HealthHIV

Your Guide to HIV PrEP Coverage and Insurance Rights

A PRIMER

KNOW YOUR COVERAGE RIGHTS

- **The law:** Under the Patient Protection and Affordable Care Act (ACA) regulations, non-grandfathered group health plans and health insurance issuers are required to cover ALL FDA-approved HIV pre-exposure prophylaxis (PrEP) medications, including generic and branded oral medications and long-acting injectables, without cost-sharing for eligible patients. This means ZERO copays, coinsurance, or deductibles.
- **Coverage specifics:** This coverage also extends to ALL necessary components of PrEP care, such as laboratory tests, provider visits, and adherence counseling.

WHAT THIS MEANS FOR YOU

- **No cost-sharing:** You should not pay for HIV PrEP medication OR related services, such as STI testing, provider follow-up visits, or adherence counseling.
- **No barriers:** Insurance companies cannot require prior authorization or step therapy ("fail-first") protocols for HIV PrEP.

STEPS TO TAKE IF YOU FACE ISSUES

- **Denied coverage?** Contact your health plan or insurer and reference the USPSTF "A" grade recommendation that mandates HIV PrEP and associated services to be covered at no cost.
- **Charged a fee by your health plan or insurance?** Request reimbursement or reversals for any out-of-pocket costs that should have been covered.
- **Ensure Correct Billing Practices:** Providers must use the correct preventive billing codes for all PrEP-related services (e.g., STI testing, HIV screening, adherence counseling) instead of diagnostic codes. Have them cross-check claims submissions to ensure ALL services tied to HIV PrEP are processed under preventive care. This ensures compliance with ACA's no-cost preventive care requirements, avoiding any patient out-of-pocket costs.
- **Barriers or delays?** File a complaint with your state's Department of Insurance or the federal CMS email at marketconduct@cms.hhs.gov.

TIPS FOR ADVOCATING FOR YOUR RIGHTS

- **Check your plan:** Verify that your plan or insurer lists HIV PrEP and related services as $0 preventive care.
- **Work with your provider:** Ask your healthcare provider to help you clarify coverage requirements with your insurer.
- **Educate frontline staff:** Request that administrative and clinic staff receive brief training sessions focused on HIV PrEP-related billing practices, patient rights, and utilization management protections. Ensure they are provided with user-friendly templates for appeals, insurer communication letters, and educational materials to better assist patients.
- **Keep records:** Save receipts, bills, and communications to use as evidence if you need to file a complaint.

ADDITIONAL RESOURCES

- **PleasePrEPMe: Improving PrEP and PEP Access** Founded in 2015, PleasePrEPMe was the first searchable directory connecting individuals to HIV PrEP and PEP services in California. Now part of HealthHIV, the program advances equitable access to care, empowering individuals through innovative resources and training for the PrEP workforce. Visit PleasePrEPMe.org for detailed access insights and assistance.
- For more information on filing complaints or addressing barriers, visit your state's Department of Insurance website. See page 5.
- Sample Letter for Patient Insurance Complaint. See page 8.

WHAT IS PREP?

http://www.whatisprep.org

HOW DO I GET PREP?

https://pleaseprepme.org/online-providers

AN EXPANDED GUIDE TO UNDERSTANDING HIV PREP COVERAGE AND YOUR RIGHTS

WHAT'S THE USPSTF?

Question: Who decides what's covered for free?

Answer: The U.S. Preventive Services Task Force (USPSTF) makes recommendations that insurers must follow under the ACA.

WHY USPSTF RECOMMENDATIONS MATTER

Question: Why are USPSTF recommendations important for PrEP access?

Answer: They require insurers to cover all PrEP options without cost-sharing to reduce disparities in HIV prevention.

COVERAGE OF HIV PREP SERVICES

Question: Which services should my insurance cover when I'm using HIV PrEP?

Answer: Insurance must cover lab tests, clinical visits, and counseling without any out-of-pocket costs.

HEALTH PLANS–INSURANCE & UTILIZATION MANAGEMENT BARRIERS

Question: Can my insurance either impose burdensome requirements or make me "jump through hoops", such as utilization management, to get HIV PrEP?

Answer: No, your insurance cannot require prior authorization or step therapy (fail-first) for HIV PrEP.

FUTURE PREP FORMULATIONS

Question: Will new types of HIV PrEP be covered right away?

Answer: Yes, future HIV PrEP medications must also be included in coverage without delays.

FEDERAL AND STATE ADVOCACY STEPS

Question: What can I do if my insurance doesn't follow the rules?

Answer: You can file complaints with state insurance departments below (see page 5) or use the federal CMS email at marketconduct@cms.hhs.gov to ensure your rights are upheld.

FILING COMPLAINTS WITH STATE INSURANCE DEPARTMENTS

See page 5 for a list of state consumer complaint resources and links to more information.

WHAT'S THE USPSTF?

USPSTF stands for the U.S. Preventive Services Task Force. It is an independent panel of national experts in prevention and evidence-based medicine that provides recommendations on various clinical preventive services—such as screenings, counseling, and preventive medications, like HIV pre-exposure prophylaxis, commonly referred to as HIV PrEP.

- USPSTF recommendations are designed to improve the health of Americans by guiding primary care practices.
- More information can be found on the USPSTF Website.

WHY DOES THE COVERAGE REQUIREMENT MATTER FOR HIV PREP PRESCRIPTIONS?

The USPSTF recommendation now encompasses all FDA-approved PrEP medications, including daily oral medications and long-acting injectables. To ensure equitable PrEP access, insurers must cover all options without cost-sharing, as each medication addresses different medical, logistical, and personal needs.

- Without this coverage, disparities in PrEP use will persist, particularly among communities disproportionately impacted by HIV.

COVERAGE OF PREP SERVICES

- Insurance plans must cover ALL ancillary (supplementary) services associated with PrEP at no extra cost to you. These services include essential healthcare for the safe and effective use of PrEP, such as routine HIV testing, kidney function tests, clinical visits, counseling, and other lab work. This also includes medical evaluations to assess suitability for PrEP, ongoing health monitoring, and the process of obtaining PrEP medication through pharmacies. These coverage protections ensure access to the full range of care needed to prevent HIV acquisition, in alignment with CDC clinical guidelines.

PATIENT-PROVIDER CHOICE

- Patients must have access to the PrEP medication deemed most appropriate by their healthcare provider, including daily oral or long-acting injectable formulations, without limitations or cost-sharing. This aligns with the USPSTF's goal of improving equitable access to diverse PrEP options.

HEALTH PLAN OR INSURANCE UTILIZATION MANAGEMENT BARRIERS

- Insurance plans must not impose utilization management barriers, such as prior authorization or step therapy (fail-first"), on PrEP access.
- Any required exceptions or processes must be clear, simple, and expedited to avoid delays in care.

PROTECTIONS FOR CONTINUED ACCESS

- Insurance plans must not impose restrictions on the number of times a patient can start or stop PrEP or limit the frequency of routine follow-ups and testing. This ensures flexibility and continuity of care for patients whose needs or circumstances may change over time.

FUTURE PREP FORMULATIONS

- Advances in HIV prevention require insurance regulators to preemptively ensure that future PrEP formulations—such as biannual injectables—are automatically incorporated into ACA-mandated coverage requirements without delays.

FEDERAL AND STATE ADVOCACY STEPS

- Insurers must comply with federal regulations to ensure all PrEP-related clinical services and ancillary testing are covered without cost-sharing across all jurisdictions. Federal agencies should issue explicit guidance to ensure insurers adopt clear, consumer-friendly formulary listings that transparently outline no-cost coverage for all PrEP medications and associated services.

STATE CONSUMER COMPLAINT RESOURCES

States and Territories	State-Level DOI Consumer Complaint Resources
ALABAMA	Alabama Department of Insurance
ALASKA	Department of Commerce, Community, and Economic Development
ARIZONA	Department of Insurance and Financial Institutions
ARKANSAS	Arkansas Insurance Department
CALIFORNIA	California Department of Insurance/Department of Managed Health Care
COLORADO	Colorado Department of Regulatory Agencies
CONNECTICUT	Connecticut Insurance Department
DELAWARE	Delaware Department of Insurance
DISTRICT OF COLUMBIA	DC Department of Insurance Securities and Banking
FLORIDA	Florida Department of Financial Services
GEORGIA	Office of Commissioner of Insurance and Safety Fire
HAWAII	State of Hawaii Department of Commerce and Consumer Affairs
IDAHO	Idaho Department of Insurance
ILLINOIS	Illinois Department of Insurance
INDIANA	Indiana Department of Insurance
IOWA	Iowa Insurance Division
KANSAS	Kansas Insurance Department
KENTUCKY	Kentucky Public Protection Cabinet
LOUISIANA	Louisiana Department of Insurance
MAINE	Maine Bureau of Insurance
MARYLAND	Maryland Insurance Administration
MASSACHUSETTS	Massachusetts Division of Insurance
MICHIGAN	Michigan Department of Insurance and Financial Services
MINNESOTA	Minnesota Department of Commerce
MISSISSIPPI	Mississippi Insurance Department

*Indicates states that must also direct complaints about health insurance coverage to MarketConduct@cms.hhs.gov

MISSOURI*	Missouri Department of Insurance
MONTANA	Montana Commissioner of Securities and Insurance
NEBRASKA	Nebraska Department of Insurance
NEVADA	Nevada Division of Insurance
NEW HAMPSHIRE	The State of New Hampshire Insurance Department
NEW JERSEY	State of New Jersey Department of Banking & Insurance
NEW MEXICO	New Mexico Office of Superintendent of Insurance
NEW YORK	New York State Department of Financial Services
NORTH CAROLINA	North Carolina Department of Insurance
NORTH DAKOTA	North Dakota Insurance Department
OHIO	Ohio Department of Insurance
OKLAHOMA*	Oklahoma Insurance Department
OREGON	Oregon Division of Financial Regulation
PENNSYLVANIA	Pennsylvania Insurance Department
PUERTO RICO	Office of The Commissioner of Insurance of Puerto Rico
RHODE ISLAND	State of Rhode Island Department of Business Regulation
SOUTH CAROLINA	South Carolina Department of Insurance Office of Consumer Services
SOUTH DAKOTA	South Dakota Department of Labor & Regulation
TENNESSEE	Tennessee Department of Commerce and Insurance
TEXAS*	Texas Department of Insurance
U.S. VIRGIN ISLANDS	U.S. Virgin Islands Division of Banking, Insurance & Financial Regulation
UTAH	Utah Insurance Department
VERMONT	State of Vermont Department of Financial Regulation
VIRGINIA	Commonwealth of Virginia State Corporation Commission
WASHINGTON	Office of Insurance Commissioner Washington State
WEST VIRGINIA	West Virginia Offices of The Insurance Commissioner
WISCONSIN	Wisconsin Office of the Commissioner of Insurance
WYOMING*	Wyoming Department of Insurance

*Indicates states that must also direct complaints about health insurance coverage to MarketConduct@cms.hhs.gov

DIRECTIONS FOR USING AND SENDING A COMPLAINT LETTER

DETERMINE THE RECIPIENT:

- Identify the correct address or contact information for your insurance provider or plan administrator. This can typically be found on the back of your insurance card or on your insurer's website.

FORMAT AND DELIVERY OPTIONS:

- Email: Send the letter to the insurance company's designated email address for customer service or appeals, if available.
- Snail-Mail: Use certified mail to send the letter to ensure there is a record of its delivery.
- Online Submission: Some insurance companies have a portal for submitting complaints or documents—consider uploading the letter there.

WHO SHOULD SEND IT:

- The letter can be sent directly by the patient/consumer to emphasize the personal impact of non-compliance.
- Alternatively, it may be more impactful if sent by a clinic or provider on behalf of the patient to show the medical necessity and urgency of compliance.

STATE AND FEDERAL PORTALS:

- For additional support, submit a copy of the letter to the federal complaint portal and the appropriate state insurance department (OIC) using the links provided in this document. This ensures regulators are aware of the non-compliance.

DOCUMENTATION:

- Include all relevant attachments, such as billing statements, plan documents, or correspondence with the health plan or insurer, to strengthen your case.

FOLLOW-UP:

- Keep a copy of the letter and delivery confirmation for your records.
- If no response is received within 30 days, follow up with both the insurance provider and the appropriate regulatory agency.

SAMPLE LETTER FOR PATIENT INSURANCE COMPLAINT

Subject: Request for Immediate Compliance with Federal PrEP Coverage Mandate

Dear [Insurance Provider or Plan Administrator],
I am writing to address an issue of non-compliance with federal guidelines requiring the coverage of pre-exposure prophylaxis (PrEP) medications and related services for HIV prevention at no cost to patients. As outlined by the Affordable Care Act (ACA) and the U.S. Preventive Services Task Force (USPSTF) "A" grade recommendation, non-grandfathered health insurance plans must cover all FDA-approved PrEP medications and their associated services—including laboratory testing, provider visits, and adherence counseling, without cost-sharing.

Despite these clear mandates, I have been charged out-of-pocket costs for PrEP medication or related services. Additionally, I have experienced [e.g., barriers to restarting PrEP, prior authorization delays, or denied coverage for recommended tests/services], which has delayed starting this life-protective medication. These practices violate federal protections and hinder my ability to access the care recommended by my healthcare provider.

I am also writing to highlight the following obligations for [Insurance Provider/Plan Administrator]:

- Comprehensive Coverage: All FDA-approved PrEP medications—including oral and injectable options—must be covered without cost-sharing, as determined by my healthcare provider. Plans may not restrict access to a single medication or impose "step therapy" or "fail first" requirements.
- Ancillary Services: PrEP-related services, such as HIV and STI screening, kidney function tests, and counseling, must also be covered without cost-sharing. Federal guidance mandates that these integral services be provided at $0 cost to patients.
- Timely Access: Plans must provide an easily accessible and transparent process for approving PrEP prescriptions and related services. Utilization management practices such as prior authorization, delays in processing, or arbitrary restrictions on starting or restarting PrEP are prohibited under federal law.

I request that [Insurance Provider/Plan Administrator]:

- Reimburse/reverse any out-of-pocket costs I have incurred for PrEP medications or related services, as these should have been covered without cost-sharing under ACA preventive care requirements.
- Ensure that all PrEP-related services—including ancillary testing and clinical visits—are covered without barriers or additional costs moving forward.
- Clearly list PrEP medications and associated services as ACA preventive benefits on your formularies and plan documents, including explicit information on $0 cost-sharing for these services.

Failure to comply with these federal mandates jeopardizes my health and violates the ACA's requirements for preventive services to which I am entitled. I request confirmation of your corrective actions within 30 days.

Sincerely,
[Your Full Name]
[Your Contact Information]
[Policy or Member Number, if applicable]

Attachments: [Include plan documents, drug formularies, billing statements, or any documentation that demonstrates non-compliance]

SAMPLE SOCIAL MEDIA POSTS

URGE STATE INSURANCE COMMISSIONERS TO ENFORCE PATIENT PROTECTIONS

NOTE: Posts are customized for social media character limits.

FOR PATIENT ADVOCATES

If federal and state regulators don't hold insurance plans accountable for covering #PrEP, people at risk of HIV will face unnecessary financial and coverage barriers.

Lack of timely enforcement and penalties put people at risk of contracting and transmitting #HIV.

PrEP can protect communities from HIV infection. It is crucial that patients know they can get #PrEP for free. Read more on how federal guidance impacts insurer compliance: https://bit.ly/PrEPCompliance

FOR CONSUMERS

Act now! Call on [INSERT STATE] to enforce no-cost coverage for HIV prevention medications for patients. Ensure health plans meet their legal requirement under the ACA to cover #PrEP and its associated services for free. Learn more: https://bit.ly/USPSTFFAQS

In all states, patients can file complaints when health plans don't cover #PrEP at no cost. Take action NOW to hold non-compliant insurers accountable. Tell [INSERT STATE] to enforce no-cost coverage for HIV prevention. Read more: https://bit.ly/covenforcement

Know Your Rights! Ensuring compliance with new federal USPSTF #PrEP guidance allows patients in INSERT STATE to receive the proper care they need. Read FAQs here: https://bit.ly/USPSTFFAQS

FOR STATE AUTHORITIES

Private insurers must comply with the new federal #PrEP coverage mandate, or they risk penalties under the #ACA. Learn how patients can access PrEP for free: https://bit.ly/PrEPguide

Make sure health plans abide by the federal #PrEP coverage mandates. State insurance commissioners must continue to remind insurers what insurers are legally required to do. Learn more: https://bit.ly/USPSTFFAQS

HEALTH PLAN AND INSURANCE GLOSSARY

ADMISSION REVIEW	Assessment of the appropriateness of urgent or emergency admissions within a limited period after hospitalization.
CO-PAY ACCUMULATOR	Policy that insurers will not count the funds received through manufacturer copay assistance towards individuals' deductibles/out-of-pocket maximum, so patients must continue to pay until they match the level with their own funds.
CONCURRENT REVIEWS	A review of medical necessity decisions made while the patient is currently in an acute or post-acute setting.
HIGH-COST CASE MANAGEMENT	Process of assessing the needs of a small group of beneficiaries who have generated or are likely to generate very high health expenditures to plan, arrange, and coordinate their recommended services. Also referred to as case management, catastrophic case management, or individual benefits management.
NON-MEDICAL SWITCHING	When a health plan's formulary changes in a way that forces a patient to switch from their prescribed medication to a "preferred therapy."
PRESCRIBER PREVAILS	A policy that protects the decision-making of medical professionals by ensuring that the treatment a provider prescribes is approved and fully covered.
PROSPECTIVE REVIEW	Includes the review of medical necessity for performing services or scheduled procedures before admission.
PRIOR AUTHORIZATION	A type of UM practice that requires physicians to gain approval from a payer (insurance company or pharmacy benefits manager) before a patient can fill a prescription or receive a service.
RETROSPECTIVE REVIEW	Assesses the appropriateness of procedures, settings, and timings after the healthcare services have been conducted.
STEP THERAPY	Patients must "fail" (fail-first) a less costly treatment option before the payer will allow the patient to access a costlier medication.

REFERENCES

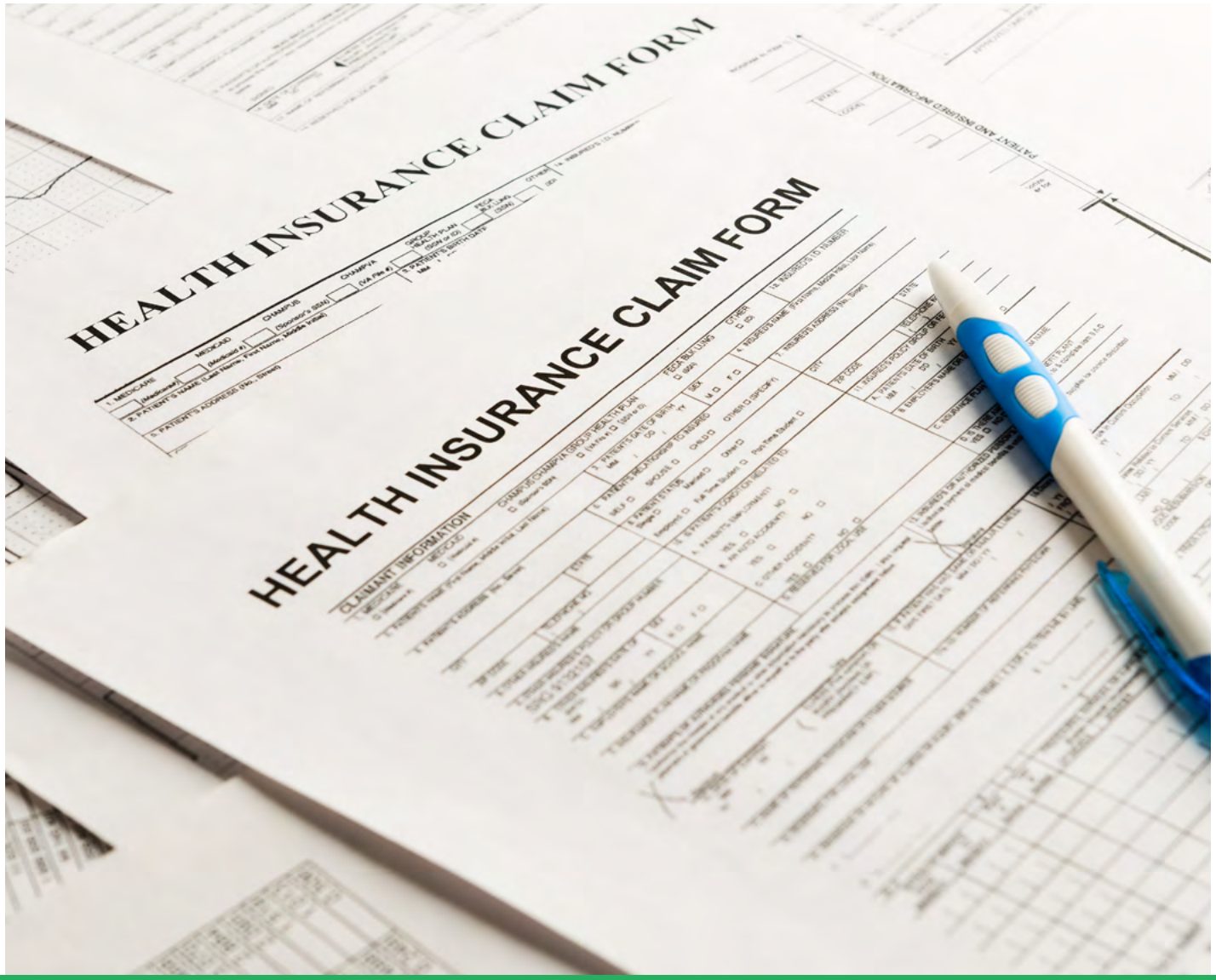
FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 47

Departments of Labor, Health and Human Services, and the Treasury: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/faqs-about-affordable-care-act-implementation-coverage-of-prep-2021.pdf

ICD-10 Billing Codes: https://www.cms.gov/medicare/coding-billing/icd-10-codes

FAQS ABOUT AFFORDABLE CARE ACT AND WOMEN'S HEALTH AND CANCER RIGHTS ACT IMPLEMENTATION PART 68

Departments of Labor, Health and Human Services, and the Treasury: https://www.cms.gov/files/document/faqs-implementation-part-68.pdf



HealthHIV

PUTTING HEALTH FIRST

HealthHIV is a national non-profit working with healthcare organizations, communities, and providers to advance effective HIV, HCV, STI and LGBTQ health care, harm reduction and health equity through education and training, technical assistance and capacity building, advocacy, communications, and health services research and evaluation.

HealthHIV leads the HealthHCV initiative, the National Center for Health Care Capacity Building, and the National Coalition for LGBTQ Health, as well as PleasePrepMe.org, AgingWithHIV.org, ReduceHarmDC.org, and the HIV Prevention Certified Provider (HIVPCP) Certification Program.

Learn more at **HealthHIV.org**.

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