April 12, 2024

Mr. Scott Kipper
Commissioner of Insurance
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City NV 87906

RE: Essential Health Benefits Comments

Submitted via DOI website: https://di.nv.gov/ins/f?p=112:21

Dear Commissioner Kipper:

The **HIV+Hepatitis Policy Institute**, a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, thanks you for the opportunity to offer comments on potential changes to Nevada's Essential Health Benefits (EHB) benchmark plan.

We support changing the state EHB benchmark plan to one that covers all FDA-approved tests and drugs to treat and prevent HIV, hepatitis B, hepatitis C, and opioid use.

It is a timely juncture for states that wish to improve access to testing, treatment, and prevention for HIV and viral hepatitis to consider an update to a more generous EHB benchmark plan. The recently finalized 2025 Notice of Benefit and Payment Parameters has created new opportunities for states to define what comprehensive health insurance should look like and to close gaps in coverage.[1] The final rule clarified that all covered drugs in excess of the EHB benchmark should be considered EHB, but state mandates continue to be considered non-EHB. Therefore, when a state has legislated new coverage mandates—as Nevada has for HIV, hepatitis B and C, and opiate use disorder medications and diagnostics[2]—insurance departments should consider changing the EHB benchmark plan so that drugs newly covered by state mandate benefit from ACA protections, such as cost-sharing limits.[3] Nevada's Division of Insurance is to be commended for considering this impactful step.

[1] https://healthlaw.org/hhs-just-took-a-big-step-towards-improving-access-to-services-and-achieving-health-equity/.

[2] https://www.leg.state.nv.us/App/NELIS/REL/82nd2023/Bill/10457/Text.

[3] Changes to a more generous benchmark also potentially save scarce state funding for defrayal of the costs for post-ACA new mandates.

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Opioid use is syndemic with HIV and hepatitis C,[4] and we support the proposed change to a benchmark plan that covers all diagnostics, prevention, and treatment for opioid use disorder. We will limit our comments here to HIV, hepatitis B, and hepatitis C.

HIV

Given Nevada's high—and growing—prevalence and incidence of HIV, bold action is urgently needed to turn the corner and move toward ending HIV in the state.

We strongly support Nevada's proposal to adopt a benchmark covering all HIV diagnostics, prevention, and treatment drugs.

Only six states and D.C. have higher prevalence of HIV than Nevada,[5] and only three states and D.C. have a higher per capita rate of new HIV diagnoses than Nevada.[6] Both the state as a whole and Clark County (which the federal government has designated as one of 48 priority Phase I jurisdictions in the *End the HIV Epidemic* initiative) have seen an increase in the number of HIV diagnoses every year since 2012—during a time when HIV diagnoses decreased across the board nationally.[7] Only 58 percent of Nevadans living with HIV are virally suppressed (and thus can transmit HIV), a rate significantly lower than the nation as a whole, with 66 percent viral suppression.[8] This means that there is very high urgency for Nevada to take any steps it can to turn the corner and decrease transmission of HIV, including the elimination of any barriers to testing, prevention, and treatment in state-regulated insurance coverage.

The development of safe and effective treatments for HIV—still thought to be a death sentence just thirty years ago—is one of the biggest triumphs of biomedical research. HIV treatment is not one-size-fits-all. A clinician prescribes a treatment regimen based on potential adverse side effects, resistance-test results, potential drug-drug interactions, pill burden, dosing frequency, and child-bearing potential/contraceptive use. Even some of the oldest drugs which are no longer in routine use are recommended for pediatric use or for pregnant persons.[9] Many regimens, including some of the most commonly prescribed ones, are now available as single-tablet regimens (STRs), which are far easier to adhere to than combinations of multiple pills. The complexity of treatment guidelines and available formulations means that Nevada's proposed benchmark covering all HIV drugs would favorably benefit all commercially insured Nevadans receiving treatment for HIV.

The importance of broad coverage of HIV medications is also recognized in the "Six Protected

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[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5884743/.

[5] District of Columbia, New York, Georgia, Maryland, Florida, Louisiana, and New Jersey, https://map.aidsvu.org/prev/state/rate/none/none/usa?geoContext=national.

[6] District of Columbia, Georgia, Louisiana, and Florida, https://map.aidsvu.org/nd/state/rate/none/none/usa?geoContext=national.

[7] https://endhivnevada.org/wp-content/uploads/2020/09/PS19-1906-Nevada-Clark-County-EHE-FINAL-Plan.pdf (page 5).

[8] https://www.cdc.gov/hiv/pdf/policies/profiles/cdc-hiv-nevada-PrEP.pdf.

[9] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/intro-and-overview.

Classes" of Medicare Part D coverage, which mandates that plans cover "all or substantially all" drugs in six categories, one of which is antiretrovirals. Uniquely among the Six Protected Classes, prior authorization is typically not allowed for antiretrovirals in Medicare Part D.[10]

Prevention of HIV was revolutionized in 2012 when the FDA approved the first drug that prevents HIV, called pre-exposure prophylaxis or PrEP. Since a substantial number of people living with HIV do not know their status (and therefore can transmit HIV), treatment alone cannot end the HIV epidemic. CDC estimates that about half of all people in Nevada who would benefit from PrEP are taking it.[11] PrEP uptake has been characterized by stark and widening racial/ethnic, gender, and geographic disparities. PrEP is more than just a drug and includes periodic HIV and other lab tests. We are pleased that the proposed EHB benchmark proposal also includes these tests that support PrEP.

Until recently, both HIV treatment and PrEP consisted of a daily oral regimen, often a single pill a day. One promising new trend in the last three years is the development of new long-acting injectable formulations for both HIV treatment (two FDA-approved drugs) and PrEP (one FDA-approved drug). Many more long-acting formulations, both injectable and oral, are in development and offer hope to many who are unable to adhere to a regimen of daily pills, such as the insecurely housed, or those who have confidentiality concerns about the storage of oral medication, or many others. In the not too distant future, people may be able to prevent or treat HIV with just one pill or injection every few months, which promises to vastly improve adherence. A benchmark plan covering all drugs including these revolutionary new formulations will do much to ensure that all Nevadans on state-regulated insurance plans have coverage for the medication they need to stay healthy.

EHB benchmark plan choice is an underused tool for states that wish to increase access to antiretroviral drugs to treat or prevent HIV. Since 2017, only nine states have changed their EHB benchmark plans: five of these states opted to increase the number of antiretrovirals required to be covered, while the other four states left the number of drugs required unchanged.[12] Illinois, in its EHB benchmark adopted for Plan Year 2020, chose a plan which covers 48 of the 51 HIV antiretroviral drugs and drug combinations, an increase of 17 over the previous benchmark.[13] Nevada's current EHB benchmark plan covers only 32 HIV drugs: only thirteen states have fewer HIV medications. Adoption of a plan similar to the current Illinois benchmark would increase the number of covered drugs by 50 percent, significantly improving access to antiretrovirals in the state.

Hepatitis C

Prior to COVID, Hepatitis C killed more people than the other 60 notifiable infectious diseases put together. While Nevada ranks in the middle of the pack among other states in prevalence

[10] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf , 30.2.5.
[11] https://www.cdc.gov/hiv/library/reports/surveillance-data-tables/vol-4-no-3/index.html , table 3b.
[12] https://www.cms.gov/marketplace/resources/data/essential-health-benefits#overview.
[13] https://www.cms.gov/cciio/resources/data-resources/downloads/2020-bpm-il.zip.

and incidence of hepatitis C, Nevada's current EHB benchmark only requires coverage of a single hepatitis C drug, which does not allow Nevadans living with HCV the options they need for the curative medication that best suits their clinical needs. With close to half of those living with HCV in the United States estimated to be unaware of their status, access to coverage for testing is critical to eliminating the HCV epidemic.

We support the adoption of an EHB benchmark covering all testing and all new curative drugs for HCV, which would dramatically transform the coverage picture for commercially insured Nevadans living with hepatitis C.

The discovery of four new classes of curative Direct Acting Antiviral (DAA) drugs for hepatitis C beginning in 2013 began a new era for people and communities impacted by hepatitis C. Treatment prior to 2013 was characterized by often intolerable side effects, with only 50-60 percent of patients achieving a cure. Clinicians prescribing hepatitis C cures take into account their patient's HCV genotype, the extent of liver damage already sustained, and other factors when choosing which DAA drug or combination will best suit their patient's clinical needs.

Twenty-two states have a higher benchmark plan requiring coverage of more medications than Nevada's, with Illinois's new benchmark adopted in Plan Year 2020 here too setting the highest standard, requiring the coverage of seven drugs.[14] Adoption of a plan similar to the current Illinois benchmark would multiply formulary coverage sevenfold and has the potential to dramatically improve access to antiretrovirals in the state.

Sadly, despite the availability of curative medication, CDC has recently found that only 1 in 3 of all insured people receive treatment for hepatitis C within 360 days of a first positive HCV RNA test.[15] Access to HCV treatments for commercially insured people would be greatly improved by increased formulary coverage as contemplated by NVDOI's benchmark plan proposal, but HCV treatment access is also affected by access barriers beyond coverage of the medically necessary DAA drug or combination drug. CDC found that prior authorization requirements, other insurance practices limiting access based on fibrosis stage or sobriety, retreatment restrictions, and restricting prescribing to specialists are critically needed in addition to formulary coverage of DAAs. We call on state insurance regulators to take all necessary steps to prohibit utilization management and other barriers to HCV treatment.

Hepatitis B

While there still is no cure for hepatitis B, there are a number of options for treatment. Advocates note that lack of coverage of certain drugs remains common.[16] With a very active drug development pipeline holding out the promise of improved treatments or even a functional cure for hepatitis B, generous formulary coverage for hepatitis B will be necessary to

[14] https://www.cms.gov/cciio/resources/data-resources/downloads/2020-bpm-il.zip.
[15] https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e1.htm?s_cid=mm7132e1_w.
[16] https://www.hepb.org/assets/PDFs/1Drug-Tiering-Consumer-Report-10.27.2020-Final-1.pdf.

ensure that Nevadans are able to take advantage of the latest scientific research.[17] As with hepatitis C, close to half of all people estimated to be living with HBV are unaware of their status, making seamless access to testing through insurance of critical importance to contain the HBV epidemic.

Hepatitis B is often overlooked compared to hepatitis C. NVDOI is to be applauded for including hepatitis B in its benchmark proposal alongside hepatitis C. We support the adoption of an EHB benchmark covering all testing and any new treatment drugs for HBV, allow commercially insured Nevadans to access testing and any newly approved drugs.

Other Considerations for State Insurance Regulators

The proposed changes to Nevada's EHB benchmark are necessary but not sufficient to improve access to testing and drugs needed by people affected by HIV, viral hepatitis, and opioid use. The proposed changes will yield better coverage, but more needs to be done. We will share a few examples of areas of concern.

Insurance plans impose excessive utilization management tools such as prior authorization and step therapy that limit access to needed medications. **We urge NVDOI to take any necessary steps to prohibit all forms of utilization management in testing, prevention, and treatment of HIV and viral hepatitis.**

Insurance plans also impose prohibitive out-of-pocket costs on covered drugs and services that limit access. Many states have taken legislative action to prohibit cost-sharing on HIV treatment and prevention drugs. We would urge Nevada state legislators—who have already demonstrated their commitment to reducing barriers to testing, treating, and preventing HIV, viral hepatitis, and opiate use—to take similar action.

Due to the high burden of cost-sharing on people who need treatment or prevention for HIV or viral hepatitis, many of those on commercial assistance plans rely on the use of copay assistance for their medications. Insurance plans can meet even the most generous benchmark while still using harmful benefit designs that affect copay assistance, such as copay accumulators, or plans that designate certain drugs as non-EHB while implementing a copay maximizer or an alternate funding program.

A DC District Court ruling in *HIV+Hepatitis Policy Institute et al v HHS et al* has reinstated the 2020 NBPP rule with respect to counting copay assistance towards patient cost-sharing, and this rule prohibiting copay accumulators is now enforceable by state insurance regulators. CMS has also moved towards eliminating the non-EHB loophole exploited by copay maximizer plans and alternate funding programs. We urge state insurance regulators to take action against these harmful benefit designs.[18]

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[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9416195/.

[18] We describe these harmful benefit designs in greater detail in recent comments on the proposed 2025 NBPP: https://hivhep.org/testimony-comments-letters/comments-on-the-nbpp-proposed-rule-for-2025/.

Insurance plans can also meet even the most generous benchmark while still imposing a discriminatory benefit design, such as discriminatory tiering, under which all or most of the drugs to treat (or prevent) a particular condition are placed on the highest-cost tier. We encourage state insurance regulators to proactively ensure that state-regulated plans are not discouraging enrollment by populations impacted by any particular disease, rather than taking action only when patient advocacy organizations file complaints.

The development of new drugs to prevent and treat HIV, hepatitis B, and hepatitis C is ongoing, yielding drugs with novel mechanisms of action, more favorable side-effect profiles, or long-acting formulations that can make adherence easier. We urge the Division of Insurance to review the EHB benchmark plan periodically to ascertain whether drug development has outpaced the number and categories of drugs required to be covered. In particular, if CMS chooses in the future to transition from USP MMG to USP DC for categorizing prescription drugs for EHB coverage, state insurance regulators must be vigilant for any unintended consequences. For example, single-tablet regimens and other combination drugs are treated differently in the two formulary classification systems.

We applaud the Nevada Division of Insurance for proposing this innovative and much needed approach to improving access to HIV and viral hepatitis medications, and we thank you for engaging stakeholders in a public comment process. Should you have any questions or comments, please feel free to contact me at cschmid@hivhep.org or Kevin Herwig at kherwig@hivhep.org. Thank you very much.

Sincerely,

Carl E. Schmid II
Executive Director