interventions. These breakthroughs, however, arrive at a time of escalating healthcare costs; health insurance coverage therefore raises pressing new questions about priority-setting and the allocation of responsibility for public health. The goals of this Article are to identify legal challenges and potential solutions for expanding access to biomedical HIV prevention through health insurance coverage. This Article discusses the public policy implications of HIV prevention coverage decisions, assesses possible legal grounds on which insurers may initially deny coverage for these technologies, and evaluates the extent to which these denials may survive external and judicial review. Because several of these legal grounds may be persuasive, particularly denials on the basis of medical necessity, this Article also explores alternative strategies for financing biomedical HIV prevention efforts.

I. INTRODUCTION

Since the 1980s, the human immunodeficiency virus (HIV) has shaped both legal systems and population curves around the world, profoundly transforming law and public health. Much of the advocacy about HIV has focused on access to treatment, but recent scientific breakthroughs are prompting a new focus on access to prevention technologies. Although HIV prevention research has long focused on *behavioral* means of reducing infection (e.g., encouraging individuals to use condoms or sterile drug injection equipment), the past decade has brought about a shift toward *biomedical* strategies for prevention.¹ This work is yielding promising, partially efficacious new methods for reducing the risk of infection, including the preventive use of antiretroviral (ARV) drugs as pre-exposure and post-exposure prophylaxis (PrEP and PEP), microbicide gels, vaccines, and adult male circumcision.² Recent studies have also identified preventive effects of established technologies, such as ARV treatment for HIV-infected individuals, the treatment of other sexually transmitted infections (STIs),

the treatment of substance use disorders, and HIV testing and counseling.³ Although individuals at elevated risk for HIV are often willing to use these interventions, many are unable or unwilling to pay the full cost of this medical care.⁴ But as mathematical models reflect, the public health impact of biomedical HIV prevention strategies will depend in part on their widespread adoption by individuals at risk.⁵ For this reason, the financing of biomedical prevention is likely to be a key question in the next phase of the U.S. response to HIV, and the costs of this care will interact with systemic priorities such as controlling health care costs and reducing the proportion of uninsured individuals.

As biomedical HIV prevention technologies gain publicity and a firmer evidentiary base, public and private health insurers will encounter requests to cover these interventions, including legal challenges if coverage is denied. But coverage may not be an easy question. Some new prevention interventions may be brief and relatively inexpensive, such as a one-time vaccine,⁶ a course of ARV drugs after near-certain exposure,⁷ or male circumcision in communities of high risk.⁸ Other interventions will entail higher costs and long-term monitoring by clinicians; cost-effectiveness remains unclear for these newer technologies. The initial and continuing costs of this preventive care could be high, and the financial benefits of averting infection may only be realized on a long-term basis because of the latency of HIV infection. Public and private insurers may also find it financially or politically problematic to provide coverage for medical interventions that mitigate the consequences of behavioral risk-taking, particularly when these risks include socially stigmatized behaviors, unprotected sex or injection drug use.⁹

This context raises new questions for public health and the law, and this Article addresses one such question: under existing law governing private and public health insurers in the United States, what legal challenges may influence the coverage of biomedical strategies for preventing HIV infection? This question specifically addresses whether existing insurers will extend coverage to specific health technologies for the purpose of reducing their policyholders' risk of acquiring HIV.¹⁰ Health insurance coverage for preventive care is problematic for the U.S. healthcare system. Substantive coverage decisions by public and private insurers generally turn on whether care is "medically necessary," and prevailing interpretations have limited this term to treatment and diagnostic care.¹¹ Coverage for preventive health care may instead depend on whether such care is cost-effective for the insurer. Although these interpretive principles support the economic functions of insurance, they can undermine the uptake of preventive care. Individuals may be less willing to pay for preventive care than for treatment,¹² and given the higher burden of infectious and chronic disease among individuals of lower socioeconomic status, the out-of-pocket costs for preventive care may be least affordable for the individuals who are most at risk.

When we focus on technologies for the prevention of HIV, which is an *infectious* condition, these access problems are magnified. HIV affects the most socially and economically marginalized populations in the United States, and preventive technologies would have the greatest impact among the groups least able to pay for this care out-of-pocket.¹³ Because HIV is infectious, efforts to reduce HIV prevalence in the most at-risk groups will in fact benefit the population as a whole. This is due to the phenomenon of "herd effects," in which all members of a community benefit from overall reductions in HIV prevalence.¹⁴

Individuals who receive preventive care will reduce their risk of acquiring HIV, which reduces their risk of transmitting HIV to future partners, which then reduces the risk that those partners will transmit HIV to others, and so forth, culminating in a reduced population-level prevalence of infection.¹⁵ Through the mechanism of herd effects, HIV prevention technologies may be cost-effective for a population as a whole—even if they are not cost-effective for individual insurers, who each may only cover a segment of the population at risk. The promise of herd effects distinguishes HIV prevention from the prevention of noncommunicable diseases (such as diabetes or heart disease). In this context, the cost-effectiveness calculations that insurers may use for coverage decisions may neglect the positive externalities that would make HIV prevention technologies potent. Given the socioeconomic features of the HIV epidemic, as well as the population-level promise of HIV prevention technologies, insurers' coverage decisions regarding biomedical HIV prevention are of paramount importance.

Where insurers' cost-effectiveness calculations do not support coverage, they may use a variety of legal grounds to avoid financing this care, including medical necessity, experimental treatment exceptions, off-label prescription exclusions, preexisting condition exclusions, and public policy arguments implicating moral hazard and adverse selection.¹⁶ Where the sole purpose of an intervention is to reduce the risk of HIV acquisition, and particularly where the intervention is costly, several of these objections may be persuasive. Public health advocates should prepare to meet these objections, and alternative sources of financing could be needed to enable at-risk individuals to adopt biomedical HIV prevention strategies.

The ensuing Parts of this Article will identify legal mechanisms that public and private health insurers may use to challenge coverage for the emerging generation of biomedical HIV prevention interventions. One implication of this inquiry is the extent to which insurers should shoulder the costs of intervention in public health when illnesses are in part brought on by individual health behaviors. This question resonates with recent changes in U.S. healthcare financing, such as the requirement in the Patient Protection and Affordable Care Act (ACA) prohibiting insurer discrimination on the basis of prior health status, even if conditions may stem in part from health behaviors.¹⁷

Part II of this Article outlines recent developments in biomedical HIV prevention, noting key features of new technologies including the use of ARV drugs, microbicides, male circumcision, vaccines, STI treatment, substance use disorder treatment, and HIV testing. It is important to note that many of these interventions (most notably antiretroviral pre-exposure prophylaxis, or PrEP¹⁸) will also include HIV testing, behavioral counseling, treatment of side effects, and long-term monitoring, increasing the costs of the intervention package.¹⁹ Part III discusses the public policy implications of insurers' coverage decisions regarding HIV prevention technologies, explaining how coverage may interact with priorities such as reducing the risk level, spreading losses, fulfilling the "right to health," controlling costs and deterring free riding, expressing norms, and incentivizing innovation. Part IV identifies the role of public and private insurers in biomedical HIV prevention, outlines sources of insurance among individuals at risk of HIV infection, and notes the difficulties in relying on at-risk individuals to internalize the entire cost of these new

technologies. Individuals at high risk for HIV infection are often uninsured or underinsured in the United States, or they may be disqualified from many policies on the basis of preexisting conditions (e.g., a history of substance use).²⁰ This coverage landscape will likely change, however, when the individual mandate and Medicaid expansion provisions of the ACA take effect. Part IV also describes principles of insurance coverage determinations and procedures for seeking coverage in the United States. Part V assesses the legal grounds that public and private health insurers may use to refuse coverage of biomedical HIV prevention, evaluating the likely success of these strategies in subsequent litigation. Finally, Part VI considers alternative mechanisms for expanding access to HIV prevention technologies, including potential actions for state or federal governments, insurers, and large employers who purchase insurance on behalf of employees.

II. BIOMEDICAL HIV PREVENTION STRATEGIES

Recent medical research has identified a variety of emerging biomedical prevention mechanisms for HIV prevention. This Article defines biomedical prevention strategies as those that involve the participation of a healthcare provider for prescription, diagnosis, or monitoring. This is not to minimize the importance of prevention strategies that take place outside clinical settings; as the HIV prevention literature identifies, efficacious strategies such as behavioral counseling,²¹ the use of male²² and female²³ condoms, or needle exchange programs²⁴ have thus far been our primary bulwark against the spread of infection. More recent developments provide exciting new possibilities for non-clinical prevention, including home-based rapid HIV testing²⁵ and microfinance programs.²⁶ The focus of this Article, however, extends only to HIV prevention that involves clinical providers.

There are several ways to classify this new cohort of interventions with relevance to insurance coverage decisions. Table 1 summarizes these characteristics along with intervention costs, and Part IV discusses the ways in which these product features will inform insurers' coverage decisions.

One way to classify these interventions is by *availability*. Several of these interventions are entirely new technologies still unavailable for use, such as vaccines or microbicides containing antiretroviral drugs.²⁷ The remainder of these interventions are new uses of existing technologies, which are already available through standard clinical care, FDA-approved uses, or off-label uses.²⁸ These strategies include ARV drugs for treatment of an HIV-infected partner, ARV drugs for oral pre- or post-exposure prophylaxis, treatment of STIs, treatment of substance use disorders, male circumcision, and HIV testing.

Another key feature for coverage decisions is whether interventions have a *dual* purpose (prevention and treatment, or diagnosis) or are solely useful for prevention. Dual-purpose interventions include STI treatment, the treatment of substance use disorders, HIV testing, and the treatment of HIV-infected people with ARV drugs. Others have an exclusively preventive benefit.

Finally, interventions can be classified according to whether they are used by a person who is already infected with HIV or by a person who is not yet infected. An HIV-positive person

can use several of these strategies to reduce the risk of *transmitting* HIV to his or her partner, such as ARV treatment, the treatment of other STIs, the treatment of substance use disorders, and HIV testing to identify the virus. An uninfected person would use strategies to reduce the risk of *acquiring* HIV, including ARV drugs for pre- or post-exposure prophylaxis, microbicides, male circumcision, vaccines, STI treatment, treatment of substance use disorders, and possibly HIV testing to motivate safer behavior.

This Part identifies each of these new biomedical strategies in turn, summarizing the current evidence for the effectiveness of each technology. This Part concludes by discussing the supporting services necessary to deliver many of these new interventions; although these services can increase the cost of care, their omission may diminish or even reverse the preventive effect on HIV transmission, paradoxically leading to *increases* in the burden of HIV infection.

A. Antiretroviral (ARV) Drugs

ARV drugs have been used to treat people living with HIV since the mid-1980s, and at least twenty-five drugs are currently in use for this purpose.³⁹ Public health scientists have recently discovered the potential for ARV drugs to *prevent* infection among HIV-negative individuals.⁴⁰ ARV drugs may reduce the risk of HIV in three different ways: (1) treatment of an HIV-infected partner, (2) post-exposure prophylaxis, and (3) pre-exposure prophylaxis.

1. Treatment of an HIV-Infected Partner

The transmission of HIV results from exposure to the bodily secretions of an infected individual, including blood, semen, vaginal fluid, or breast milk. The likelihood of infection depends not only on exposure, but also on the *concentration* of virus within those secretions, also called viral load.⁴¹ Viral load, expressed as number of copies of the virus per milliliter of fluid, may be the most significant factor in any type of transmission event.⁴² When an HIV-infected person takes ARV drugs, one effect of the therapy is to decrease viral load in blood and other fluids.⁴³ Empirical evidence indicates that when an HIV-infected person begins ARV therapy, this reduced viral load can diminish the risk of transmitting HIV to others through mother-to-child transmission⁴⁴ and sexual contact (by approximately 95 percent when treatment is initiated early, compared to initiating treatment at a later stage of infection).⁴⁵ A universal strategy of annual voluntary HIV testing and *immediate* ARV treatment of HIV-infected individuals could “nearly stop transmission ... within one to two years of reaching 90 percent of progra[m] coverage.”⁴⁶ Infected individuals do not usually start ARV treatment until more advanced phases of infection, but immediate treatment could reduce the number of AIDS-related deaths by 55 percent over the next forty years.⁴⁷ Insurers have encountered coverage requests for ARV treatment since the first antiretroviral drug, AZT, was introduced in 1987;⁴⁸ given new findings, the possibility of using ARV treatment to *prevent* infection may prompt requests for coverage in earlier stages of infection, or coverage for the HIV-infected partner of an uninfected policyholder.

2. Post-Exposure Prophylaxis: PEP and nPEP

Post-exposure prophylaxis (PEP) refers to the use of ARV drugs by uninfected individuals after exposure to HIV. PEP was originally evaluated in occupational contexts, such as needlestick injuries among healthcare professionals.⁴⁹ Among healthcare workers who take the ARV drug zidovudine after exposure, the odds of acquiring HIV may be reduced by approximately 81%.⁵⁰ No randomized trial has evaluated PEP, but the use of ARV post-exposure prophylaxis is now routine following occupational exposure.⁵¹ Guidelines issued by the Centers for Disease Control and Prevention (CDC) guidelines recommend a twenty-eight-day course of PEP, which must begin as soon as possible following an accidental exposure.⁵²

When PEP is used in other settings, such as following unprotected sex or rape, it is called nonoccupational PEP or “nPEP.” Evidence for the effectiveness of nPEP comes from observational studies of HIV exposure through birth, consensual sex, sexual assault, and injection drug use.⁵³ The CDC recommends a twenty-eight-day course of ARV drugs for individuals exposed to HIV, when treatment is sought within seventy-two hours.⁵⁴ Despite this evidence, however, use of nPEP has been rare; this is due in part to low rates of nPEP prescription to eligible patients, which may be motivated in part by costs, perceived low medication adherence, perceived low HIV risk among eligible users, and concerns about ARV-associated side effects.⁵⁵

3. Pre-Exposure Prophylaxis: PrEP

Pre-exposure prophylaxis (PrEP) refers to the use of ARV drugs by uninfected individuals *before* exposure to HIV. PrEP is the newest ARV-based prevention strategy, and trials are testing the efficacy and safety of various ARV drugs.⁵⁶ Recent studies have found that these drugs may be safe for HIV-negative people, including heterosexual men and women, men who have sex with men, people who inject drugs, and couples in which one partner is HIV-positive.⁵⁷ Several trials have suggested that the HIV medication Truvada (a combination of tenofovir and emtricitabine) may be 44 to 92 percent efficacious for preventing HIV infection, with higher efficacy depending on how well users adhere to medication schedules.⁵⁸ On the basis of these studies, the FDA approved Truvada for an HIV prevention indication in July 2012,⁵⁹ and the World Health Organization (WHO) and the Centers for Disease Control (CDC) have issued guidelines for the prescription of daily Truvada to sexually active adults as PrEP.⁶⁰

Population-level models have suggested that PrEP could have a substantial impact on HIV transmission in the US.⁶¹ People at risk of HIV infection also appear to be willing to use PrEP, including those in high-incidence populations.⁶² Although reports of actual PrEP use suggest that off-label use of ARV drugs as PrEP has been rare,⁶³ the new WHO guidelines and recent FDA approval may increase public demand for Truvada as PrEP. Beyond Truvada, additional ARV drugs are in the pipeline for testing as PrEP;⁶⁴ initial uses of these drugs as prophylaxis will be off-label, but judging from the experience with Truvada, manufacturers will likely seek FDA approval of prophylaxis indications as clinical trials demonstrate efficacy.

B. Microbicides

Microbicides include gels, creams, films, vaginal rings, and suppositories designed for vaginal or rectal use by HIV-negative people to reduce the risk of infection during sex.⁶⁵ This field had its first success in 2010: in a trial of high-risk women, a vaginal gel containing the ARV drug tenofovir was shown to safely reduce HIV infections by approximately 39%.⁶⁶ At least thirty-five trials are now testing new microbicide products.⁶⁷ Although no microbicide is yet available for sale, efficacious products will play a key role in the future response to HIV. Women have reported high willingness to use microbicides, which may serve as an undetectable means of preventing HIV for women whose partners refuse to use condoms.⁶⁸

C. Male Circumcision

Evidence suggests that circumcision can reduce men's risk of acquiring HIV,⁶⁹ which may be explained by several different biological mechanisms.⁷⁰ Trials have found that the circumcision of adult men can reduce HIV risk by between 38 and 66 percent, with few adverse effects.⁷¹ This benefit has only been shown for heterosexual men, and circumcision does not appear to limit the transmission of HIV from an infected male to a female sex partner.⁷²

The CDC has noted that circumcision can play a role in the United States,⁷³ and its benefits have been observed among U.S. individuals exposed to HIV.⁷⁴ Approximately 79 percent of adult U.S. men report having been circumcised,⁷⁵ as are a majority of male newborns, although the percentage is lower in states where Medicaid does not cover the procedure.⁷⁶

D. Vaccines

There is no effective vaccine for HIV prevention.⁷⁷ In 2009, however, the *New England Journal of Medicine* reported the first signs of success, identifying a vaccine candidate with approximately 31 percent efficacy for preventing HIV.⁷⁸ Although these findings have not yet translated to a marketable vaccine, at least twenty-two ongoing trials are now testing new formulations.⁷⁹

E. Treatment of Other Sexually Transmitted Infections (STIs)

Epidemiological evidence has suggested that having an STI can increase an individual's chances of acquiring HIV, particularly ulcerative infections such as syphilis or herpes.⁸⁰ Similarly, when an HIV-infected individual has another STI, the HIV viral load in genital secretions can increase, which increases the risk of transmitting HIV to others.⁸¹ Despite mixed evidence, STI diagnosis and treatment is now recognized as a potentially critical strategy for HIV prevention.⁸² The Advisory Committee for HIV and STD Prevention in the United States has recommended that "early detection and treatment of curable [STIs] should become a major, explicit component of comprehensive HIV prevention."⁸³

F. Treatment of Substance Use Disorders

Although rarely included in discussions of biomedical HIV prevention, the clinical management of substance use disorders—including pharmacological treatments such as

methadone maintenance therapy, buprenorphine, and naltrexone—can be a potent HIV prevention strategy.⁸⁴ Drug treatment can advance HIV prevention by improving access and adherence to ARV treatment among individuals who are HIV-infected, and by reducing drug-related behaviors that put uninfected people at risk (e.g., drug injection, needle-sharing, and transactional sex).⁸⁵

G. HIV Testing and Counseling

Voluntary HIV testing and counseling can reduce HIV transmission by diagnosing infected individuals (enabling them to receive ARV treatment and counseling),⁸⁶ and by motivating HIV-negative individuals to engage in safer behaviors.⁸⁷ An HIV-infected person who is unaware of his or her HIV status may transmit HIV at an annual rate of 8.8 percent, but this rate drops to about 2.4 percent among individuals who know they are infected.⁸⁸ One study among uninfected people has found that testing and counseling led to a 20 percent reduction in STI incidence.⁸⁹ The CDC recommends universal opt-out testing among primary care patients aged thirteen to sixty-four,⁹⁰ although some suggest that a targeted strategy would be more cost-effective.⁹¹

H. Combination Interventions and the Need for Supporting Services

Coverage of biomedical HIV prevention technologies may also entail the cost of supporting services, which may include a combination of biomedical and behavioral components.⁹² For example, a complete prevention package might include condoms, PrEP, behavioral counseling, treatment for other STIs, and routine HIV testing.⁹³ The inclusion of behavioral counseling is particularly important, because the effectiveness of biomedical prevention will depend in part on users' adopting new technologies, using them correctly, and avoiding increases in risk behavior. Medical concerns such as side effects and the need for periodic HIV testing will also be important for long-term interventions involving ARV drugs.

These supporting services are potentially costly, but delivering biomedical HIV prevention without complementary services can cause harm. These harms may include not only side effects, but also *increases* in the population-level HIV burden through viral resistance or increased behavioral risk-taking. If an uninfected person acquires HIV while taking ARV-based PrEP, but continues taking PrEP because he is unaware of the infection, the virus in his body could develop resistance to that class of ARV drugs.⁹⁴ This limits his HIV treatment options, and he could transmit the resistant strain to others. Another potential hazard is risk compensation behavior,⁹⁵ a phenomenon by which people who expect that they are protected from HIV may take more behavioral risks.⁹⁶ Moderate increases in risk-taking could even reverse the preventive effect of PrEP drugs, paradoxically increasing HIV incidence.⁹⁷ Risk compensation could also exacerbate other health problems linked to HIV risk behaviors, such as STIs or soft tissue infections among people who inject drugs.

III. COVERAGE AND PUBLIC POLICY: IMPLICATIONS OF COVERAGE DECISIONS REGARDING BIOMEDICAL HIV PREVENTION

Biomedical interventions may be powerful tools in the United States response to HIV. The benefit of these technologies, however, will depend on the proportion of at-risk individuals

able to use them. Insurance coverage is often a necessary condition for access to health care, particularly for populations with little capacity to pay for services out of pocket.⁹⁸ Populations at elevated risk for HIV infection are among those least able to finance this care.⁹⁹ This Part addresses the priorities at stake in insurers' decisions about HIV prevention technologies, examining arguments both for and against coverage.¹⁰⁰

A. Insurance as a Means of Health Promotion and Achieving the Right to Health

A clear public policy argument in favor of expanding insurance coverage for biomedical HIV prevention is the promotion of public health. The reduction of HIV incidence is a public priority in the United States, recognized as part of the Department of Health and Human Services Healthy People 2020 Objectives,¹⁰¹ the White House National HIV/AIDS Strategy,¹⁰² and the mission of the CDC.¹⁰³ Coverage will expand access to biomedical HIV prevention technologies, allowing greater uptake by at-risk individuals and a correspondingly larger reduction in HIV incidence.

Although insurance coverage of biomedical HIV prevention is a domestic public health issue, these coverage decisions have global implications for patented drugs and devices, such as vaccines, microbicides, and PrEP. Manufacturers of these interventions are likely to engage in differential pricing; for instance, Gilead Sciences Inc. has committed to providing Truvada-based PrEP at cost in developing countries, but not in high-income countries like the United States.¹⁰⁴ Differential pricing yields profits at every price point, so long as those prices do not dip below the marginal cost of production.¹⁰⁵ But the large profits available from sales in high-income countries—which may be impossible without insurance coverage—can provide the main incentives for the development and testing of new health technologies with global benefit.¹⁰⁶ Coverage of biomedical HIV prevention technologies in high-income countries will continue to incentivize scientific advancement and public health improvements in this field.

1. Locating the Duty with Insurers—This public policy rationale raises the question of why insurers and policyholders should defray the costs of public health efforts such as biomedical HIV prevention—as opposed to other possible payers such as individuals, states, the federal government, charitable organizations or donors, or manufacturers of preventive technologies. If coverage of a preventive technology is cost-effective, financing by insurers and policyholders is a cost-saving proposition. But if coverage is not cost-effective, deciding who should bear the costs is more complicated.

One way to locate responsibility is to identify who will gain from the reductions in HIV incidence. Many of the costs saved through averting an HIV infection—namely, the costs of treating someone with HIV—will be recaptured by health insurers, and then potentially passed on to policyholders via reduced premiums. Medicare may recoup a portion of these savings: the life expectancy of adults living with HIV/AIDS has increased to over twenty-four years after beginning care, suggesting a median life expectancy of about sixty-three.¹⁰⁷ Savings recouped by Medicare or Medicaid are spread throughout the taxpayer base. Taxpayers may also gain through reduced costs of AIDS Drug Assistance Programs, which operate using a combination of state and federal funds.¹⁰⁸ Other savings from an averted

HIV infection, such as economic productivity, will accrue to society more generally; as Timothy Jost has observed, many “benefits of preventive services accrue to society as a whole, while immediate costs are borne by insurers or individuals.”¹⁰⁹ Increased health and life expectancy will accrue to the policyholder who receives coverage. Additionally, when a policyholder avoids acquiring HIV, his or her subsequent sex or drug use partners will experience the same health and life expectancy gains.

From an administrative costs standpoint, path dependency makes it cheapest to locate the duty to finance biomedical HIV prevention with health insurers. Biomedical HIV prevention technologies involve clinical providers, testing laboratories, and drugs or devices. Health insurers have already established procedures for paying and exercising oversight of these actors. Insurers are also well-placed to bargain with manufacturers and clinical providers to reduce the cost of biomedical prevention. Bargaining would increase the cost-effectiveness of this care for insurers, but it may also have adverse consequences. For instance, public insurers’ successes in controlling hospital costs may have driven up prices for private insurers and those paying for care out-of-pocket.¹¹⁰ The Medicaid expansion provision of the ACA may intensify this dynamic due to a potential rise in the proportion of individuals covered by public insurance,¹¹¹ but a recent analysis suggests that cost-shifting behavior by healthcare providers may only explain a small part of the differential in care pricing.¹¹²

Insurers are designed to spread health care costs over time and across populations, and loss-spreading is a persuasive reason to locate healthcare financing duties with insurers and their policyholders; public and private insurers, however, are not equally suited to this function. Private insurers are designed to spread risks within individual pools of policyholders, but because public insurance programs are financed through tax revenues, the government can spread these risks over the entire taxpaying society. Guido Calabresi has argued that private insurance has a limited capability to spread risks, compared to government or “social” insurance.¹¹³

The promotion of public health is widely recognized as the remit of the states (through the police power¹¹⁴) and federal government (realized through both the requirement to provide for the general welfare and the power to tax and spend¹¹⁵), which would justify coverage by public insurance programs or another governmental mechanism instead of private insurers. This view is founded on theories of democracy that identify the state’s responsibility to provide constituents with “protection against natural and man-made hazards.”¹¹⁶ Organized leadership backed by credible and effective power to compel action is essential to maintaining many preconditions to health, such as sanitation, a safe blood supply, control of environmental hazards, and the monitoring of infectious diseases.¹¹⁷ Because biomedical HIV prevention prevents an infectious disease, arguments founded on the historical responsibility for public health promotion may locate the responsibility for financing these technologies with the state. Nevertheless, these arguments may also recognize the state’s power to mandate coverage by private insurers as a means of fulfilling these goals, given the ability of private insurers to distribute these costs among citizen policyholders.

Finally, private and public health insurance is increasingly viewed as a mechanism for realizing the right to health, apart from the economic functions of insurance.¹¹⁸ A long

series of international and regional agreements have recognized the right to health as a human right, but the United States has ratified only two of these agreements: the Universal Declaration of Human Rights and the International Covenant on the Elimination of All Forms of Racism.¹¹⁹ The U.S. Constitution does not explicitly confer a right to health or healthcare, although five state constitutions either require that the state promote or protect public health (Alaska, Hawaii, Wyoming, and South Carolina) or create a right to a healthful environment (Montana).¹²⁰

The ACA has come closer to embracing the idea that insurance is a means of achieving optimal health, rather than a market mechanism to reduce the risk level or to insulate voluntary purchasers from future losses. The Act's prohibition of discrimination based on health status, like its requirement that insurers cover preventive interventions specified by the U.S. Preventive Services Task Force (USPSTF),¹²¹ is a fundamental policy decision intended to promote the health of the general U.S. population. To prohibit discrimination, the Act relies on insurers' ability to spread the costs of health inequalities across a broad population of policyholders. The individual mandate to purchase insurance is intended to offset these and other requirements by increasing and diversifying the pool of policyholders (across all plans);¹²² these policy decisions are supported by a health-promotion rationale.¹²³ Rights-based arguments tend to be altogether critical of for-profit private insurance,¹²⁴ acknowledging few advantages beyond the capacity for loss-spreading.

2. Complicating the Public Health Rationale for Coverage—Arguments rooted in public health and the right to health are complicated by the need for cost control, the approach of health care rationing, and the potential long-term economic effects of raising premiums to cover biomedical HIV prevention. At an extreme, increases in premiums could restrict the availability or affordability of health insurance to individuals of low socioeconomic status. Moreover, concerns about expenses for biomedical HIV prevention could in fact lead insurers to refuse policy applications altogether from individuals likely to be at risk for HIV—at least until the preexisting condition provisions of the ACA come into effect in 2014.¹²⁵

Widespread coverage of biomedical HIV prevention has also raised opposing public health arguments, particularly in discussions about the availability of PrEP. Some medical providers and advocacy groups have opposed expanding access to PrEP, citing concerns about increases in sexual risk behavior, the spread of resistant viral strains, and long-term side effects.¹²⁶ The possibility that users of biomedical HIV prevention technologies will engage in riskier sexual or drug use behaviors is known variously as “risk compensation,” “behavioral disinhibition,” “offsetting behavior,” or “moral hazard,” and this phenomenon has been extensively studied in other public health contexts.¹²⁷ Preliminary research suggests that individuals who choose to use PrEP will vary in their behavioral responses to this new technology; some target users predict that they will use condoms less frequently or engage in sex with more partners, while others do not.¹²⁸ Given the novelty of this intervention, little evidence is available to assess how this will work in practice, and real-world behavior cannot be measured until PrEP is widely accessible outside trials. The recent FDA approval of Truvada as PrEP was conditioned on implementation a risk evaluation and mitigation strategy (REMS). The REMS requires the manufacturer to warn providers and

end-users that Truvada should only be used as part of a “comprehensive” HIV prevention strategy, including safer sex and frequent HIV testing.¹²⁹ Concerns about risk compensation should not presumptively bar the approval of these new technologies, given the possibility of disseminating these technologies along with behavioral counseling, as well as the potential injustice of denying beneficial technologies to users who will not increase their risky behavior. It will be important to assess this phenomenon using methodologically rigorous strategies after these new technologies are approved, and it is preferable to use noncoercive measures to optimize product use before limiting product access.¹³⁰

It is also important to note the concern that new technologies for the prevention of HIV are not biologically costless. Side effects, particularly those associated with antiretroviral drugs, may adversely affect users’ quality of life, and long-term toxicity may be unknown when new devices or drug indications are approved for use. This assessment of insurance coverage decisions should not be construed to advocate the approval or financing of untested, ineffective, or dangerous technologies;¹³¹ nor does this Article intend to diminish the role of FDA oversight or health technology assessment in coverage decisions. Much has also been written about the profit motives of pharmaceutical and medical device manufacturers, who benefit from favorable coverage decisions. But individuals at risk for HIV infection have a range of preferences, and individual perceptions of an acceptable balance between costs and benefits of an HIV prevention strategy may vary widely. When an intervention proves efficacious for the prevention of infection, it may be too hasty to assume that its risks outweigh its benefits for all users, and the FDA must make approval decisions on a case-by-case basis. Decisions about safety, efficacy, and acceptability have a crucial role to play in product access, and this Article’s focus on insurance coverage should not detract from their importance.

As this Article has noted above, coverage decisions can present a trade-off between coverage and premium pricing; if the decision to cover an HIV prevention technology has the net effect of increasing health insurance premiums for a given health plan, individuals at the margin may be priced out of the plan. Reducing the proportion of individuals who are uninsured is an important priority, and some may argue that this goal is more important than the coverage of new technologies. But to the extent that HIV prevention technologies are cost-effective—that is, the costs of these technologies are outweighed by the savings from the infections they avert—coverage may expand the availability of insurance by decreasing premiums. The real-world cost-effectiveness of many of these new technologies is as yet unknown.

Competing public health priorities also complicate the public health rationale for insurance coverage of biomedical HIV prevention technologies. The majority of the U.S. disease burden stems from modifiable health behaviors, including poor nutrition, physical inactivity, smoking, and alcohol consumption; one third of American adults are obese, and 70 percent of deaths are due to chronic disease.¹³² These behaviors could be improved through preventive interventions, including behavioral counseling, education, and interventions that focus on workplaces, schools, or families. But dissemination of behavioral interventions is low and generally relies on financing by nonprofit groups, rather than insurance.¹³³ In contrast, the U.S. HIV prevalence is below 1%, but it has a disproportionate and devastating

impact on socially disadvantaged groups.¹³⁴ Policymakers allocating healthcare resources in the United States must balance the public health needs of the general population alongside priorities for communities affected by HIV. Insurance coverage for expensive preventive technologies might therefore be weighed against competing public health priorities. Public health advocates concerned about “AIDS exceptionalism” have levied criticisms against funding for HIV/AIDS at the global level, pointing to other public health priorities that have been overlooked.¹³⁵ Even within the field of HIV/AIDS, similar distributional concerns arise when we consider relative expenditures on *prevention* compared to *treatment* for HIV. This is particularly contentious for the new prophylactic uses of ARV drugs: as long as some HIV-infected people lack access to ARV drugs for treatment, it may be difficult to prioritize their use by uninfected people.

B. Insurers as Market Actors: Cost-Effectiveness, Cost Control, and Free Riding

Cost control continues to be an indispensable and urgent focus of health policy. Cost-effectiveness analysis is becoming more salient in coverage determinations, with the acknowledgement that cost control is intimately tied to the availability of insurance. Preventive care may not always be cost-effective for an individual payer,¹³⁶ although many methods of HIV prevention may be.¹³⁷ Cost-effectiveness for individual insurers will depend on factors such as policyholder HIV risk, demand, user behaviors, and downstream effects. One downstream effect is a question of which cause of death may replace AIDS-related mortality, if someone avoids HIV infection, and the comparative costs of that disease. Another question is whether new biomedical interventions may induce more individuals to initiate contact with healthcare providers. Once they make contact with the healthcare system, these individuals may seek additional services such as mental health care, treatment for substance use disorders, or other specialist or routine care.¹³⁸ Given that populations at risk of HIV infection are highly medically underserved, new prevention technologies present exciting opportunities for treatment but also may present higher-than-anticipated costs.

Coverage also raises questions of positive externalities including who will capture savings from averted infections. If enough people can reduce their risk of HIV infection through preventive care, then even those who *do not* receive care will benefit from reduced HIV prevalence in the community. For example, one model of PrEP use among men who have sex with men in New York City predicts that 59 percent of prevented infections could be among individuals *not* taking PrEP.¹³⁹ These indirect benefits are known as “herd effects,”¹⁴⁰ and they result from the overall reduced prevalence of infection.

The benefits of herd effects introduce opportunities for free riding among health care payers. That is, it would be rational for any individual insurer to withhold coverage if other insurers provide it. For example, suppose that public insurers such as Medicaid cover PrEP, but private insurers do not. Medicaid policyholders will then access PrEP and benefit from a reduced risk of HIV infection, and the overall prevalence of HIV in the community will decline compared to projected trends. The policyholders of private insurance companies will *also* benefit from overall reductions in HIV prevalence, even if they do not use PrEP, because they are less likely to be exposed to the virus. Private insurers will thus benefit from

reduced incidence of HIV and AIDS among their policyholders, but they will not incur the costs of PrEP coverage. This dynamic may lead to unwillingness among insurers to pay for PrEP or to be the “first mover” in coverage for any form of biomedical HIV prevention. Given herd effects, it is possible that covering PrEP may be cost-effective *in general* for a population at risk, but not for a particular healthcare payer.

Herd effects may conversely *boost* the cost-effectiveness of biomedical HIV prevention when policyholders are clustered into at-risk communities. Suppose that Medicaid is the most common insurer for a community of people who inject drugs, perhaps because a local clinic assists with enrollment. If Medicaid covers PrEP, it is unlikely that *every* eligible beneficiary will use it. But if *some* beneficiaries take PrEP, then the overall prevalence of HIV in the community will diminish. Many of the averted infections will also be among Medicaid-insured individuals who are not taking PrEP, allowing Medicaid to capture these savings. This would improve the cost-effectiveness of PrEP for Medicaid, and these dynamics should be considered when Medicaid contractors decide on coverage.

Legislation is often used to solve free riding problems,¹⁴¹ and a state or federal coverage mandate would overcome insurers’ reluctance to finance biomedical prevention. But even if all insurers provide coverage, the distribution of expenses and savings remains uncertain. Insurers who serve high-incidence populations would likely spend more on preventive care, but they may also benefit more from averted infections. Insurers who would benefit *most* under such a mandate would be those whose policyholders do not seek preventive care, but who are nevertheless at risk for HIV and benefit from herd effects. This may give rise to strange incentives to discourage the uptake of prevention services among one’s own policyholders while supporting activities that encourage use by others.

C. The Expressive and Social Functions of Coverage: Individual Behaviors and Social Stigma

Insurers’ coverage determinations regarding biomedical HIV prevention may also serve at least two cultural functions: expressing existing social norms and redirecting those norms through coverage policy.

Insurance coverage of particular technologies is often perceived as expressing and reinforcing social norms, denoting the value of those who seek coverage.¹⁴² This dynamic is particularly salient in health insurance because illness threatens survival and the ability to engage in meaningful activities; coverage can determine access to technologies that are indispensable to meet these goals. The ongoing controversy regarding prescription contraceptives has emphasized this expressive effect of coverage decisions. When Viagra was approved for the treatment of erectile dysfunction, insurers’ rapid decisions to provide coverage led to claims of discrimination against women denied coverage for prescription contraceptives on medical necessity grounds.¹⁴³ Apart from debates over the meaning of “medical necessity,” this disparity in coverage was interpreted to mean that men’s sexual pleasure is more valuable than women’s ability “to enjoy sexuality free from the anxiety of an unwanted pregnancy.”¹⁴⁴ Insurers who classified contraception as a “lifestyle drug” were seen to express negative messages about women, “tread[ing] dangerously close to stereotyping women who elect to control their fertility as ‘promiscuous’ or ‘scandalous.’”¹⁴⁵

Precisely the same arguments could be applied to biomedical HIV prevention technologies, and insurers who consider these to be “lifestyle” interventions may express a message that devalues the freedom of at-risk people to enjoy sex with less fear of acquiring HIV.

Similar conversations arise regarding insurers who deny coverage for transgender individuals who seek to transition away from their biological sex through sex reassignment surgery or hormone therapy.¹⁴⁶ These coverage denials have been upheld on the ground that medical necessity is a nondiscriminatory reason for denial,¹⁴⁷ but many believe that these decisions express discrimination against transgender individuals.¹⁴⁸

Coverage denials for biomedical HIV prevention may express a discriminatory message, suggesting that people at elevated risk of HIV infection (including groups that are protected to varying degrees, such as women, racial or ethnic minorities, transgender individuals, and men who have sex with men) are inherently less valuable than those at lower risk. Social stigma against HIV and discrimination against HIV-infected people is pervasive, and it carries over to populations with a high incidence of infection.¹⁴⁹ Some may see these coverage denials as appropriate sanctions for socially stigmatized behavior, such as unprotected sex or commercial sex work. This view would neglect scientific evidence regarding the ways that risky behaviors are shaped by social forces; moreover, reinforcing these punitive views exacerbates discrimination against people affected by HIV/AIDS, which is a key driver of risky behavior.

Insurance coverage of biomedical HIV prevention could also influence social norms regarding the acceptability of these interventions. If insurers cover these technologies, and particularly if insurers choose to encourage their broad uptake among people at risk of infection, these interventions may be seen as “routine” (and less stigmatized) rather than “extraordinary.”¹⁵⁰ If coverage leads to widespread uptake, social norms may even shift to the point where *nonuse* of these technologies is seen as irresponsible. Insurer efforts to encourage smoke detector use have produced this type of norm shift, and nonuse of smoke detectors now provokes social disapproval.¹⁵¹ Insurer decisions to deny or restrict coverage may foster the idea that biomedical HIV prevention is somehow ineffective, unacceptable, or appropriate only for people at the most extreme risk. This may ultimately limit the potentially transformative impact of such technologies on public health.

D. The Incentivizing Function of Coverage: Encouraging Innovation

Insurance coverage is a critical incentive for medical innovation, and biomedical HIV prevention technologies are on the scientific cutting edge. Coverage is important not only for incentivizing the development of new drugs and devices, such as microbicides and vaccines, but also for renewing the scientific investigation of procedures such as male circumcision, HIV testing, and management of substance use disorders. Because most medical and surgical procedures are not approved by a governmental agency such as the FDA, “coverage policy is the most important incentive to conduct studies of efficacy” for these types of care.¹⁵² Many state statutes mandate some insurance coverage for experimental or off-label care;¹⁵³ these statutes, along with public insurer coverage options such as “Continuing Evidence Development” determinations in Medicare¹⁵⁴ attempt to not only encourage innovation, but also offer policyholders rapid access to developing

technologies. Insurance coverage decisions favoring biomedical prevention technologies would serve this goal.

E. The Risk-Reduction Function of Insurance

A primary economic function of insurance is to reduce the overall risk level in a population of policyholders—that is, to reduce uncertainty about the extent of future losses in the population, and therefore the financial reserves that must be set aside to defray these losses.¹⁵⁵ Insurers have advantages in predicting losses based on aggregate data. As a result, these firms can reduce the premiums needed to insure against risk, compared to the funds that policyholders would need to self-insure against these losses.¹⁵⁶ Coverage of biomedical HIV prevention technologies would reduce the risk of *acquiring HIV* among policyholders, but it would *not* advance the goal of improving predictive accuracy regarding losses due to illness. This does not mean that coverage cannot lower premiums. A specific biomedical HIV prevention technology may be cost-effective for a pool of policyholders: the increases in premiums needed to provide coverage for this care may be outweighed by the decreases in premiums that result from reduced HIV incidence. To the extent that this results in cheaper premiums, coverage would expand the accessibility of the plan to new policyholders. This effect, however, would be unrelated to changes in predictive accuracy—covering HIV prevention technology will not affect insurers' ability to predict overall losses.

This section discusses how biomedical HIV prevention relates to three separate features of insurance that reduce the risk level: aggregation of risks, segregation of risks into separate pools of policyholders, and mechanisms to reduce moral hazard.¹⁵⁷

1. Aggregation of Risks—As George Priest has described in *How Insurance Reduces Risks*, insurance reduces the risk level when it aggregates risks or losses that are *uncorrelated* (statistically independent) and *probabilistic*—when there is uncertainty about whether or when the loss will occur.¹⁵⁸ In a probability distribution describing a loss, the mean denotes the likelihood of the loss, while the error distribution indicates the extent of uncertainty about the occurrence.¹⁵⁹ When uncertainty is greater, the cost of insuring against the loss rises, no matter what the average cost of the loss may be,¹⁶⁰ because the insurer must set aside proportionally more reserves to protect against a higher-than-expected cost.¹⁶¹ When insurers aggregate risks across a pool of policyholders with independent losses, the error distribution around the mean decreases.¹⁶² This decrease in error allows the insurer to predict losses with greater accuracy, limiting the need to set aside reserves for higher-than-expected costs. When we consider the coverage of biomedical HIV prevention, two separate “risks” are involved. One is the cost of the preventive intervention; the other is the cost of HIV infection. Each loss will lie on a probability scale.

The cost of a preventive intervention is neither probabilistic for individual users, nor independent across a pool of users. For a policyholder who chooses to use a preventive intervention like PrEP, the cost is certain. Demand for preventive care is a function of the default state of *health*: here, this is the state of being HIV-negative and wishing to stay that way despite the risk of infection. The cost of preventive care is therefore elected by the policyholder, not imposed by a probabilistic event.¹⁶³ A certain cost is generally not

insurable, because it does not increase predictive accuracy to pool these types of risks—“one can only accumulate savings before the loss occurs or after the loss is suffered to restore the previous economic position.”¹⁶⁴ The use of biomedical HIV prevention may also be correlated across a population of policyholders, responding to community advocacy or word of mouth.

The second cost at stake in biomedical HIV prevention is the risk of infection. Coverage of a preventive technology will reduce the likelihood of HIV infection for each policyholder-user, as well as for the policyholders who are in the same community but not using the intervention.¹⁶⁵ Although this will adjust the mean risk of infection downward, it likely will not change the error distribution—the accuracy with which insurers can predict the number of infections that will occur among the risk pool. As a result, coverage of biomedical prevention will not contribute to the risk-reduction function of insurance through aggregating the risk of HIV infection.

2. Risk Segregation and Controlling Adverse Selection—Segregating low-risk and high-risk policyholders into different pools can reduce the risk level by further increasing predictive accuracy in each pool, and by allowing insurers to charge differential premiums to match the risks posed by each pool.¹⁶⁶ Risk segregation also limits adverse selection, the phenomenon in which low-risk policyholders abandon plans that charge premiums that are disproportionately high for their needs, while high-risk policyholders gravitate toward plans that shift the costs of their insurance to lower-risk policyholders.¹⁶⁷ A problematic way to respond to expensive HIV prevention technologies would be to segregate policyholders who are more likely to use these interventions into higher-risk pools that charge higher premiums, based on risk factors such as history of STIs or substance use disorders. This strategy would be unacceptable for many reasons: for example, it would violate provisions of the ACA barring discrimination by preexisting conditions or “health status-related factor[s],”¹⁶⁸ it would lead to more invasive and costly underwriting, it may lead to unequal treatment on the basis of protected characteristics, and it may violate state laws prohibiting certain types of discrimination in insurance.¹⁶⁹ Furthermore, although such segregation may expand insurance availability by keeping premiums low for people who are less likely to use biomedical HIV prevention, it would run counter to moral arguments in favor of spreading the costs of this care more broadly.

3. Limiting Moral Hazard—Insurance can also reduce risk by controlling moral hazard. Moral hazard is a behavioral response among policyholders: when insurance reduces the costs of health care for an individual, he may respond by engaging in offsetting behavior that results in consuming more care.¹⁷⁰ Policyholders manifesting *ex ante* moral hazard reduce the protections they take against losses that are covered by insurance, while policyholders manifesting *ex post* moral hazard increase their use of health services that they would not have purchased out-of-pocket.¹⁷¹ The extent to which either of these phenomena occurs is an empirical question, but both are feasible here.

Ex post moral hazard is the clearest problem posed by insurance coverage of preventive care, particularly when that care is expensive. When insurance coverage lowers the cost of care below what an individual policyholder would need to pay out-of-pocket, she may be

more likely to use that care. Because the uptake of preventive care is determined by user demand, this converts a potential loss to a certain loss for the insurer.¹⁷² At the unlikely extreme, if the insurer charges a premium that is less than the cost of an HIV prevention technology, then *every* policyholder who is HIV-negative could rationally demand coverage, which would maximize public health impact but could also impact the insurer's financial sustainability. This is why insurers generally cover preventive care on grounds of cost-effectiveness, rather than insurability of the risks.¹⁷³ In other fields such as commercial general liability insurance, homeowners insurance, and life insurance, losses due to intentional acts, such as suicide, are excluded from coverage on grounds of moral hazard.¹⁷⁴

Ex ante moral hazard may also be reflected in behavioral choices prior to seeking coverage if it is conditional on specific criteria. For example, the CDC currently recommends PrEP for adults "at ongoing, very high risk for acquiring HIV infection."¹⁷⁵ Policyholders who are willing to use PrEP may report nonuse of other methods for preventing HIV (such as condoms), thereby meeting the high-risk criterion for PrEP prescription. If they are satisfied with PrEP, moral hazard theory would predict that PrEP users would continue engaging in these behaviors (or reporting that they do so) to continue qualifying. This phenomenon has not yet been studied, however, in the scientific literature on PrEP acceptability.¹⁷⁶

Several insurer responses could reduce ex post and ex ante moral hazard. These mechanisms include deductibles, coinsurance or co-pay requirements, and restrictions on eligibility for coverage. These strategies may permit coverage without producing excessive costs or premium increases that reduce insurance availability. From a public health perspective, narrow restrictions on eligibility are preferable to imposing cost-sharing requirements, particularly for ARV-based technologies.¹⁷⁷ Cost-sharing for ARV drugs could lead to inconsistent medication adherence among policyholders who are unable to consistently pay out-of-pocket costs. As Timothy Jost has noted, individuals "often forgo seeking preventive services for which they must pay copayments or coinsurance because the costs are immediate but the benefits may not accrue for some time."¹⁷⁸ One danger of poor ARV adherence is the development and transmission of drug-resistant strains of HIV.¹⁷⁹ Minimizing cost-sharing will reduce this problem,¹⁸⁰ and narrowing eligibility to the policyholders at highest risk of HIV infection will also maximize the cost-effectiveness of preventive care.

Minimizing cost-sharing would also deter pharmaceutical companies from inflating demand by financing deductibles or co-pays on behalf of policyholders. This has rapidly increased claims for some medications, particularly for brand-name medications that are more attractive than generic equivalents.¹⁸¹ Several states prohibit this practice,¹⁸² as do federal insurance programs including Medicare and Medicaid.¹⁸³ If this phenomenon occurs for biomedical HIV prevention, the failure of cost-sharing requirements may prompt outright coverage exclusions.

F. Redistribution, Justice, and the Loss-Spreading Function of Insurance

Beyond reducing the risk level using the mechanisms discussed above, another economic function of insurance is to spread losses across people and time, making them less burdensome for an individual at the time of loss.¹⁸⁴ Insurers serve this function by gathering

premiums over time from multiple policyholders.¹⁸⁵ Public insurers such as Medicaid and Medicare primarily serve a loss-spreading function rather than a risk-reduction function;¹⁸⁶ Medicaid does not operate on the basis of actuarial risk principles, but rather serves as a financing mechanism for people who cannot afford care.¹⁸⁷

If insurers decide to cover HIV prevention technologies, they can spread this cost of this care across many policyholders by adjusting premiums. If biomedical HIV prevention is cost-effective for this pool of policyholders—if the cost of care is outweighed by the savings of reduced HIV infections—then the savings will benefit all policyholders. But if the care is not cost-effective for the pool, it will lead to an overall increase in premiums. If risk pools include people at both high and low risk of HIV infection, this loss-spreading effectively redistributes resources toward people who are at higher risk and could not finance the care out-of-pocket. Those at lower risk are less likely to use preventive technologies, making it less likely that they will benefit from this care.

A possible argument against this redistribution is that it requires low-risk people to “subsidize” people who voluntarily engage in potentially harmful behaviors, such as unprotected sex. But similar arguments could be levied against coverage for preventing other conditions with behavioral linkages, including heart disease, diabetes, and lung cancer. A fuller understanding of HIV risk suggests that there are social justice reasons to favor redistribution.

A useful, empirically derived public health model for HIV risk is the social-epidemiological approach, which describes how an individual’s risk of infection is determined by *individual factors* (e.g., gender, race, age, socioeconomic status, sexual orientation, and behavior), which are influenced by *social factors* (e.g., community norms, residential segregation, family effects, and sexual networks), which are in turn shaped by *structural factors* (e.g., sexism, racism, incarceration patterns, and drug control policy).¹⁸⁸ With the exception of sexual assault victims, most people exercise a degree of control over the behaviors that give rise to HIV risk.¹⁸⁹ When we exercise that control, however, we choose among behavioral options that are constrained by overlapping social and structural factors that disadvantage some people more than others. For instance, transgender women (who are born biologically male but express their gender identity as female) experience high rates of discrimination due to their gender identity. As a result of this discrimination, transgender women in San Francisco report poor access to employment, housing, and healthcare; low social support; a narrow range of viable male partners; high rates of depression; and unfulfilled needs for love and intimacy.¹⁹⁰ These social influences are primary drivers for drug and alcohol use, unsafe injection of hormones without medical supervision, employment in sex work, and inability to insist on monogamy or condom use with sexual partners.¹⁹¹ Consequently, HIV prevalence is higher among transgender women than any other group in San Francisco.¹⁹² Furthermore, in a community of high baseline HIV prevalence, behaviors such as unprotected sex also carry far greater risk than the same actions by someone in a low-prevalence community.

As this demonstration suggests, viewing insurance coverage of biomedical HIV prevention as “subsidizing risky behavior” neglects the social factors that shape that behavior, imposing

more personal responsibility (and moral culpability) than a broader view would warrant. Some of the factors that increase HIV risk, including racial discrimination and sexism, are pervasive societal problems that we address through other legal means, such as nondiscrimination laws and strict judicial scrutiny of state actions with discriminatory purpose or disparate impact. There are many ways to morally justify some redistribution from people who are at low risk for HIV to those who are at high risk, and insurance coverage of biomedical HIV prevention technologies would advance this goal.

IV. COVERAGE DETERMINATIONS BY PUBLIC AND PRIVATE INSURERS

Both public and private health insurers in the United States cover individuals at risk of HIV infection. The goals of this Part are to describe the sources of health insurance for the population at risk, and to outline how public and private insurers make substantive coverage decisions. As described later in this Part, coverage determinations by both private and public insurers tend to rest on the determination that care is “medically necessary,” “medically appropriate,” or “medically beneficial.”¹⁹³ Determinations by private and public insurers may be correlated; private insurers often follow the government’s lead in coverage determinations,¹⁹⁴ and most have adopted Medicare’s criteria for determining medical necessity.¹⁹⁵

A. Sources of Insurance among the Population at Risk

Biomedical HIV prevention strategies will be most cost-effective for individuals at high risk of HIV infection, and efforts to develop these strategies have consistently targeted several key groups. In the United States, populations at elevated risk for HIV infection include men who have sex with men, people who inject drugs, racial and ethnic minorities,¹⁹⁶ and transgender women.¹⁹⁷ The following sections describe sources of insurance coverage for each of these groups. Individuals at risk of HIV infection are also more likely to be uninsured, underinsured, or publicly insured than the general U.S. population.¹⁹⁸ According to 2010 data, proportions of the nonelderly U.S. population holding each type of coverage are as follows: 58.7 percent have private employment-based coverage, 7.1 percent have private individual coverage, 16.9 percent are covered by Medicaid, 3 percent are covered by Medicare, 3.3 percent are covered by Tricare/CHAMPVA, and 18.5 percent are uninsured.¹⁹⁹

1. Men Who Have Sex with Men—The distribution of health insurance coverage among men who have sex with men reflects higher proportions of uninsured individuals compared to the general U.S. population. In a national survey of metropolitan men who have sex with men, 66 percent reported having private health insurance, 4 percent had public health insurance, and 25 percent lacked insurance.²⁰⁰ A subset of 452 men in New York found that 29 percent were uninsured, 56 percent were covered through private insurance, and 15 percent were publicly insured.²⁰¹

2. People Who Inject Drugs—A large percentage of people who inject drugs (37 to 72 percent)²⁰² lack health insurance. The percentage of people who inject drugs who use public sources of insurance may also exceed that of the general population, with surveyed rates from 36 to 52 percent.²⁰³ Substance use disorders may result in coverage denials from

private insurance plans,²⁰⁴ although this may change when ACA provisions barring discrimination based on health status take effect.

3. Transgender Women—Survey studies and qualitative research have also found that a large proportion of transgender women are uninsured. A San Francisco survey found that 52 percent lacked health insurance, while 34 percent were enrolled in public health insurance and 14 percent had insurance through private sources.²⁰⁵ In a more recent New York sample, 23 percent reported being uninsured, while 58 percent had public health insurance and 19 percent were privately insured.²⁰⁶

4. Racial and Ethnic Minority Populations—Individuals identifying as part of a racial or ethnic minority group are also more likely to be uninsured or publicly insured than the general U.S. population. Among nonelderly African-Americans, rates of public insurance and lack of insurance in 2010 were higher than rates in the general population; 34 percent had public insurance, and 22 percent were uninsured. The distribution of insurance sources among Hispanics and Latinos showed a larger proportion of uninsured; 29 percent had public insurance, and 32 percent were uninsured.²⁰⁷

5. Elevated HIV Risk among the Uninsured: Predicting a Larger Role for Insurers in 2014—Research has also found elevated risk of HIV infection among the uninsured. One national study has found elevated HIV risk among people who are uninsured over the long term, compared with those who are insured or uninsured for shorter periods of time.²⁰⁸ Individuals without health insurance are more likely to have substance use disorders²⁰⁹ and to delay treatment for STIs,²¹⁰ which increase the risk of acquiring HIV. Geographically, states reporting 20 percent of uninsured individuals or higher are in the southern-central portion of the United States,²¹¹ overlapping with many states with higher rates of new HIV infections.²¹² Uninsured people are also likely to be members of low-income families,²¹³ and ecologic studies have consistently found associations between low socioeconomic status indicators and the incidence and prevalence of HIV.²¹⁴

Under the ACA, many currently uninsured individuals at risk for HIV infection may obtain coverage. The most controversial provision of the Act—which was upheld by a majority of the Supreme Court in June 2012²¹⁵—requires that as of January 1, 2014, each individual be “covered under minimum essential coverage,” subject to a financial penalty for forgoing insurance.²¹⁶ This minimum essential coverage can consist of a government-sponsored program, an employer-based plan, an individual plan, a grandfathered health plan, or another coverage source.²¹⁷ Although this mandate exempts limited categories of individuals (namely for religious reasons, nonresidency, and incarceration),²¹⁸ it is expected to “achieve[] near-universal coverage,”²¹⁹ likely reaching many but not all of the uninsured groups who are the focus of biomedical HIV prevention efforts. As of January 2014, the Act will also preclude insurers from excluding adults on the basis of preexisting conditions,²²⁰ expanding access among groups such as people who inject drugs.

The Act also originally planned to expand Medicaid in January 2014, mandating coverage for individuals with incomes at or below 133 percent of the federal poverty line,²²¹ if a state failed to implement this expansion, the ACA originally provided for the withdrawal of all

federal Medicaid funds.²²² Based on this version of the Act, estimates by the Congressional Budget Office and Joint Committee on Taxation suggested that the ACA overall would reduce the number of nonelderly uninsured residents by 32 million by 2019, of which 16 million would be newly enrolled in Medicaid and Children's Health Insurance Programs.²²³ In June 2012, however, the Supreme Court found that the Medicaid expansion enforcement provision permitting full withdrawal of federal Medicaid funds exceeded Congressional authority under the Spending Clause.²²⁴ This provision was accordingly struck from the Act, leaving the planned expansion without an enforcement mechanism.²²⁵ To date, a number of Republican governors have stated that they will decline to expand Medicaid coverage, and expansion remains uncertain even in states where governors appear sympathetic to the Act's goals.²²⁶ It is unclear as of yet how the Supreme Court decision will affect the scope of Medicaid coverage once the ACA takes full effect, but permitting states to opt out of the expansion without penalty may undermine the extension of coverage to individuals at risk of HIV.

6. Out-of-Pocket Costs and the Need for Financing—Given the costs of biomedical HIV prevention, it is unrealistic to rely on out-of-pocket financing by the groups who are the primary focus of prevention efforts. For example, willingness to use PrEP is inversely related to cost,²²⁷ even though interest in PrEP is higher among those who are uninsured, publicly insured,²²⁸ or of lower socioeconomic status.²²⁹ Cost is similarly likely to affect access to vaccines²³⁰ and microbicides.²³¹ Studies have also documented a lower willingness to pay for general preventive care than for treatment, even when overall health benefit is held constant.²³² If out-of-pocket financing is not feasible, then access to biomedical HIV prevention will rely on financing through insurers or other third parties.

B. Coverage Determination by Private Insurers

Because this Article deals in part with emerging technologies, coverage determinations by private insurers will turn on not only contract interpretation, but also health technology assessment (HTA). This section discusses procedures for determining coverage under employer-based health insurance, because approximately 90 percent of privately insured policyholders are insured under this type of plan.²³³ These plans consist of employer-purchased commercial group insurance or employer-funded medical care, often administered by a commercial insurer.²³⁴ Employer-based plans are regulated by an overlapping system of internal policies, state laws, and federal laws, principally the Employee Retirement Income Security Act (ERISA) and the ACA.²³⁵ Coverage determinations are also shaped by state and federal insurance mandates, which are enforceable under ERISA.²³⁶ Under the ACA, individual and small-group insurance plans sold in state exchanges must provide coverage for services determined to be “essential health benefits.”²³⁷ Where no mandate exists, however, insurance coverage will be a question of contract interpretation. This section discusses principles of interpretation for substantive coverage decisions and the use of HTA.

1. Interpreting Insurance Contracts—Private insurers' coverage decisions for biomedical HIV prevention interventions are a question of contract interpretation. Benefits vary widely under self-funded employer plans and policies purchased by individuals. Group

insurance, however, accounts for the majority of health insurance,²³⁸ and most policies are multi-peril plans that provide coverage for a variety of conditions that qualify as “sickness” or “disease,” often naming certain conditions to be excluded or included.²³⁹ These multi-peril plans require that a policyholder meet two requirements to obtain coverage for care: (1) he or she must have an “illness, disease, sickness, injury or ... pathological state” that occurs while the policy is in force (or within a window after the policy comes into force), and (2) the expense must be related to that condition and almost always must be “medically necessary” to his or her health.²⁴⁰ Litigation since the 1960s has blurred these criteria in overall determinations of “medical necessity,”²⁴¹ a requirement originally imposed by private insurers and managed care organizations to control costs.²⁴² When determining whether a request for coverage meets the first requirement, courts have construed “sickness” and “illness” to have a plain-language, popular meaning²⁴³—namely, a condition affecting one’s usual activities²⁴⁴—and sickness is deemed to last until one is cured.²⁴⁵ “Disease,” on the other hand, refers to “an alteration in the state of the body or of its organs or tissues, interrupting or disturbing the performance of its vital functions, and causing or threatening pain or weakness.”²⁴⁶ “Medical necessity” is generally understood to denote care that is “medically appropriate or medically beneficial.”²⁴⁷

In coverage litigation, health insurance contracts tend to be construed in favor of coverage.²⁴⁸ The construction of this contractual language generally rests on “the meaning conveyed to the average person applying for such insurance and reading such provisions.”²⁴⁹ Although clear language is not liberally interpreted, most courts follow the principle of *contra proferentum* to interpret ambiguous provisions in favor of the policyholder,²⁵⁰ or seek to fulfill the policyholder’s “reasonable expectations.”²⁵¹ While some courts have suggested that ERISA preempts state contract interpretation rules for employer-based health insurance contracts,²⁵² others have held that *contra proferentum* remains applicable when “normal principles of contract construction are unavailing.”²⁵³ Any exclusions of coverage must be “conspicuous, plain, and clear” and drafted “such that a reasonable purchaser of insurance would have both noticed and understood it.”²⁵⁴

A policyholder denied coverage has recourse to several mechanisms of review. Under the ACA (which reinforced preexisting state laws,²⁵⁵ ERISA provisions,²⁵⁶ and Department of Labor regulations),²⁵⁷ insurers must provide an internal claims review and an external review process; external review procedures must meet the consumer protection standards set by the National Association of Insurance Commissioners and applicable state standards.²⁵⁸ Beneficiaries may also access judicial review under either ERISA²⁵⁹ or the ACA.²⁶⁰ Review is usually *de novo*;²⁶¹ if the plan, however, grants the administrator the authority to determine eligibility, decisions may only be reviewable based on abuse of discretion.²⁶² Research suggests that approximately half of judicial²⁶³ and external reviews²⁶⁴ tend to decide in favor of coverage.

2. Coverage of New Interventions and Health Technology Assessment²⁶⁵—

When new medical interventions arise, such as a new vaccine, insurers increasingly use HTA in determining coverage. HTA is a process that “examin[es] ... properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences.”²⁶⁶ The

use of HTA has grown along with trends toward priority-setting and cost-containment among health care payers, as well as evidence-based medicine by practitioners.²⁶⁷ Compared to public insurers, private insurers have made greater advancements in HTA,²⁶⁸ including setting procedures for case-by-case analyses, establishing internal HTA units, and subscribing to private assessment services.²⁶⁹ In 2001, a national survey found that HTA reports were the most frequently used sources of information for reviewing new interventions;²⁷⁰ a more recent assessment of six of the seven largest national U.S. insurers and five smaller regional insurers found that every plan relied on both internal and external HTA when making certain coverage decisions.²⁷¹

Despite widespread use, HTA procedures vary widely,²⁷² and efforts to create national HTA institutions have been unsustainable.²⁷³ Approximately sixty-four U.S. entities are organized to perform HTA.²⁷⁴ The largest may be the Technology Evaluation Center run by Blue Cross/Blue Shield in partnership with Kaiser Permanente,²⁷⁵ which assesses approximately thirty new technologies per year. HTA reports by this unit contribute to local coverage determinations that affect approximately 25 percent of the U.S. population.²⁷⁶ An analysis of HTAs comparing this center's recommendations with Medicare determinations found that both processes examined not only effectiveness, but also demand among beneficiaries and potential for overall health benefit.²⁷⁷

Many have commented on the use of cost-effectiveness criteria to inform coverage policy. Although HTA in the United States “consistently fails to incorporate a standard method of economic analysis,”²⁷⁸ cost concerns inform coverage decisions in 90 percent of plans.²⁷⁹ Mechanisms for addressing costs include formal cost-effectiveness analysis, requiring selective preauthorization, explicitly excluding coverage, or requiring that the policyholder use less costly interventions before accessing more expensive care.²⁸⁰ Some commentators have noted that private insurers face a conflict of interest in deciding whether to cover expensive new technologies, given incentives for containing costs²⁸¹ and the confidential nature of most decisions.²⁸² For public insurers, political pressure and publicity may mitigate this conflict.²⁸³ Regulations promulgated under the ACA have attempted to minimize conflicts of interest in coverage decisions by private insurers.²⁸⁴

C. Coverage Determination by Public Insurers

Government-sponsored health insurance programs in the United States include Medicare, Medicaid, the State Children's Health Insurance Program, Tricare, the Veteran's Administration, the Indian Health Service, and other public clinics and state programs. Public insurers' coverage decisions largely mirror decisions by private insurers—these public plans echo the requirement of medical necessity, provide procedures for coverage determinations and appeals, use HTA to weigh new technologies, and issue determinations that are subject to judicial review. This section discusses Medicaid and Medicare as examples of public insurers, describing the principles for making coverage decisions and the use of HTA.

1. Interpretation of Statutorily Authorized Benefits—Coverage under public plans depends on whether the treatment falls under the applicable statute and accompanying

regulations. Like private insurers, Medicare and Medicaid rely on determinations of medical necessity.²⁸⁵ The federal Medicaid statute does not impose this restriction directly,²⁸⁶ but it allows states to “place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.”²⁸⁷ Restrictive coverage decisions are one method of controlling Medicaid costs.²⁸⁸ Medicare authorizes coverage for many categories of services, but excludes coverage for treatments that are “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”²⁸⁹ Coverage decisions occur at several levels, including case-by-case decisions about individual claims, local coverage determinations by Medicare contractors, and national coverage determinations by the Centers for Medicare and Medicaid Services (CMS).²⁹⁰

States vary in their rules for reviewing adverse claims determinations under Medicaid, but all beneficiaries are entitled to a hearing before denial is final.²⁹¹ The standard of review is whether the decision was “supported by substantial evidence in the record,” unless the beneficiary requests *de novo* review.²⁹² Although the federal Medicaid statute does not specifically offer judicial review, beneficiaries may make civil claims for coverage denials under other laws, such as 42 U.S.C. § 1983.²⁹³ Medicare beneficiaries can appeal individual claims denials to a series of reviewers,²⁹⁴ including *de novo* review by an administrative law judge,²⁹⁵ culminating in *de novo* review by the Medicare Appeals Council.²⁹⁶ Review by the Medicare Appeals Council may be followed by judicial review depending on the amount in controversy; upon judicial review, agency findings of fact are conclusive “if supported by substantial evidence.”²⁹⁷ Both Medicaid and Medicare beneficiaries can appeal local and national coverage determinations to an administrative law judge, to the Appeals Board, and ultimately to the courts for judicial review.²⁹⁸

2. Coverage of New Interventions and Health Technology Assessment—Public insurers’ coverage decisions on new technologies are frequently publicized, and Medicare builds in procedures for public comment during centralized coverage determinations.²⁹⁹ Public comment almost invariably adds pressure in favor of coverage,³⁰⁰ drawing the attention of program beneficiaries,³⁰¹ drug and device manufacturers,³⁰² advocacy groups, other administrative agencies, and lawmakers.³⁰³ Medicare beneficiaries are a “large and politically powerful constituency,” while Medicaid beneficiaries may be less politically influential.³⁰⁴ Although formal cost-effectiveness analysis is rare,³⁰⁵ Medicare appears to scrutinize high-cost technologies more closely for effectiveness.³⁰⁶

Medicaid coverage determinations vary by state, and the system “has taken little initiative in implementing HTA with cost-effectiveness analysis into some of its coverage programs.”³⁰⁷ Nevertheless, many state contractors use some form of HTA,³⁰⁸ often with assistance from clinical consultants and external organizations.³⁰⁹

Most Medicare coverage determinations are made locally, either through informal assignment of a billing code, or through a formal local coverage determination proceeding.³¹⁰ Procedures for local coverage determinations vary, but usually include literature reviews, contacting other Medicare contractors, and consulting advisory committees.³¹¹ Decisions that “restrict or substantially change” existing policies usually

require a public commentary period.³¹² Coverage decisions may be requested by manufacturers, healthcare providers, and beneficiaries.³¹³ National coverage determinations are issued by CMS in approximately 25 percent of new billing code assignments, setting coverage policy for all contractors.³¹⁴ The Medicare Coverage Advisory Committee advises these decisions,³¹⁵ and Agency for Healthcare Research and Quality can provide additional guidance.³¹⁶ For coverage, a technology must fall under a statutory benefit category and must not be excluded by another statutory provision.³¹⁷ The relevant inquiry is whether the technology “is safe and effective per the Food and Drug Administration regulatory process,” and whether “adequate evidence leads [CMS] to conclude that the health technology improves net health outcomes.”³¹⁸

V. CHALLENGES TO INSURANCE COVERAGE OF BIOMEDICAL HIV PREVENTION

This Part identifies legal and economic grounds on which public and private insurers may limit or refuse coverage for HIV prevention technologies. These grounds may support coverage denials for individuals or for entire groups of policyholders. There is some overlap among these justifications, but courts have upheld each as a distinct basis for coverage refusal. Insurers’ most persuasive arguments for denying coverage may be contractual or statutory interpretations of “medical necessity” that exclude preventive care. Although insurers may—and potentially *should*—provide coverage due to market factors, cost-effectiveness, or public policies favoring public health, there may be slim legal basis to require favorable coverage determinations under existing interpretations.

A. Medical Necessity

The primary obstacle to insurance coverage for biomedical HIV prevention is establishing that these technologies are medically necessary.³¹⁹ Coverage will depend on whether the contractual or statutory definition of medical necessity includes the prevention of disease. The majority of private insurance contracts and public insurance provisions may exclude preventive care.

1. Interpretations of Medical Necessity—Medical necessity determinations are central to healthcare cost control efforts in the United States.³²⁰ The conception of medical necessity arose in private insurance plans after World War II, and the Medicare statute incorporated this restriction into public insurance in 1965.³²¹ Insurers, particularly managed care organizations,³²² have increasingly used medical necessity exclusions to reduce costs,³²³ and litigation over medical necessity denials is common.³²⁴ Public concern over coverage denials spurred state statutes providing for external review of insurer decisions,³²⁵ and the ACA took up this concern by mandating procedures for external review.³²⁶ Essentially every public and private health insurer reviews claims for medical necessity;³²⁷ to be enforceable, however, a medical necessity provision must be included in the contract.³²⁸ Medical necessity definitions are often complemented by specified treatment exclusions, including care that is “experimental,” “investigational,” “cosmetic,” or “for the convenience of the patient.”³²⁹

Commentators have widely critiqued insurers' interpretations of medical necessity have been widely critiqued,³³⁰ and Sara Rosenbaum and colleagues have collected an extensive list of definitions in use.³³¹ Contractual definitions are often nonspecific,³³² and contracts may incorporate guidelines outside the policy that are consistent with general medical standards.³³³ "Multidimensional definitions" are common practice, and these generally permit insurers "to select among the treatments that ostensibly are all appropriate in favor of one that is the safest, the least costly, and not only for the convenience of the member or provider."³³⁴ As Rosenbaum and colleagues have found, most medical necessity definitions extend only to the treatment and diagnosis of illness or disease;³³⁵ despite notable exceptions and guidance drafted by the American Medical Association³³⁶ and National Health Law Program,³³⁷ few definitions explicitly extend to cover care necessary "to prevent" or "for the purpose of preventing" illness or disease.

When contesting a medical necessity denial, the policyholder has the burden of proving medical necessity,³³⁸ and a court may consider all relevant evidence bearing on the question.³³⁹ Courts have interpreted "necessary" variously to mean "appropriate" (favoring policyholders)³⁴⁰ or, more rarely, "indispensable, essential, unavoidable, compulsory, or required" (favoring insurers).³⁴¹ Although the judgment of the treating physician receives substantial weight in coverage determinations,³⁴² outweighing the opinions of clinicians who have not personally examined the patient,³⁴³ insurers may permissibly disagree with the physician³⁴⁴ as long as the denial is not arbitrary.³⁴⁵

2. Application to Biomedical HIV Prevention—When an insurance contract or statutory provision does not specifically include preventive care, policyholders seeking coverage for biomedical HIV prevention will face challenges meeting insurers' criteria for medical necessity. As detailed above, insurers will conduct a two-part inquiry to determine that (1) the policyholder has an "injury," "illness," "sickness," or "disease," and (2) the care is "medically appropriate or medically beneficial" to treat the condition.³⁴⁶ Insurers may come to different determinations for policyholders who are *HIV-negative* and seeking to avoid initial infection, compared to policyholders who are *HIV-infected* and seeking to avoid infecting others. Determinations will likely also differ based on whether the intervention serves an exclusively *preventive* purpose, compared to interventions that are *dual purpose* for HIV prevention and another diagnostic or treatment purpose.

a. Exclusively Preventive Technologies: When an HIV prevention technology is exclusively preventive, insurers may seek to deny coverage based on the first prong of medical necessity. Policyholders who are not infected with HIV are seeking preventive technologies precisely *because* they are healthy; they lack an injury, illness, sickness, or disease as needed to trigger coverage. Even when a policy does not specify the need for sickness or illness, policy language that limits coverage to treatment and diagnosis is another means of codifying the first prong of medical necessity. Individuals who receive treatment and diagnostic care are presumed to have an illness or disease, and courts have upheld medical necessity denials when policyholders do not present proof of a "condition" requiring treatment.³⁴⁷ Coverage denials of contraception have relied on medical necessity definitions,³⁴⁸ and the same arguments may be raised for HIV prevention technologies.

Although insurers may cover less costly preventive care due to market demand and cost-effectiveness, expensive prophylactic interventions are more likely to fail medical necessity criteria.³⁴⁹

If insurers deny coverage based on lack of an illness or disease, policyholders may argue that the risk of HIV infection *is itself* a pathology. Although biological vulnerability to HIV is a universal human condition (and unlikely to be deemed a pathology), *elevated* risk of HIV infection—a risk above that of the general population—may present a closer case. Individuals who engage in risky behaviors may attribute some of these actions to underlying morbidities, such as a substance use disorder or a psychological condition like depression. Reasoning this way, elevated HIV risk could be reclassified as a symptom of another illness, and policyholders could argue that HIV prevention technologies are in fact *treatment* for that symptom.

Although this argument would expand coverage, it has disturbing implications, including the potential for increased discrimination against vulnerable communities. For example, a majority of new HIV infections in the United States are attributable to sex between men.³⁵⁰ Classifying same-sex attraction and behavior as *pathological* has contributed to discrimination against individuals who identify as gay, lesbian, and transgender.³⁵¹ Arguments that define elevated HIV risk as an illness or symptom thereof would exacerbate this problem. Policyholders may also experience increased HIV risk due to biology (e.g., women are at higher risk from heterosexual sex³⁵²) or local epidemiology (e.g., in communities where prevalence is high). But the argument that it is pathological to be female or part of a high-prevalence community can also be used to stigmatize members of those groups.

When insurance policies provide coverage for preventive care, or when they do not require proof of an illness or disease, coverage of biomedical HIV prevention is more likely. But despite this advantage, coverage claims may yet fail based on the *second* prong of medical necessity—namely, whether the care is “medically appropriate or medically beneficial.” Preventing HIV through the use of condoms or sterile injection drug use equipment is inexpensive, safe, and efficacious. Many definitions of medical necessity allow insurers “to select among [appropriate] treatments in favor of one that is the safest, the least costly, and not only for the convenience of the member or provider.”³⁵³ Insurers may balk at covering more expensive care such as PrEP drugs or microbicides, given their costs, side effects, and the existence of behavioral alternatives for preventing infection (e.g., condom use).³⁵⁴ Insurers may also claim that policyholders seek prevention technology in order to avoid using condoms, allowing them to deem this care solely “for convenience.”

Coverage denial based on the second prong of medical necessity may also occur if insurers require that a policyholder use less expensive technologies *before* obtaining more expensive care.³⁵⁵ As long as an individual continues to be HIV-negative, he or she cannot demonstrate the need to access a more expensive prevention option—but once she acquires HIV, the technology will no longer be useful. Insurers that permit doctors to choose among medically accepted treatments may be more lenient in these coverage decisions, if biomedical HIV prevention technologies are recommended by a treating physician.³⁵⁶

For these reasons, HIV-negative individuals seeking insurance coverage of exclusively preventive technologies may fail on medical necessity grounds, even when the definition of medical necessity includes preventive care. These denials may reach PrEP, PEP, nPEP, microbicides, male circumcision, vaccines, and any services requested by a policyholder for his or her HIV-infected partner.³⁵⁷ State Medicaid plans already deny coverage for male circumcision on medical necessity grounds, leading to decreased rates of utilization among Medicaid-covered males.³⁵⁸ PEP is also rarely used due to costs; coverage under Medicaid and insurers is inconsistent,³⁵⁹ and despite several free PEP clinics,³⁶⁰ PEP remains underutilized.³⁶¹ It remains to be seen whether insurers will cover emerging technologies such as PrEP, microbicides, and vaccines, although some have already decided to cover Truvada for use as PrEP.³⁶² If these technologies fail in medical necessity determinations, the need for out-of-pocket financing would make them inaccessible to a majority of individuals at risk of HIV.

b. Dual-Purpose Technologies: Dual-purpose interventions available for both HIV-negative and HIV-infected people include the treatment of STIs, the treatment of substance use disorders, and HIV counseling and testing. Every definition of medical necessity provides for treatment, and most provide for diagnosis, of pathologies; individuals seeking coverage of this care should emphasize its treatment or diagnosis function, rather than its preventive effects. An individual presenting with an STI or a substance use disorder would qualify as having an “illness” or “disease” under the first prong of medical necessity.³⁶³ As long as the form of treatment is medically beneficial, this care will likely be covered by most insurance plans (aside from care excluded for other reasons such as preexisting conditions).³⁶⁴

Coverage for substance use treatment is mandated by several federal and state statutes. As of 2012, 38 states required parity or minimum benefits for the treatment of substance use disorders.³⁶⁵ Federal statutes requiring coverage of substance use treatment now include the Mental Health Parity and Addiction Equity Act³⁶⁶ and the ACA.³⁶⁷

HIV testing and counseling serves a diagnostic function, and at least one court has held that diagnostic tests ordered by a treating physician are medically necessary.³⁶⁸ Some insurers historically have not provided this coverage, however, when the test was not related to a primary diagnosis—that is, when the test was not ordered in response to a symptom of HIV infection or a known exposure incident.³⁶⁹ This would prevent coverage for people who were healthy and asymptomatic. Section 2713 of the ACA now requires private insurers to provide full coverage without cost-sharing for preventive services rated “A” or “B” in recommendations by the USPSTF.³⁷⁰ Under Section 4106, Medicaid must similarly cover these preventive services, with increased federal subsidies for Medicaid programs that eliminate cost-sharing for these services.³⁷¹ One “A” recommendation states that “the USPSTF strongly recommends that clinicians screen for [HIV] all adolescents and adults at increased risk for HIV infection.”³⁷² Those “at increased risk” include not only specified high-incidence populations, but also *all “[p]ersons who request an HIV test despite reporting no individual risk factors.”*³⁷³ As a result of the ACA, therefore, insurers must provide coverage to any individual who requests an HIV test.

c. Dual-Purpose Technologies for People Who Are HIV-Infected (ARV Treatment):

For individuals who are already infected with HIV, ARV treatment can reduce the likelihood of transmitting HIV to one's partner. Treatment with ARV drugs falls squarely within the terms of medical necessity—HIV-infected individuals generally undergo treatment for the primary purpose of treating infection, and reduced infectiousness is an additional benefit. There is little debate over whether ARV treatment is “medically necessary” for an HIV-infected person with a CD4 cell count within the treatable range.

Medical guidelines differ, however, regarding when an HIV-infected person should start ARV treatment, meaning that an HIV-infected person who wishes to reduce his infectiousness may wish to start treatment *earlier* than some guidelines may suggest.³⁷⁴ This may present problems under the second prong of medical necessity, which requires that the treatment be medically beneficial. Preventing the transmission of HIV to a policyholder's partner may not be deemed beneficial to the policyholder (regardless of the social, financial, and mental health benefits). The cost savings produced by the averted infection may not flow to the insurer, if the policyholder's partner is covered by another plan. The physician who treats the HIV-infected person, however, may recommend that he began ARV treatment early, which will receive some deference in coverage determinations. Recent studies have also indicated improved survival and reduced tuberculosis incidence when ARV treatment is started earlier, which would support claims to early coverage on medical necessity grounds.³⁷⁵ At least one court has also required that Medicaid cover AIDS drugs for off-label use during early stages of HIV infection, despite the fact that the FDA had only approved the drug for late-stage indications.³⁷⁶ Several states, including Massachusetts and Maine, have also explicitly mandated that insurers cover AIDS drugs for off-label treatment of HIV-infected policyholders.³⁷⁷

3. Coverage Exclusions for Experimental Treatment³⁷⁸—When a technology is new, or only recently used for the purpose of preventing HIV, insurers may deny coverage under exclusions for experimental treatment or off-label use.³⁷⁹ Experimental treatment and off-label exclusions may affect coverage for biomedical HIV prevention technologies in two scenarios. First, these exclusions would apply when an intervention is not proven for *any* use, which is currently the state of the science for vaccines and microbicides.³⁸⁰ Second, these exclusions could apply when an intervention is approved for another purpose, but then is *also* discovered to prevent HIV infection; these exclusions may be used to challenge coverage for PEP, nPEP, off-label PrEP, and male circumcision for HIV prevention.³⁸¹

a. Experimental Treatment: Experimental treatment exclusions are a class of medical necessity denials that contribute to cost control efforts;³⁸² these consist of refusing payment for care that is deemed “experimental” or “investigational.” Insurers have defined experimental in a variety of ways, including treatments “under clinical investigation,” “not generally recognized by the medical profession as tested and accepted medical practice,” “still requiring future ‘approval by the [FDA] or other governmental agency,’” or “furnished in connection with medical or other research.”³⁸³ Insurance contract clauses that use the term “experimental” but do not define it may be deemed ambiguous;³⁸⁴ any definition provided must be understandable to ordinary consumers.³⁸⁵ Although many insurance

contracts specifically exclude experimental treatment from coverage, insurers may reject payment on general medical necessity grounds, stating that the treatment is medically inappropriate or insufficiently likely to confer a benefit. Courts have found the denial of coverage for experimental treatment to be an acceptable form of cost control,³⁸⁶ and they often rely on expert medical testimony to review these coverage denials.³⁸⁷ As one court opined, “subscriber premiums should not have to ... subsidize every scientist stirring a magic potion in some laboratory at the top of a mountain with lightning flashing about.”³⁸⁸

Beyond cost control, public policy justifications for experimental treatment denials include reducing policyholders’ vulnerability to interventions that are ineffective or likely to cause harm, as well as ensuring that the burden of enrollment in clinical research does not fall disproportionately on uninsured individuals—if insured individuals can access experimental care outside trials, they have less incentive to enroll in research studies.³⁸⁹ But courts have also recognized countervailing interests: coverage could enable quicker access to effective treatments and provide powerful incentive for innovation.³⁹⁰ At least one court has required Medicare to cover a technology still under investigation because developers “need to be assured that they will be reimbursed for their efforts during these investigational periods. Withdrawing Medicare coverage ... [may cause the] industry’s remarkable level of invention [to] decrease dramatically That is not the American way.”³⁹¹

b. Off-Label Use: Coverage denials for *off-label* use of prescription medications are a further subclass of denials related to experimental treatment. Physicians in the United States may legally prescribe medications for specific uses (“indications”) that have not been approved by the FDA,³⁹² so long as they do not deviate from standards for malpractice liability. Currently all prescription of PEP and nPEP is an off-label use of ARV drugs, and with the exception of Truvada-based PrEP, the use of any ARV drug as PrEP will also be off-label until FDA approval is secured.³⁹³ Legislative and regulatory changes have introduced mechanisms to permit manufacturers to inform physicians about these potential uses,³⁹⁴ which can reduce the need for these companies to pursue FDA approval for every newly discovered use. By some estimates, as much as 21 percent of prescription drug use in the United States consists of off-label prescriptions.³⁹⁵ But while off-label prescription does not necessarily bar coverage, courts have upheld coverage denials of off-label drug use under experimental treatment exclusions.³⁹⁶ These denials depend on contractual definitions of experimental treatment, and at least one court has determined that a provision excluding experimental treatment was ambiguous as applied to off-label drug use.³⁹⁷

Even when off-label drug use meets definitions for experimental treatment, public and private insurers generally permit coverage if the use is supported by sufficient peer-reviewed evidence or included in a specified pharmaceutical reference compendium, such as the American Hospital Formulary Service Drug Information or the Thompson Micromedex DrugDex system.³⁹⁸ Public insurers such as Medicaid and Medicare cover off-label uses once they have met the standards for inclusion in an approved compendium; indeed, some commentators have noted that “compendia and peer-reviewed literature have assumed a quasi-FDA role with respect to off-label indications.”³⁹⁹ CMS may also designate experimental or off-label treatments as requiring “continuing evidence development.”

According to this determination, Medicare may provide coverage *contingent* on the beneficiary's enrollment in a clinical trial.⁴⁰⁰

Manufacturers seeking to publicize off-label uses for public plan beneficiaries walk a fine line, and they may face criminal liability under the federal False Claims Act if they induce beneficiaries to seek reimbursement for unrecognized off-label drug indications.⁴⁰¹ This liability does not apply when reimbursement is sought from private insurers, and private insurers usually follow CMS in providing coverage for an off-label use once the indication is included in a recognized pharmaceutical compendium.⁴⁰² Where coverage is sought for an off-label use outside CMS guidelines, insurers subject these claims to standard determinations of medical necessity and experimental treatment, consulting peer-reviewed medical literature or professional practice guidelines.⁴⁰³ Some insurance policies set forth precise procedures by which policyholders may claim coverage for off-label drug use, including the types of medical evidence that the policyholder may present to prove medical benefit.⁴⁰⁴

Off-label and experimental treatment exclusions are also governed by a patchwork of state laws. Over thirty states require private insurers to cover at least some forms of off-label medication use.⁴⁰⁵ Many mandates only apply when policyholders suffer from a "life-threatening" condition,⁴⁰⁶ including at least one law mandating off-label coverage for people diagnosed with AIDS.⁴⁰⁷ Other mandates apply to all policyholders,⁴⁰⁸ although many also require some evidence of medical benefit.⁴⁰⁹ Some state laws, such as that of California, do not necessarily mandate coverage, but rather require external reviews of coverage denials on experimental use grounds.⁴¹⁰ Seventeen states have also enacted laws mandating coverage for patients who enroll in clinical trials for a life-threatening condition (sometimes limited to cancer),⁴¹¹ and Medicare similarly provides coverage for participation in certain clinical trials.⁴¹²

c. Application to PEP and PrEP: PEP is an off-label use of antiretroviral drugs for prevention indications, and it is thereby vulnerable to exclusions both as experimental treatment and as off-label drug use. PEP has never been tested in a randomized controlled trial, which is typically required for FDA approval of a new indication, but it is widely recommended for use.⁴¹³ CDC guidelines for PEP prescription identify a variety of medications available for use as post-exposure prophylaxis, but note that PEP recommendations "might not represent FDA approval or approved labeling for the particular product or indications in question."⁴¹⁴ Despite the availability of peer-reviewed literature and guidelines on PEP, insurers may succeed in denying coverage on experimental treatment grounds. Because experimental trials of PEP are not occurring at this time, coverage cannot be sought through participation in research.

As of July 2012, the ARV drug Truvada is available for FDA-approved prescription to sexually active adults as PrEP.⁴¹⁵ Prior to FDA approval, several insurers had already expressed the intention of approving off-label prescription of this drug to high-risk individuals for HIV prevention.⁴¹⁶ Unlike PEP, Truvada has been evaluated in several randomized controlled trials for use as PrEP, and it is sanctioned for use by the CDC and the WHO.⁴¹⁷ But it is unlikely that the testing of ARV drugs as PrEP will end with Truvada;

additional drugs are already being tested as PrEP using animal models,⁴¹⁸ and the threat of viral resistance to Truvada-based PrEP will motivate the search for additional candidates. Prescription of any other ARV drugs as PrEP before FDA approval would be off-label and thereby subject to experimental treatment exclusions. Insurers who provide coverage for policyholders to participate in research may extend coverage to participants in PrEP trials, depending on the sponsor of the trial (coverage is more likely if trials are sponsored by governmental institutions such as the National Institutes of Health).⁴¹⁹

As noted above, Maine⁴²⁰ and Massachusetts⁴²¹ specifically require insurers to cover off-label prescriptions for the treatment of HIV or AIDS, provided that the treatment indications are supported by peer-reviewed literature or a drug compendium. Maine further specifies that insurers shall not deny coverage on the grounds of medical necessity.⁴²² Both mandates, however, are limited to treatment—neither extends to the use of the drugs by *HIV-negative* people to prevent infection.⁴²³ Although a policy argument for extending such coverage can be made, these statutes may not extend to require off-label coverage for PrEP or PEP.

d. Application to Male Circumcision: Male circumcision sought *expressly for HIV prevention* may also fall under the “experimental treatment” category. FDA approval is not required for surgical procedures,⁴²⁴ but the CDC has yet to issue guidance to educate providers about the use of male circumcision to prevent HIV infection.⁴²⁵ The American Academy of Pediatrics has hesitated to recommend male circumcision for HIV prevention; although the Academy has noted that the benefits of circumcision outweigh the risks, it recommends that parents decide individually whether they want their sons to be circumcised.⁴²⁶ Three large randomized trials have shown significant preventive benefits of male circumcision for reducing the likelihood of infection,⁴²⁷ and the medical literature reflects a consensus that the procedure is effective for reducing risk.⁴²⁸ Even though male circumcision is no longer in trials for HIV prevention, the state of this evidence may present a close call for insurers considering coverage for the purpose of preventing HIV infection.

B. Preexisting and Chronic Conditions

Before the ACA takes full effect in January 2014, insurers may seek to deny coverage for biomedical HIV prevention technologies on the ground that the risk of HIV infection is a preexisting or chronic condition. The “condition” could be defined as risk of HIV infection, *elevated* risk of HIV infection, or the behaviors and characteristics that put an individual policyholder at elevated risk. Health insurers have long excluded coverage or increased premiums for treating policyholders’ medical conditions that existed prior to the period of coverage.⁴²⁹ These provisions exist primarily to reduce the risk of adverse selection—the concern that individuals will obtain health insurance expressly for the purpose of shifting losses, rather than insuring against the risk that an uncertain loss will occur.⁴³⁰ At the group level, adverse selection forces insurance premiums up, and low-risk members will drop out of the risk pool to obtain cheaper policies.⁴³¹ This dynamic can ultimately reduce insurance availability.⁴³² Courts have interpreted preexisting condition exclusions since the 1950s,⁴³³ and they have found these provisions valid as a means of cost control.⁴³⁴ Regardless, courts tend to interpret such clauses narrowly;⁴³⁵ preexisting condition exclusion clauses are subject to standard principles of determining whether the language is ambiguous, with

ambiguous definitions construed against the drafter.⁴³⁶ Definitions of “preexisting condition” differ across policies and courts,⁴³⁷ and circuit courts are split regarding whether a diagnosis of the condition is necessary to trigger these exclusions.⁴³⁸

Although preexisting condition limitations are frequent in modern policies, limitations due to “chronic” conditions were more common in the past.⁴³⁹ These restrictions excluded coverage for diseases “of long standing” or “accepted as [chronic] by the medical community,” regardless of whether they existed before the inception of the policy.⁴⁴⁰ Some health conditions that increase risk for HIV, such as substance use disorders, would meet these criteria.⁴⁴¹ Insurers sometimes softened these exclusions by providing cyclical coverage, requiring “expense free” periods between time-limited periods of coverage.⁴⁴² These restrictions are rarely used today, although insurers may still exclude coverage for named conditions.⁴⁴³

State and federal laws have limited insurers’ ability to exclude coverage on the basis of preexisting and chronic conditions. By 2000, thirty-one states had passed some form of legislative restraint on preexisting condition exclusions.⁴⁴⁴ The federal Health Insurance Portability and Accountability Act of 1996 restricted the length of preexisting condition limitations to twelve months for group health insurance plans, and it required insurers to credit policyholders for months that they were covered under another plan.⁴⁴⁵ As of 2010, the ACA eliminated insurers’ ability to exclude coverage based on health status or preexisting conditions, or to charge differential premiums for policyholders based on health status, medical history, claims experience, or “other health status-related factor[s].”⁴⁴⁶ This provision went into effect as applied to children as of September 2010, and it will take effect for adult policyholders in January 2014.⁴⁴⁷ The transition has not been smooth; fears of increased costs prompted a number of private insurers to stop covering children altogether, rather than cover preexisting conditions as scheduled.⁴⁴⁸ Neither Medicaid nor Medicare restricts coverage on the basis of preexisting or chronic conditions.⁴⁴⁹

As applied to biomedical HIV prevention, preexisting condition exclusions could lead to the denial of coverage. This argument is in some ways the inverse of a favorable medical necessity determination—if elevated risk for HIV infection is indeed a pathology requiring medically necessary treatment, then that pathology may have preexisted the policy period. These coverage denials could be highly damaging, given the implications of classifying certain behaviors (e.g., sex between men) or personal characteristics (e.g., gender or ethnic background) as pathological. Of course, the risk of HIV could increase during the policy period—for example, a policyholder could move to an area with higher HIV prevalence, or begin dating an HIV-infected partner. But allowing preexisting condition determinations based on HIV risk would encourage unacceptably invasive underwriting based on sexual behaviors and other characteristics. Once the preexisting condition coverage mandate of the ACA takes effect, these exclusions will not be viable.

C. Treatment-Specific Exclusions

Insurers are free to specify categories of services that will not be covered under the policy, as long as these exclusions do not contravene a statutory mandate to provide certain forms of coverage. If a contract specifically excludes a named service from coverage, an insurer is

not required to determine medical necessity for that service on a case-by-case basis; regardless of medical need, coverage that is plainly excluded from the contract need not be provided.⁴⁵⁰ Because some of the technologies described here are new or not yet available, they are unlikely to appear in currently specified exclusions. Instead, these technologies—such as PrEP, vaccines, or microbicides—may be specifically excluded from future contracts if insurers decide to refuse coverage. Of existing technologies, some insurers explicitly exclude coverage for substance use treatment,⁴⁵¹ although the ACA will eventually require coverage as part of an “essential health benefits package.”⁴⁵²

D. Illegal Activity Exclusions

Some activities that give rise to HIV risk are also violations of state or federal law, including transactional sex work and the use of illicit drugs. Insurers may attempt to exclude coverage for technologies under “illegal activities” exclusions, which bar coverage during the commission of an illegal act.⁴⁵³ But these exclusions would be a poor fit for biomedical HIV prevention; these technologies protect against risks arising from legal as well as illegal activities. They may also be used before illegal activities take place, separating the time of use from the time of the activity.

VI. STRATEGIES FOR EXPANDING ACCESS

Where insurance plans do not cover biomedical HIV prevention technologies, it is useful to explore arrangements to expand access, such as modifying plan features, rationing access, mandating coverage by state or federal law, or seeking alternative financing sources. This Part briefly considers several of these options.

A. Statutory Mandates

States and the federal government may legally require private insurers to cover specified types of health care, and these mandates typically reflect public policy choices that respond to advocacy of particular communities or patient groups. Most states mandate a variety of benefits;⁴⁵⁴ state laws have been used, for example, to ensure coverage for infertility treatment, prostate exams, child vaccinations, contraceptive drugs, surgery for the removal of breast implants, and substance abuse treatment.⁴⁵⁵ Starting in 2014, however, provisions of the ACA will require states to provide financing via tax credits to individuals enrolled in the exchange system for state-mandated coverage that exceeds the “essential benefits package.”⁴⁵⁶ The cost of these credits will presumably be spread throughout the tax base. The federal mandates in the ACA recently required private and public insurers to cover certain preventive services; if the USPSTF adds new biomedical HIV prevention strategies to its recommendations, insurers must provide coverage.⁴⁵⁷ This statute may protect some decisions about coverage of preventive technologies from the political process, which could be hostile to expensive forms of HIV prevention. Coverage of biomedical HIV prevention by public insurers could be centrally accomplished by modifying federal or state regulations (for Medicaid) or issuing a national coverage determination (for Medicare).

A requirement to cover biomedical HIV prevention could also take the form of a parity requirement, similar to the Mental Health Parity Act, but this may be ineffectual if insurers

can avoid triggering the requirement. For example, the statute could require any plan that covers ARV drugs for HIV *treatment* to also cover ARV drugs for *prevention*. Insurers' response to this requirement, however, may be to exclude coverage for ARV drugs, thereby inflicting extensive harm on those who are already infected. In order to accomplish the policy goal of widespread access to biomedical HIV prevention, an unconditional mandate may be needed.

A state or federal mandate to provide coverage would serve many of the public policy ends discussed in Part II, including advancing the right to health, encouraging innovation, and shaping social norms that are supportive of HIV prevention and the communities affected by HIV/AIDS. A governmental mandate would also serve a loss-spreading rationale, distributing the costs of biomedical HIV prevention among all beneficiaries of public and private plans. This would overcome potential free riding problems, giving all insurers a stake in both the costs of prevention and the savings that arise from averted infections. This mandate may be cost-effective across society as a whole, even if it is not cost-effective for every insurer. A mandate would not, however, serve the goal of reducing uncertainty about risk, and insurance could become marginally more expensive for some policyholders if these technologies are not cost-effective for the risk pool.⁴⁵⁸

B. Governmental Financing

As pointed out above, many of the gains of public health interventions accrue to society generally, suggesting that the broadest possible loss-spreading may be the fairest way of financing biomedical HIV prevention. Loss-spreading serves the purpose of redistributing some resources towards people who are at greater risk of HIV by virtue of socioeconomic disadvantage. The most extreme form of loss-spreading would be direct financing of biomedical interventions by the federal government, paid by means of a general tax. Government actors could provide these services by funding specialized HIV prevention clinics, setting up an optional public plan that finances biomedical HIV prevention, or establishing a separate reimbursement process for healthcare providers. The creation of these separate systems would be administratively inefficient, however, because most of the U.S. population is not already enrolled in federally sponsored health insurance. Direct governmental financing of biomedical HIV prevention may lead to crowd-out or exclusion of this care from private insurance policies; insurers would have little incentive to cover this care if policyholders could obtain it from the government. If this crowd-out occurred, access to care would depend on sustained governmental subsidies, which may be difficult to safeguard against political opposition.

Instead of direct financing, the government could subsidize biomedical HIV prevention through other mechanisms, such as tax credits for private insurers or for individuals who report paying for biomedical HIV prevention services; the latter approach, however, would not optimally serve the goals of expanded access, since this would require initial out-of-pocket expenditures that people are unlikely to make for HIV prevention.

C. Insurer Options: Plan Design and Negotiated Discounts

Insurers can use several features of plan design to control the costs presented by biomedical HIV prevention, making widespread coverage more feasible. As discussed earlier, one method is cost-sharing, requiring policyholders to bear copay requirements, deductibles, caps, or co-insurance for biomedical HIV prevention. Among policyholders who can consistently afford copays or deductibles, insurance with cost-sharing will be cheaper than financing the care out-of-pocket.⁴⁵⁹ As pointed out above,⁴⁶⁰ however, cost-sharing requirements for preventive care tend to result in suboptimal uptake. Use of these new technologies would likely be lowest among those who are the most socially disadvantaged and at highest risk for HIV. This would produce a mismatch between the people who most need the care and the people who can afford it. High cost-sharing could also lead to poor adherence to ARV drugs, encouraging the development of viral resistance.

Similar factors limit the potential for using risk segregation or high-risk pools to improve access—that is, to segregate people at risk for HIV prevention into plans that provide this benefit, and to charge them higher premiums to defray the costs. Insurers' ability to engage in risk segregation will also be limited by the preexisting condition provisions of the ACA as of 2014; and as described above, insurer actions to segregate policyholders at high HIV risk could also encourage discrimination or unacceptably invasive underwriting.⁴⁶¹

Among existing insurer options for expanding coverage, it seems most appropriate to cover biomedical HIV prevention technologies on a restricted basis, by narrowly specifying who should qualify or capping coverage at the minimum level necessary to preserve efficacy. Either of these options could work for biomedical HIV prevention. Restricting eligibility to policyholders at highest risk of HIV infection would improve the cost-effectiveness of this care and limit premium increases that could price the most disadvantaged individuals out of the insurance market. Eligibility screening may require clinicians to ask uncomfortable questions about HIV risk, but this could be done on an as-needed basis as benefits are actually sought (rather than screening everyone prospectively), and it does not pose the problem of differential pricing that would violate discrimination laws. Insurers could develop these coverage restrictions as part of medical necessity definitions, or in a separate contract clause addressing biomedical HIV prevention coverage. If these eligibility requirements are drawn from the medical literature and encompass those at highest risk of HIV infection, they are less likely to run afoul of discrimination laws based on unequal access to coverage.

This strategy is not free of limitations, however. Possible drawbacks include perverse behavioral incentives to qualify for coverage (ex ante moral hazard); reliance on self-reported data to appraise to HIV risk; privacy concerns inherent in requiring policyholders to disclose sensitive information to receive benefits;⁴⁶² and the chance that people who truly *do* qualify will not seek benefits because they fear repercussions or stigma after disclosing their risk factors. The USPSTF addressed the latter scenario when it required that insurers cover any individual who requests an HIV test; this requirement ensures that people at risk for HIV infection can obtain testing without the burden of revealing their risk behaviors. If demand for biomedical HIV prevention is low, eligibility restrictions may not be needed,

and the fact that a policyholder has requested coverage may be a sufficient indicator of risk. But if demand is so high as to make coverage decisions difficult, restricting eligibility to individuals who acknowledge a high HIV risk is one way to maintain access without resorting to cost-sharing.

Insurers may also attempt to negotiate discounts on behalf of their policyholders from manufacturers and healthcare providers.⁴⁶³ Negotiating reduced payments to clinicians, hospitals, and manufacturers is one way in which managed care has functioned to slow the rise in healthcare costs. Although these arrangements may make care less expensive for insurers, potentially allowing expanded access to care for insured individuals, they have the corresponding effect of increasing costs for out-of-pocket purchasers and putting care further out of reach for the uninsured. Given the socioeconomic characteristics of people at risk of HIV infection, this would be an undesirable result.

D. Employer Options: Emphasizing Demand

Large employers who purchase insurance plans on behalf of many employees may have sufficient bargaining power to demand that those plans provide coverage for biomedical HIV prevention, or they could purchase plans from among insurers that already provide this coverage. Employers may benefit more from financing preventive care than from financing treatment, since prevention averts illness and lost work time. Plans that include extensive coverage for preventive care may also be more appealing for employers who use such benefits to attract and retain employees. But without advocacy by employees or community groups, some employers may resist taking a strong position with respect to biomedical HIV prevention. Higher premiums could affect employee salaries, and employee turnover and HIV infection latency may be perceived as limiting the benefits to employers of averting HIV infections. Moreover, employers who believe that their employees are at low risk of HIV may not see this type of care as necessary. Advocates for access to biomedical HIV prevention technologies may wish to focus their efforts on employers along with community groups, insurers, and policymakers at the state and federal levels.

VII. CONCLUSION

Since the inception of the HIV epidemic, behavioral strategies for preventing initial infection have been an important counterpart to biomedical research advancing the treatment of individuals infected with HIV. Over the past decade, developments in *biomedical* HIV prevention have merged the paths of treatment and prevention, identifying the preventive capacity of HIV treatment; the prophylactic use of ARV drugs by uninfected people as PrEP, PEP, and nPEP; the promising potential of microbicides and new vaccine candidates; and the preventive benefit of long-established technologies such as substance use treatment, HIV testing, and male circumcision. The effective delivery of these technologies will require financing for clinical services, laboratory services, and drugs or devices, as well as the active participation of individuals at risk of HIV infection. But where these interventions are accessible to individuals at risk, their impact will exceed individual-level benefits. Reducing the risk of HIV acquisition among some individuals can benefit entire communities through herd effects, reducing the population-level burden of HIV/AIDS.

Given the socioeconomic character of the HIV epidemic, realizing the full benefit of biomedical HIV prevention technologies will depend on financing strategies beyond out-of-pocket payments. In the U.S. healthcare context, coverage of these new technologies by public and private health insurers can harness existing systems for purchasing clinical services, laboratory services, and drugs or devices; insurance coverage also offers attractive advantages for spreading costs across the population and over time. Insurance in the United States is understood as the principal way to fulfill the right to health, as well as a means of incentivizing innovation and expressing the social value of particular populations and activities. Public and private insurance coverage for HIV prevention technologies will likely be a flashpoint in the next decade of the U.S. response to HIV, and advocacy efforts will draw on decades of experience in promoting access to HIV treatment technologies.

Decisions by public and private insurers to cover biomedical HIV prevention technologies, however, may not be simple. This Article has examined the issues that may arise in determining whether public and private health insurers should provide coverage for biomedical HIV prevention technologies. Coverage will rest on the interpretation of contractual clauses and statutory language regarding medical necessity, which generally does not extend to exclusively preventive care. Moreover, even when medical necessity definitions extend to prevention, insurers may nonetheless decline coverage on the ground that cheaper mechanisms of prevention exist, such as the use of condoms or sterile needle injection equipment. Medical necessity requirements may make it difficult to reverse negative coverage decisions, where insurers do not voluntarily cover biomedical HIV prevention technologies on the grounds of cost-effectiveness. Exclusively preventive technologies may also fall under exclusion clauses for experimental care, off-label use, and treatment for preexisting conditions. This Article has emphasized the difficulty of making insurance coverage decisions regarding biomedical HIV prevention technologies on the grounds of cost-effectiveness for individual insurers. Insurer-level decisions on biomedical HIV prevention technologies may run the risk of rejecting coverage for interventions that would be cost-effective at the population level because insurers cannot capture the benefits of positive externalities.. The phenomenon of herd effects in the response to infectious diseases may justify locating responsibility for public health with governmental entities, which have a superior capacity for spreading losses and gains across the entire population that may benefit.

Drawing on this justification, this Article has examined several government-led alternative financing strategies for expanding access to biomedical HIV prevention technologies, such as statutory insurance mandates by individual states (which now require state subsidies due to the ACA), an insurance mandate by the federal government (e.g., via a recommendation by the USPSTF), direct financing by governmental entities such as AIDS Drug Assistant Programs, or financing through a system of tax credits. Each of these strategies is a plausible means of expanding access, but is important to note that strategies relying on up-front payment by individual users will fail to reach the individuals most at risk of infection due to low socioeconomic status. These strategies will also involve political challenges and explicit debates about prioritizing HIV prevention and the populations most at risk.

Where favorable coverage decisions may raise premiums, this Article has identified several insurer-initiated mechanisms by which public and private insurers may expand coverage while limiting premium increases. These include mechanisms such as negotiating lower prices for clinicians and manufacturers, restricting policyholders' eligibility for coverage (i.e., providing prevention services to policyholders most at risk of infection), and limiting coverage to the minimum required to maintain intervention efficacy. Employers who purchase insurance on behalf of their employees can also encourage coverage by making demands on insurers. Each of these strategies has limitations, including difficulty in mobilizing political will and overcoming the stigma associated with HIV risk. But given the high stakes of HIV risk, advocacy efforts in every sector can play an important role in expanding access to these technologies.

As we proceed through the fourth decade of the U.S. response to HIV and AIDS, the promise of new biomedical HIV prevention technologies has galvanized the research and advocacy communities. As these technologies prove to be safe and effective in clinical research, moving from research to practice becomes the next major challenge. The financing of biomedical HIV prevention can help to transform the future of the HIV epidemic in the United States, and the prevention of new infections continues to be a vital objective for national public health. By examining the legal doctrines and public policy priorities that may shape insurance coverage decisions for biomedical HIV prevention, this Article has aimed to contribute to this goal.

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150. *See* Abraham, *supra* note 120, at 4–5.
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157. Priest, *Government*, *supra* note 158, at 221–25.
158. *Id.* at 221.
159. Priest, Manuscript, *supra* note 158, at 1–2.
160. *Id.* at 2.
161. *See id.* at 3.
162. Priest, *Government*, *supra* note 158, at 221. This has been described as the law of large numbers.
163. This may differ for PEP, since the exposure to HIV that triggers PEP use may have been unpredictable.
164. Priest, Manuscript, *supra* note 158, at 1. Coverage may even temporarily decrease predictive accuracy, given uncertainty about demand and downstream effects.
165. Johnston & Fauci, *supra* note 142, at 889.
166. Priest, Manuscript, *supra* note 158, at 4–11.
167. *Id.* at 8–9; *see also* Priest, *Government*, *supra* note 158, at 223.
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169. For example, Vermont and Washington both prohibit insurance discrimination based on sexual orientation, which would forbid any effort to segregate men who have sex with men into a pool based on a higher likelihood of using HIV prevention technology. *See* Inst. of Real Estate Mgmt. Legislative Staff. Laws Prohibiting Discrimination Based on Sexual Orientation and Gender Identity. 2007:4, 7.
170. *See* Priest, *Government*, *supra* note 158, at 223; Priest, Manuscript, *supra* note 158, at 10–11.
171. Priest, Manuscript, *supra* note 158, at 11.
172. *See* Priest, Manuscript, *supra* note 158, at 9 n.19. This conversion generally makes risks uninsurable. *See id.* They may nevertheless be covered if it is cost-effective for the insurer.
173. *See id.*
174. *See* Abraham, *supra* note 120, at 533–46.
175. Smith et al., *supra* note 61 589.
176. *See, e.g.,* Padian et al., *supra* note 2, at 591–92; Rotheram-Borus et al., *supra* note 1, at 150–51; Van der Straten et al., *supra* note 58.
177. *Cf.* Underhill, *Implementation Science*, *supra* note 19, at 214.
178. Jost, *supra* note 111.
179. *See* Rotheram-Borus et al., *supra* note 1, at 150.

180. This may inadvertently increase the incentives for ex ante moral hazard among policyholders seeking to qualify for coverage.
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183. Pollack, *supra* note 184.
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185. See *id.* at 42, 47–48.
186. See Priest *Government*, *supra* note 158, at 225–28.
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191. *Id.*
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193. See *infra* Section V.A.
194. See Berenson, Robert A.; Dowd, Bryan E. Medicare Advantage Plans at a Crossroads—Yet Again. Health Aff. 2008; 28(Web Exclusive):w29, w35. ("Commercial insurers also look to Medicare to make initial technology approval decisions and to initiate more-aggressive payment denials"), cited in Hacker, Jacob S. The Case for Public Plan Choice in National Health Reform: Key to Cost Control and Quality Coverage. :14.2008available at http://institute.ourfuture.org/files/Jacob_Hacker_Public_Plan_Choice.pdf
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196. See, e.g., Hall, H Irene, et al. Estimation of HIV Incidence in the United States. JAMA. 2008; 300:520, 524. [PubMed: 18677024] Div. of HIV/AIDS Prevention. Epidemiology of HIV Infection Through 2010. CDC<http://www.cdc.gov/hiv/topics/surveillance/resources/slides/general/slides/general.pdf> (last visited Mar. 2, 2012)
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208. Ayanian, John Z., et al. Unmet Health Needs of Uninsured Adults in the United States. *JAMA*. 2000; 284:2061, 2063. tbl.1. [PubMed: 11042754]
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213. Fronstin, *supra* note 202, at 16 fig. 15.
214. Poundstone et al., *supra* note 191, at 26.
215. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*. S Ct. 2012; 132:2566.
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217. Patient Protection and Affordable Care Act § 1501(f).
218. Patient Protection and Affordable Care Act § 1501(d).
219. Patient Protection and Affordable Care Act § 1501(a).
220. Patient Protection and Affordable Care Act § 1201.
221. Patient Protection and Affordable Care Act § 2001.
222. *Id.*
223. Letter from the Cong. Budget Office to Nancy Pelosi, Speaker, House of Representatives, at 9Mar. 20, 2010 available at <http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf>; *see also Summary of Coverage Provisions in the Affordable Care Act*, Kaiser Family Found. <http://www.kff.org/healthreform/upload/8023-R.pdf> (last updated July 27, 2012)
224. *Nat'l Fed'n of Indep. Bus. v. Sebelius*. S Ct. 2012; 132:2566, 2607.
225. *Id.*
226. *See, e.g.*, Cooper, Michael. Many Governors Are Still Unsure About Medicaid Expansion. *NY Times*. Jul 14.2012 <http://www.nytimes.com/2012/07/15/us/governors-face-hard-choices-over-medicaid-expansion.html> Goodnough, Abby. Lines Are Drawn over Opting out of Medicaid Plan.

NY Times. Jul 12, 2012 <http://www.nytimes.com/2012/07/13/health/policy/in-florida-a-fight-brews-over-governors-vow-to-opt-out-of-medicaid-expansion.html?pagewanted=all>

227. Mimiaga et al., *supra* note 4, at 80.
228. Barash, Elizabeth Anne; Golden, Matthew. Awareness and Use of HIV Pre-Exposure Prophylaxis Among Attendees of a Seattle Gay Pride Event and Sexually Transmitted Disease Clinic. *AIDS Patient Care & STDs*. 2010; 24:689, 690. [PubMed: 20863247]
229. *See, e.g.*, Eisingerich et al., *supra* note 4; Mimiaga et al., *supra* note 4, at 80.
230. *See, e.g.*, Newman, Peter A., et al. Preventive HIV Vaccine Acceptability and Behavioral Risk Compensation Among a Random Sample of High-Risk Adults in Los Angeles. *Health Services Res*. 2010; 44:2167.
231. Hammett, Theodore M., et al. Acceptability of Formulations and Application Methods for Vaginal Microbicides Among Drug-Involved Women: Results of Product Trials in Three Cities. *Sexually Transmitted Diseases*. 2000; 27:119, 124.
232. Corso et al., *supra* note 13, at 97–98.
233. *See* Fronstin, *supra* note 202, at 5 fig. 1.
234. Steven Plitt et al., Couch on Insurance § 144.32-.34 (West 3d ed. 2010).
235. *See* Employee Retirement Income Security Act, 29 U.S.C. §. 2006:1181–91. Patient Protection and Affordable Care Act, Pub L. No. 111–148. Stat. 2010; 124:119.
236. *See* Metro. Life Ins. v. Massachusetts. US. 1985; 471:724.
237. Patient Protection and Affordable Care Act § 1302.
238. Steven Plitt et al., *supra* note 238, § 144.2.
239. *Id.* § 144.3. Debate still occurs over how to quantify what is a “medical necessity” and similar terms. *See* Jessie Hill B. What Is the Meaning of Health? Constitutional Implications of Defining “Medical Necessity” and “Essential Health Benefits” Under the Affordable Care Act. *Am JL & Med*. 2012; 38:445.
240. *Id.* §§ 144.32, .34.
241. *Id.* § 144.34.
242. *See* Blanchard, Timothy P. “Medical Necessity” Determinations—A Continuing Healthcare Policy Problem. *J Health L*. 2004; 37:599. Hall, Mark A.; Anderson, Gerard F. Health Insurers’ Assessment of Medical Necessity. *U Pa L Rev*. 1992; 140:1637, 1645. Sage, William M. Managed Care’s Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance. *Duke LJ*. 2003; 53:597.
243. *See, e.g.*, Succession of Coddington v. Time Ins. Co., 26,992 (La. App. 2 Cir. 5/10/95); 658 So.2d 1326.
244. *E.g.*, Price v. State Capital Life Ins. Co., 134 S.E.2d 171, 173 (N.C. 1964) (“[S]ickness’ is a condition interfering with one’s usual activities, whereas disease may exist without such result.”).
245. Steven Plitt et al., *supra* note 238, § 144.32.
246. *Id.* § 144.33 (citing McGregor v. Gen. Acc. Fire & Life Assur. Corp., 198 S.E. 641 (1938)); *see also* Aetna Life Ins. Co. v. Hays, 510 So. 2d 829, 830 (Ala. Civ. App. 1987) (“‘Disease’ ... is a serious illness, which has impaired the constitution or left in its wake some organic or chronic effect undermining general health.”)
247. Hall & Anderson, *supra* note 247, at 1646 n.27.
248. Steven Plitt et al., *supra* note 238, § 22.14.
249. *Id.* § 144.4.
250. *Id.*; *see* Hall & Anderson, *supra* note 246, at 1648–49; *see also* Abraham, *supra* note 120, at 37.
251. Hall & Anderson, *supra* note 247, at 1648.
252. *See, e.g.*, Maxa v. John Alden Life Ins. Co., 972 F.2d 980 (8th Cir. 1992); Brewer v. Lincoln Nat’l Life Ins. Co., 921 F.2d 150 (8th Cir. 1990). *cited in* Couch, *supra* note 238, § 144.4.
253. Smith v. Hartford Ins. Grp., 6 F.3d 131, 140 n.9 (3d Cir. 1993); *see also* Barnes v. Indep. Auto. Dealers Ass’n of Cal. Health & Welfare Benefit Plan, 64 F.3d 1389 (9th Cir. 1995); Phillips v. Lincoln Nat’l Life Ins. Co., 978 F.2d 302 (7th Cir. 1992). *But see* Winters v. Costco Wholesale

- Corp., 49 F.3d 550, 554 (9th Cir. 1995) (holding *contra proferentum* does not apply when self-funded ERISA plan grants administrator explicit discretion to determine eligibility).
254. *Hunter v. N. Am. Co. for Life & Health Ins.*, 671 F. Supp. 2d 1182, 1186, 1188 (S.D. Cal. 2009); *see also* *Citizens Ins. Co. of Am. v. MidMichigan Health ConnectCare Network Plan*, 449 F.3d 688, 692 (6th Cir. 2006); *Peterson v. Am. Life & Health Ins. Co.*, 48 F.3d 404, 411 (9th Cir. 1995).
 255. Rosenbaum, Sara, et al. U.S. Dep't of Health & Human Servs. Medical Necessity in Private Health Plans: Implications for Behavioral Healthcare. 2003. p. 64tbl.5 available at http://sphhs.gwu.edu/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_3A45C497-5056-9D20-3DAA24F165B5678A.pdf
 256. Employee Retirement Income Security Act § 503. USC §. 2006; 29:1133.
 257. *See* 29 C.F.R. § 2560.503–1(b) (2011).
 258. Patient Protection and Affordable Care Act, Pub L. No. 111–148, § 1001. Stat. 2010; 124:119, 242–49. (to be codified as amended at 42 U.S.C. § 300gg-19).
 259. Employee Retirement Income Security Act § 502; *see also* Abraham, *supra* note 120, at 385.
 260. Interim Final Rules for Group Health Plans and Health Insurance Issuers, 75 Fed. Reg. 43,329, 43,334 (July 23, 2010) (to be codified at 26 C.F.R. pts. 54, 602; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147).
 261. Abraham, *supra* note 120, at 385.
 262. *Id.*
 263. Rosenbaum et al., *supra* note 259, at 20.
 264. Politz, Karen, et al. Kaiser Family Found. Assessing State External Review Programs and the Effects of Pending Federal Patients' Rights Legislation. 2002:3., *cited in* Sage, *supra* note 247, at 625.
 265. For more information, see Jost, Timothy Stoltzfus Health Care Coverage Determinations: An International Comparative Study. 2005 Rettig, Richard A. Health Care in Transition: Technology Assessment in the Private Sector. 1997 Garber, Alan M. Cost-Effectiveness and Evidence Evaluation as Criteria for Health Policy. Health Aff. 2004; 23(Web Exclusive):W4–284. [hereinafter Garber, *Cost-Effectiveness*]; Garber, *Evidence-Based*, *supra* note 155; Parisi, Thomas J. How Much Did You Pay for Your Heart: Is a Centralized Entity Performing Health Technology Assessment with Cost-Effectiveness Analysis the Answer to the Rising Costs of Health Care? *Jurimetrics*. 2009; 49:285.
 266. Rettig, *supra* note 269, at 3 (quoting Comm. for Evaluating Med. Techs. in Clinical Use, Inst. of Med., *Assessing Medical Technologies 2*, (Frederick Mosteller et al. eds., 1985)); *see also* Parisi, *supra* note 269.
 267. Health Care Coverage Determinations, *supra* note 269, at 4–5.
 268. *Id.* at 208.
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 270. Bergthold, Linda, et al. Using Evidence and Cost in Managed Care Decision-Making. Aug 23. 2002 p. 9 (unpublished manuscript), available at http://content.healthaffairs.org/content/suppl/2009/11/25/hlthaff.w4.284v1.DC2/garber_supp.pdf
 271. Trosman, Julia R.; Van Bebber, Stephanie L.; Phillips, Kathryn A. Health Technology Assessments and Private Payers' Coverage of Personalized Medicine. *J Oncology Prac*, no 3S, at 18s. 2011; 7:19s.
 272. Parisi, *supra* note 269, at 292–93.
 273. *Id.* at 292.
 274. *Id.*
 275. *See* Garber, *Evidence-Based*, *supra* note 155, at 69.
 276. Health Care Coverage Determinations, *supra* note 269, at 208.
 277. Garber, *Evidence-Based*, *supra* note 155, at 75.
 278. Parisi, *supra* note 269, at 293.
 279. Garber, *Cost-Effectiveness*, *supra* note 269, at W4–290.

280. *Id.*
281. *See supra* note 269, at 8–9 (citing Norman Daniels & James E. Sabin, *Setting Limits Fairly: Learning to Share Resources for Health* (2002)).
282. *See* Rosenbaum et al., *supra* note 259, at 11.
283. *See* Health Care Coverage Determinations, *supra* note 269, at 8–9.
284. *See, e.g.,* Interim Final Rules for Group Health Plans and Health Insurance Issuers, 75 Fed. Reg. 43,329, 43,344 (July 23, 2010) (to be codified at 26 C.F.R. pts. 54, 602; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147).
285. Hall, Mark A., et al. *The Law of Health Care Finance and Regulation* (2). :270.2008; Blanchard, *supra* note 246, at 600.
286. Blanchard, *supra* note 246, at 600.
287. 42 C.F.R. § 440.230(d) (2011).
288. Garber, *Cost-Effectiveness*, *supra* note 269, at W4–293.
289. 42 U.S.C. § 1395y(a)(1)(A) (2006).
290. Health Care Coverage Determinations, *supra* note 269, at 209–19.
291. 42 C.F.R. § 431.205(a)-(b) (2011); 42 U.S.C. § 1396a(a)(3) (2006).
292. 42 C.F.R. § 431.233(a) (2011).
293. Kinney, Eleanor D. Procedural Protections for Patients in Capitated Health Plans. *Am JL & Med.* 1996; 22:301, 318.
294. Health Care Coverage Determinations, *supra* note 269, at 220.
295. 42 C.F.R. § 405.1000 (2011).
296. *Id.* § 405.1100.
297. *Id.* § 405.1136.
298. Health Care Coverage Determinations, *supra* note 269, at 219.
299. *Id.* at 214–16.
300. *Id.* at 230.
301. Garber, *Cost-Effectiveness*, *supra* note 269, at W4–293.
302. Parisi, *supra* note 269, at 301.
303. Health Care Coverage Determinations, *supra* note 265269, at 229.
304. Garber, *Cost-Effectiveness*, *supra* note 269, at W4–293.
305. *See* Parisi, *supra* note 269, at 299, 301; Neumann, Peter J. Using Cost-Effectiveness to Improve Health Care. 2005; 19; Health Care Coverage Determinations, *supra* note 269, at 217–18; Garber, *Evidence-Based*, *supra* note 269, at 71.
306. Health Care Coverage Determinations, *supra* note 269, at 218.
307. Parisi, *supra* note 269, at 302. Oregon’s famous experiment with cost-effectiveness based on quality-adjusted life-year gains was heavily criticized. *Id.*
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309. *Id.*
310. Health Care Coverage Determinations, *supra* note 269, at 212; *see also* Parisi, *supra* note 269, at 301.
311. Health Care Coverage Determinations, *supra* note 269, at 213.
312. *Id.*
313. *Id.*
314. Parisi, *supra* note 269, at 301.
315. Health Care Coverage Determinations, *supra* note 270, at 215.
316. Parisi, *supra* note 269, at 301.
317. *Id.*
318. *Id.*
319. *See generally* Hill, *supra* note 242 (explaining the difficulty in defining medical necessity).

320. Jost, *supra* note 111, at 3; Lee R. Russ & Thomas F. Segalia, Couch, *supra* note 239, § 181:1.
321. Jost, *supra* note 111, at 1.
322. Hall & Anderson, *supra* note 246, at 1646; Sage, *supra* note 246, at 605.
323. Jost, *supra* note 111, at 1–2.
324. Id.
325. Kesselheim, Aaron Seth. What's the Appeal? Trying to Control Managed Care Medical Necessity Decisionmaking Through a System of External Appeals. U Pa L Rev. 2001; 149:873, 874–75.
326. See *supra* note 262 and accompanying discussion.
327. Blanchard, *supra* note 246, at 600.
328. See Schroeder by Swanson v. Blue Cross & Blue Shield, United of Wisconsin, 450 N.W.2d 470, 475 (Wis. Ct. App. 1989).
329. Sage, *supra* note 246, at 605; see Steven Plitt et al., *supra* note 238, § 181:1.
330. For a fuller discussion, see Blanchard, *supra* note 246; Glazier, Alexandra K. Genetic Predispositions, Prophylactic Treatments and Private Health Insurance: Nothing Is Better than a Good Pair of Genes. Am JL & Med. 1997; 23:45.; Kesselheim, *supra* note 329; Rosenbaum et al., *supra* note 260; Sage, *supra* note 246; Singer, Sara J.; Berghold, Linda A. Prospects for Improved Decision Making About Medical Necessity. Health Aff. 2007; 20:200.
331. Rosenbaum et al., *supra* note 259, at 45–63 tbls.1, 2, 3 & 4 (gathering medical necessity definitions from published literature, managed care documents, judicial decisions, and state statutes).
332. Rosenbaum et al., *supra* note 259, at 25. A variety of synonyms have been used in contracts to specify this concept. See Steven Plitt et al., *supra* note 238, § 181:1.
333. See, e.g., Weiss v. CIGNA Healthcare, Inc., 972 F. Supp. 748, 755 (S.D.N.Y. 1997); see also Hughes v. Blue Cross of N. Cal., 263 Cal. Rptr. 850 (Ct. App. 1989).
334. Rosenbaum et al., *supra* note 260, at 20.
335. Id.
336. See, e.g., Council on Med. Serv. Am Med Ass'n, CMS Report 13 – I-99, Report of the Council on Medical Service. 1999; 1
337. Medical Necessity Definition: Model Medicaid Managed Care Contract Provisions. Nat'l Health Law Program. http://www.healthlaw.org/index.php?option=com_content&view=article&id=281:medical-necessity-definition-model-medicaid-managed-care-contract-provisions&catid=42 (last visited Mar. 1, 2012). The insurance industry trade group, America's Health Insurance Plans, also encourages insurers to consult preventive care guidelines when issuing coverage determinations. See Public Health and Prevention Statements of Support. America's Health Ins Plans. <http://216.52.120.13/content/default.aspx?bc=38|65|20356|285> (last updated July 18, 2007)
338. 31–186 Appleman on Insurance § 186.03 (2010).
339. Harrison v. Aetna Life Ins. Co., 925 F. Supp. 744, 748 (M.D. Fla. 1996).
340. Abernathy v. Prudential Ins. Co. of Am., 264 S.E.2d 836, 838 (S.C. 1980).
341. See 46 C.J.S. Insurance § 1337 (2007).
342. See, e.g., Carmouche v. CNA Ins. Cos., 535 So.2d 1279 (La. Ct. App. 1988) (finding that the trial court may afford greater weight and probative value to testimony of treating physician); Shumake v. Travelers Ins. Co., 383 N.W.2d 259, 264 (Mich. Ct. App. 1985).
343. 1 Emp't Coordinator Benefits § 5:10 (2011) (citing Donaho v. FMC Corp., 74 F.3d 894 (8th Cir. 1996)).
344. Appleman, *supra* note 341 § 186.03; Steven Plitt et al., *supra* note 238, § 181:2; see, e.g., Sheppard & Enoch Pratt Hosp., Inc. v. Travelers Ins. Co., 32 F.3d 120 (4th Cir. 1994).
345. Tillery v. Hoffman Enclosures, Inc., 280 F.3d 1192, 1199 (8th Cir. 2002); Franks v. La. Health Servs. & Indem. Co., 382 So. 2d 1064, 1068 (La. Ct. App. 1980).
346. See *supra* Section IV.B.1.
347. See, e.g., Wait v. Metro. Life Ins. Co., 564 N.Y.S.2d 535 (App. Div. 1990) (“[Plaintiffs’ affidavit] does not argue that any medical diagnosis exists”).

348. *See supra* notes 145–148 and accompanying text.
349. *See Couch, supra* note 237, at § 181:3 (“The high cost of prophylactic treatments has led insurers to resist coverage on the grounds that prophylactic measures are not medically necessary because they do not treat an actual disease.”).
350. Div. of HIV/AIDS Prevention, *supra* note 199.
351. *See generally* American Psychological Association. APA Policy Statements on Lesbian, Gay, Bisexual, & Transgender Concerns. 2011; 3 available at <http://www.apa.org/about/policy/booklet.pdf#page=31>. (describing the American Psychiatric Association’s decision to remove homosexuality from the official list of mental disorders, emphasizing that “the American Psychological Association urges all mental health professionals to take the lead in removing the stigma of mental illness that has long been associated with homosexual orientations.”). *See also id.* at 29 (describing how efforts to promote homosexuality as “symptomatic” often appear “embedded within the larger context of conservative religious political movements that have supported the stigmatization of homosexuality on political or religious grounds”).
352. *See* Div. of HIV/AIDS Prevention, *supra* note 199.
353. Rosenbaum et al., *supra* note 260, at 19.
354. *See, e.g.,* Underhill, *Implementation Science, supra* note 19, at 214 (discussing the potential reluctance of policymakers to finance PrEP when behavioral prevention strategies could be used instead).
355. Garber, *Cost-Effectiveness, supra* note 269, at W4–290.
356. Mount Sinai Hosp. v. Zorek, 271 N.Y.S.2d 1012 (Civ. Ct. 1966), *cited in* 31–186 Appleman on Insurance § 186.03.
357. These claims would likely also fail on the grounds that the HIV-infected partner is not the policyholder; providing this care would require the insurer to incur the costs of treating an HIV infection, in the hopes that the policyholder would not also become infected.
358. *See* Leibowitz et al., *supra* note 77, at 143; Morris et al., *supra* note 77.
359. *See* Landovitz & Currier, *supra* note 31; Cadman, Jill. PEP Talk. The Body. Jul-Aug;1999 <http://www.thebody.com/content/art13461.html> (noting that insurers may refuse to cover all the costs of PEP).
360. Cadman, *supra* note 362.
361. *See supra* note 55 and accompanying text.
362. Shen, *supra* note 130.
363. *See supra* Section IV.B.1.
364. Substance abuse treatment has been denied on grounds of medical necessity, but these cases either lack a final decision on the merits or were factually unique. Jones v. Kodak Med. Assistance Plan, 169 F.3d 1287, 1290 (10th Cir. 1999) (ERISA plan granted administrator “full discretion to determine eligibility for benefits,” and external medical examiner found that the policyholder did not meet the policy’s medical criteria for inpatient care); Koenig v. Metro. Life Ins. Co., No. 92 C 5588, 1993 WL 45944, at *1 (N.D. Ill. Feb. 17, 1993) (insurer cited policyholder’s “numerous past treatment opportunities” and “lack of personal responsibility”). Both cases were also cited by Rosenbaum et al., *supra* note 259, at 21.
365. *See* National Conference of State Legislatures, State Laws Mandating or Regulating Mental Health Benefits. Dec.2011 available at <http://www.ncsl.org/issues-research/health/mental-health-benefits-state-laws-mandating-or-re.aspx>
366. *See* 42 U.S.C.A. § 300gg-26 (West 2011).
367. *See* Patient Protection and Affordable Care Act § 1302, 42 U.S.C.A. § 18022 (West 2011) (defining “[m]ental health and substance use disorder services” as part of an “essential health benefits package”).
368. *See* Tudor v. Metro. Life Ins. Co. 539 N.Y.S.2d 690, 691–92 (Dist. Ct. 1989).
369. *See, e.g.,* Cal Health Benefits Review Program, Executive Summary: Analysis of Assembly Bill 1894: HIV Testing. 2008 available at http://www.chbrp.org/docs/index.php?action=read&bill_id=45&doc_type=2

370. Koh, Howard K.; Sebelius, Kathleen G. Promoting Prevention Through the Affordable Care Act. *New Eng J Med.* 2010; 363:1296, 1297. [PubMed: 20879876]
371. Patient Protection and Affordable Care Act § 4106; Jost, *supra* note 111.
372. USPSTF A and B Recommendations. U.S. Preventive Servs. Task Force; <http://www.uspreventiveservicestaskforce.org/uspstf/uspabrecs.htm> (last updated Aug. 2010)
373. U.S. Preventive Servs. Task Force. Screening for HIV: Recommendation Statement. *Annals Internal Med.* 2005; 143:32, 33. (emphasis added).
374. *See, e.g.*, Thompson, Melanie A., et al. Antiretroviral Treatment of Adult HIV Infection: 2010 Recommendations of the International AIDS Society—USA Panel. *JAMA.* 2010; 304:321, 322–23. [PubMed: 20639566] (recommending expanding highly active antiretroviral therapy, also known as HAART, eligibility to asymptomatic patients with a CD4 cell count of 500 per μ L, which is less severe than prior recommendations indicate, as well as to patients when there is “a heightened risk of HIV transmission,” such as serodiscordant couples).
375. *See, e.g.*, Kitahata, Mari M., et al. Effect of Early Versus Deferred Antiretroviral Therapy for HIV on Survival. *New Eng J Med.* 2009; 360:1815. [PubMed: 19339714] Severe, Patrice, et al. Early Versus Standard Antiretroviral Therapy for HIV-Infected Adults in Haiti. *New Eng J Med.* 2010; 363:257. [PubMed: 20647201]
376. *Weaver v. Reagan*, 886 F.2d 194, 198 (8th Cir. 1989) (also cited by Hall et al., *supra* note 289, at 271).
377. Me. Rev. Stat. Ann. tit. 24, § 2320-G (2011); Me. Rev. Stat. Ann. tit. 24-A, §§ 2745-F, 2837-G, 4234-E (West 2011); Mass. Gen. Laws Ann. ch. 175, §§ 47O, 47P (West 2012); Mass. Gen. Laws Ann. ch. 176A, § 8Q (West 2012); Mass. Gen. Laws Ann. ch. 176B, § 4P (West 2012); Mass. Gen. Laws Ann. ch. 176G, § 4G (West 2012).
378. For more information, see Ader, Mary. Investigational Treatments: Coverage, Controversy, and Consensus. *Annals Health L.* 1997; 5:45. Francis, Leslie Pickering. Legitimate Expectations, Unreasonable Beliefs, and Legally Mandated Coverage of Experimental Therapy. *Ind Health L Rev.* 2004; 1:213. Hoffman, Sharona. A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments. *Or L Rev.* 1999; 78:203. Gregory Lahr J. What is the Method to their “Madness?”: Experimental Treatment Exclusions in Health Insurance Policies. *J Contemp Health L & Pol’y.* 1997; 13:613. Commentary.
379. *See* Steven Plitt et al., *supra* note 238, § 181:4 (specifying these two types of denials).
380. *See supra* Sections II.B, II.D.
381. Although the preventive effects of dual-purpose technologies such as substance use treatment and STI treatment were also discovered recently, these likely will not receive experimental treatment denials. Policyholders seeking these technologies can instead claim that they are seeking the dual-purpose care for its treatment or diagnostic effect, instead of its more recently discovered preventive purpose.
382. Steven Plitt et al., *supra* note 238, § 181:4 (citing Lahr, *supra* note 381).
383. Hoffman, *supra* note 381, at 208–09 (citing references). *See also* Rosenbaum et al., *supra* note 259 (collecting definitions of medical necessity in several dozen cases, which included twenty-two denials of experimental care).
384. Steven Plitt et al., *supra* note 238, § 181:5 (citing cases including *Dahl-Eimers v. Mut. of Omaha Life Ins. Co.*, 986 F.2d 1379 (11th Cir. 1993); *Lubeznik v. HealthChicago, Inc.*, 644 N.E.2d 777 (Ill. App. Ct. 1994)).
385. *Id.*
386. *See* *Fuja v. Benefit Trust Life Ins. Co.*, 18 F.3d 1405, 1412 (7th Cir. 1994) (suggesting that some experimental treatments “are so cost prohibitive that requiring insurers to cover them might result in the collapse of the healthcare industry”).
387. Steven Plitt et al., *supra* note 238, § 181:5; *see, e.g.*, *Fuja*, 18 F.3d at 1411.
388. *Rollo by Rollo v. Blue Cross/Blue Shield of N.J.*, Civ. A. No. 90–597, 1990 WL 312647, at *7 (D.N.J. Mar. 22, 1990) (also cited in 2 *Health L. Prac. Guide* § 18:11 (2012)).
389. *See, e.g.*, Steinberg, Earl P.; Tunis, Sean; Shapiro, David. Insurance Coverage for Experimental Technologies. *Health Aff.* 1995; 14:143:149–150.

390. *Id.* at 150
391. *Am. Soc’y of Cataract & Refractive Surgery v. Sullivan*, 772 F. Supp. 666, 672–73 (D.D.C. 1991), *vacated*, 986 F.2d 546 (1993) (also cited by Hall et al., *supra* note 290, at 271).
392. Dresser, Rebecca; Frader, Joel. Off-Label Prescribing: A Call for Heightened Professional and Government Oversight. *JL Med & Ethics*. 2009; 37:476, 476. Ratner, Mark; Gura, Trisha. Off-Label or Off-Limits? *Nature Biotechnology*. 2008; 26:867, 867.
393. *See supra* Section II.A.3.
394. *See* Dresser & Frader, *supra* note 396, at 478, 482–83.
395. Cohen, Joshua, et al. Off-Label Use Reimbursement. *Food & Drug LJ*. 2009; 64:391, 392. Fugh-Berman, Adriane; Melnick, Douglas. Off-Label Promotion, On-Target Sales. *PLoS Med*. 2008; 5:1432, 1432.
396. *See, e.g., Cassanese v. United Healthcare Ins. Co.*, No. 8:08-cv-373-T-26MAP, 2008 WL 4642292 (M.D. Fla. Oct. 20, 2008).
397. *See I.V. Servs. of Am., Inc. v. Trustees of the Am. Consulting Engineers Council Ins. Trust Fund*, 136 F.3d 114, 119–20 (2d Cir. 1998).
398. *See* Cohen et al., *supra* note 398, at 396–97.
399. *See id.* at 396 (also noting that Medicare has recently added three compendia to its list of approved uses); *see also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (2006) (noting that the drug use review program will examine covered drugs against standards consistent with three compendia and peer-reviewed medical literature).
400. Pearson, Steven D., et al. Medicare’s Requirement for Research Participation as a Condition of Coverage: Is It Ethical? *JAMA*. 2006; 296:988, 988. [PubMed: 16926358]
401. *See* Wang, Sally. Recent Case Development, False Claims Act: The Right Treatment for Off-Label Marketing? *JL Med & Ethics*. 2010; 38:708.
402. *See* Cohen, Wilson & Faden, *supra* note 398, at 396–97.
403. *See id.* at 396 (“Generally, whether an off-label use is reimbursable depends on its inclusion in one or more recognized pharmaceutical compendia If a compendium ... is not at hand, off-label use reimbursement may depend on publication of supportive clinical evidence for the particular indication in peer-reviewed medical literature or clinical practice guidelines established by medical professional societies.”).
404. For an example of one such policy provision, *see Haw. Med. Serv. Ass’n v. Adams*, 209 P.3d 1260, 1263 n.5 (Haw. Ct. App. 2009).
405. *See* Francis, *supra* note 381, at 235.
406. *Id.*
407. *See, e.g., Mass. Gen. Laws Ann. ch. 175, § 47O* (West 2012); *see also* Francis, *supra* note 382, at 235 (collecting statutes).
408. *See* Francis, *supra* note 381, at 235 (collecting statutes).
409. These mandates do not necessarily require that the empirical evidence be of rigorous methodological quality. *See, e.g., id.* at 236.
410. *See, e.g., Cal. Health & Safety Code § 1370.4* (West 2010).
411. Francis, *supra* note 381, at 238 (collecting statutes); Health L. Prac. Guide § 18:11 (2010).
412. *See, e.g., Francis, supra* note 381, at 232.
413. *See* Panlilio et al., *supra* note 53.
414. *Id.* at 1.
415. *See supra* Section II.A.3 and accompanying notes.
416. *See, e.g., Hazelton, Patrick*. Project Inform, Financing and Delivery Mechanisms to Increase Pre-Exposure Prophylaxis (PrEP) Access in Populations at High-Risk of HIV Infection. 2011; 26 available at http://www.projectinform.org/pdf/prep_finance_0611.pdf. ; Shen, *supra* note 130.
417. *See supra* note 61.
418. *See, e.g., Preston Neff C, et al*. Oral Pre-Exposure Prophylaxis by Anti-Retrovirals Raltegravir and Maraviroc Protects Against HIV-1 Vaginal Transmission in a Humanized Mouse Model.

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419. Francis, *supra* note 381, at 233.
420. *See* Me. Rev. Stat. Ann. tit. 24, § 2320-G (West 2012); Me. Rev. Stat. Ann. tit. 24-A, §§ 2745-F, 2837-G, 4234-E (West 2012).
421. *See* Mass. Gen. Laws Ann. ch. 175, §§ 47O, § 47P (West 2012); Mass. Gen. Laws Ann. ch. 176A, § 8Q (West 2012); Mass. Gen. Laws Ann. ch. 176B, § 4P (West 2012); Mass. Gen. Laws Ann. ch. 176G, § 4G (West 2012).
422. *See supra* note 422.
423. *See supra* notes 422–243.
424. Garber, *supra* note 155, at 67.
425. CDC, *supra* note 70, at 5.
426. *See* Rabin, Roni Caryn. Benefits of Circumcision Are Said to Outweigh Risks. The New York Times. Aug 27.2012 , at A3; Task Force on Circumcision, American Academy of Pediatrics. Circumcision Policy Statement. Pediatrics. 2012; 130:585. [PubMed: 22926180]
427. Siegfried et al., *supra* note 72, at 2 (citing sources).
428. *See supra* note 77.
429. *See generally* Glazier, Alexandra K. Genetic Predispositions, Prophylactic Treatments and Private Health Insurance. Am JL & Med. 1997; 23:45, 60–62.
430. Epstein & Stannard, *supra* note 17, at 265.
431. *Id.* at 254.
432. Priest Manuscript, *supra* note 158, at 8–9.
433. *See* Glazier, *supra* note 333, at 59–61.
434. *See, e.g.,* Farley v. Ark. Blue Cross & Blue Shield, 147 F.3d 774 (8th Cir. 1998); Salvaggio v. Time Ins. Co., 553 F. Supp. 2d 577 (D.S.C. 2008); Leddy v. Miss. State Med. Ass’n, 7 F. Supp. 2d 819 (S.D. Miss. 1998).
435. Glazier, *supra* note 333, at 60.
436. *See* Lawson v. Fortis Ins. Co., 301 F.3d 159, 160 (3d Cir. 2002).
437. *See* Steven Plitt et al., *supra* note 238, § 144:88–92 (discussing standards for determining whether conditions are preexisting).
438. *Id.*
439. *Id.* § 144:39.
440. *Id.* (citing cases).
441. Thomas McLellan A, et al. Drug Dependence, a Chronic Medical Illness. JAMA. 2000; 284:1689. [PubMed: 11015800]
442. Steven Plitt et al., *supra* note 238, § 144:39.
443. *Id.*
444. *See* Pendo, Elizabeth. Working Sick: Lessons of Chronic Illness for Health Care Reform. Yale J Health Pol’y L & Ethics. 2009; 9:453, 461. n.46. (citing Williams, Claudia H.; Fuchs, Beth C. Robert Wood Johnson Found. Policy Brief No 4, Expanding the Individual Health Insurance Market: Lessons from the State Reforms of the 1990s, at 3 fig 3. 2004available at <http://www.rwjf.org/content/dam/web-assets/2004/06/expanding-the-individual-health-insurance-market>).
445. *See* 42 U.S.C. § 300gg; Abraham, *supra* note 121, at 377–78.
446. Patient Protection and Affordable Care Act § 1201, 42 U.S.C.A. § 300gg-4 (West 2012).
447. *Id.*
448. Ableson, Reed. U.S. Turns to Waivers to Address Talk of Dropping Health Coverage. NY Times. Oct 6.2010 , at B1; Berry, Emily. Insurers Drop Child-Only Coverage on Eve of Health Reform Mandates. Am Med News. Oct 4.2010 <http://www.ama-assn.org/amednews/2010/10/04/bil11004.htm>
449. Rosenbaum & Rousseau, *supra* note 190, at 12–13.
450. *See, e.g.,* Haw. Med. Serv. Ass’n v. Adams, 209 P.3d 1260, 1268 (Haw. Ct. App. 2009).

451. Steven Plitt et al., *supra* note 238, § 144:56–57.
452. *See supra* notes 218–219 and accompanying text.
453. These exclusions appear frequently in litigation after drunk driving accidents. *See, e.g.*, *Tourdot v. Rockford Health Plans, Inc.*, 439 F.3d 351 (7th Cir. 2006); *Carter v. ENSCO Inc.*, 438 F.Supp. 2d 669 (W.D. La. 2006); *Bekos v. Providence Health Plan*, 334 F. Supp. 2d 1248 (D. Or. 2004).
454. Abraham, *supra* note 177, at 401.
455. 31–186 Appleman on Insurance § 186.03 (2010).
456. Patient Protection and Affordable Care Act § 1311(d)(3)(B), 42 U.S.C.A. § 18031(d)(3)(B) (West 2012); Ctr. for Consumer Info. & Ins. Oversight, Dep’t of Health & Human Servs., Essential Health Benefits Bulletin 9 (2011).
457. *See Koh & Sebelius, supra* note 373, at 1296.
458. Under most market conditions these increased premiums would constrict access to insurance.
459. *See Calabresi, supra* note 115, at 39.
460. *See supra* Section III.E.3.
461. *See supra* Section III.E.2.
462. Rigorous privacy protections would be necessary to ensure that these data would be kept confidential.
463. *See, e.g.*, Penny E. Mohr et al., Project HOPE Ctr. for Health Affairs, Paying for New Medical Technologies: Lessons for the Medicare Program from Other Large Health Care Purchasers 9–12 (2003).

Table 1

Characteristics of Biomedical HIV Prevention Strategies

Intervention	United States Availability as of August 2012	Dual-Purpose vs. Preventive	HIV Status of User	Estimated cost per user, excluding support services*
ARV Drugs for Treatment of HIV Infection	Available, FDA-approved indications	Dual-Purpose	Infected	\$13,024 per year ¹
ARV Drugs for Post-Exposure Prophylaxis	Available off-label	Preventive	Negative	\$597 to \$1000 for a full course ²
ARV Drugs for Pre-Exposure Prophylaxis	Available, FDA-approved indications for adults	Preventive	Negative	\$9,036 to \$12,000 per year ³
Microbicides	Not Available	Preventive	Negative	\$0.25 per application; \$91.25 per year assuming daily use of a single dose ⁴
Male Circumcision	Available	Preventive	Negative	\$257 for newborns; ⁵ \$2,200 for adults ⁶
Vaccines	Not Available	Preventive	Negative	Unknown ⁷
Treatment of Other STIs	Available	Dual-Purpose	Both	Variable, can range from \$26 to \$6,738 in lifetime costs for treatment or cure ⁸
Treatment of Substance Use Disorders	Available	Dual-Purpose	Both	Variable; \$4,277 to \$13,395 per episode of methadone maintenance therapy ⁹
HIV Counseling and Testing	Available	Dual-Purpose	Both	\$27–\$74 for one testing and counseling session ¹⁰

* Costs are provided per year when use is intended to continue for the full year; otherwise, costs assume a single dose or episode of treatment.

¹ Ray Y. Chen et al., *Distribution of Health Care Expenditures for HIV-Infected Patients*, 42 Clinical Infectious Diseases 1003, 1007 (2006); Kelly A. Gebo et al., *Contemporary Costs of HIV Healthcare in the HAART Era*, 24 AIDS 2705, 2712 (2010).

² Raphael J. Landovitz & Judith S. Currier, *Postexposure Prophylaxis for HIV Infection*, 361 New Eng. J. Med. 1768, 1772–73 (2009); Steven D. Pinkerton et al., *Cost-Effectiveness of HIV Postexposure Prophylaxis Following Sexual or Injection Drug Exposure in 96 Metropolitan Areas in the United States*, 18 AIDS 2065, 2066 (2004).

³ Samuel B. Keller & Davey M. Smith, *The Price of Tenofovir-Emtricitabine Undermines the Cost-Effectiveness and Advancement of Pre-Exposure Prophylaxis*, 25 AIDS 2308, 2309 (2011); Paltiel, *supra* note 6, at 809.

⁴ *AIDS 2010: Study Finds Microbicide Containing HIV Drug Lowers Infection Risk in Women by 39 percent*, Kaiser Family Found. (July 20, 2010), <http://globalhealth.kff.org/Daily-Reports/2010/July/20/GH-072010-AIDS-2010-Gel-Study.aspx>; see also David P. Wilson & Paul M. Coplan, *Mathematical Models and Health Economic Aspects of Microbicides*, 3 Current Opinion HIV & AIDS 587, 590 (2008).

⁵ Stephanie L. Sansom et al., *Cost-Effectiveness of Newborn Circumcision in Reducing Lifetime HIV Risk Among U.S. Males*, PLoS ONE, Jan. 18, 2010, at 3, available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0008723>.

⁶ Edgar J. Schoen et al., *Cost Analysis of Neonatal Circumcision in a Large Health Maintenance Organization*, 175 J. Urology 1111, 1113 (2006).

⁷ Models [contain/show/predict] varied costs of the vaccine from \$2000 to \$10,000. See, e.g., Rochelle P. Walensky et al., *A Therapeutic HIV Vaccine: How Good Is Good Enough?*, 22 Vaccine 4044, 4047 (2004).

⁸ Harrell W. Chesson, Dayne Collins & Kathryn Koski, *Formulas for Estimating the Costs Averted by Sexually Transmitted Infection (STI) Prevention Programs in the United States*, 6 Cost Effectiveness & Resource Allocation 10 (2008). These costs include sequelae such as pelvic

inflammatory disease in women, epididymitis in men, and neurosyphilis or cardiovascular syphilis for untreated syphilis cases. The cost of STI treatment is lower in low-income countries. See Disease Control Priorities Project, Sexually Transmitted Infections Are Preventable and Treatable, but the Full Benefit Depends on the Local Context 5 tbl.2 (2007), available at <http://www.dcp2.org/file/144/DCPP-STI.pdf> (estimating the average cost of treatment or cure at \$39.49).

⁹Michael T. French et al., *The Economic Costs of Substance Abuse Treatment: Updated Estimates and Cost Bands for Program Assessment and Reimbursement*, 35 J. Substance Abuse Treatment 462, 466 (2008).

¹⁰Ying-Ying Meng et al., *Financial Impact of California's New Law to Increase HIV Screening by Mandating Insurance Coverage*, 23 AIDS Care 206, 209 (2011); Deborah A. Cohen et al., *Cost-Effective Allocation of Government Funds to Prevent HIV Infection*, 24 Health Aff. 915, 921 (2005).