HIV Health Care Access Working Group

November 2, 2016

US Pharmacopeial (USP)
USP Healthcare Quality Expert Committee
Submitted via email: modelguidelines@usp.org

Dear Committee members:

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) with recommendations for the Model Formulary Guidelines Version 7.0, which currently inform Medicare Part D prescription drug plan (PDP) and Qualified Health Plan (QHP) minimum formulary requirements. According to the Kaiser Family Foundation, 25% of individuals living with HIV in care rely on Medicare coverage with the number tripling from around 42,000 in 1997 to 120,000 in 2014.[1] Our comments will address anti-hepatitis C (HCV) and anti-hepatitis B (HBV) agents in addition to anti-HIV agents because of the prevalence of HCV and HBV among individuals with HIV and the clinical importance of effectively treating HCV and HBV in co-infected individuals.[2]

We are pleased that USP is shortly initiating a process to develop a new classification system to inform non-Medicare Part D outpatient formularies that will be updated annually. With ongoing advances in HIV and viral hepatitis treatments, more frequent updates are appropriate to keep pace with medical progress and the latest treatment standards for the QHPs and other health programs that may reference the USP model formularies. We recommend consideration of merging these processes to better ensure Medicare Part D beneficiaries also benefit from the latest treatment advances.

HIV Agents - Drug Classes and Example Drug List

Regarding the anti-HIV antiviral drug classes, we strongly urge for the inclusion of additional antiretroviral agents that are currently absent from the “example drug list.” We are particularly concerned that drugs recommended in the Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents (DHHS HIV/AIDS Treatment Guidelines)*[3] are not included on the list. HIV infection continues to require access to the full spectrum of available antiretroviral drugs for Medicare beneficiaries to benefit from the multi-drug regimen that will most effectively suppress the virus. Factors considered in identifying the most effective drug regimen include drug resistance, tolerability of treatment

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[1] Kaiser Family Foundation. Medicare and HIV. October 2016. Available online at: http://kff.org/hivaids/fact-sheet/medicare-and-hiv/.

[2] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Available online at: http://www.hcvguidelines.org.

[3]See Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents (DHHS HIV/AIDS Treatment Guidelines.* Available online at: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines.

side effects, co-morbid conditions, and drug-to-drug interactions. In many cases, if a drug regimen is available as a single-tablet regimen, this option will be preferable given that Medicare beneficiaries are more likely to be sicker, treatment experienced and require additional medications to treat co-morbid conditions. With this in mind, **we strongly urge the following antiretroviral drugs to be added to the example drug list:**

- **NRTI drug class: Emtricitabine/Tenofovir Alafenimide (Descovy)**
- **NRTI drug class: Rilvirine/emtricitabine/tenofovir alfanemide (Odefsey)**
- **INSTI drug class: Dolutegravir/abacavir/lamivudine (Triumeq)**
- **Anti-HIV agent, other: Cobicistat (Tybost)**
- **INSTI drug class: Elvitegravir (Vitekta)**
- **NRTI drug class: Didanosine delayed-release (Videx EC)**
- **NNRTI drug class: Nevirapine extended-release (Viramune XR)**

Anti-hepatitis Agents - Drug Classes and Example Drugs

We appreciate the addition of the anti-hepatitis B agent class in the proposed "example drug list" and recommend that this class be included in the "category and classes" document as well. Since 2013, there have been significant advances in treatment options for HCV that offer individuals with HCV a high likelihood of achieving sustained virologic suppression (SVR) and being cured of hepatitis C. The new category of anti-hepatitis C agents approved since 2013 known as Direct Acting Antivirals (DAAs) are better tolerated, require shorter treatment durations and have very high cure rates.

Effective HCV treatment requires a combination of agents to achieve SVR and the anti-hepatitis C oral agent regimen that will be most effective for individuals with HCV depends on a number of factors, including an individual's genotype, treatment history, level of cirrhosis, co-morbidities and potential drug-to-drug interactions. Guidance developed by the Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America (IDSA) is updated as new treatment and data becomes available, and is widely recognized as setting the standard of care for HCV treatment nationwide.[4] We strongly urge for Medicare Part D PDP and QHP coverage to reflect these standards of care by requiring coverage of at least one option for each of the major patient groups identified within the guidance, e.g., patients with renal insufficiency and HIV-co-infection.

Hepatitis C treatment options continue to advance at a rapid pace with four new treatment options expected to receive approval by the U.S. Food and Drug Administration within the next 12 months. We strongly recommend updating the anti-hepatitis drug classes to better ensure Medicare Part D beneficiaries and QHP enrollees have appropriate access to HCV treatment. This is particularly important given that individuals born between 1945 and 1965 are at higher risk for having hepatitis C[5] and are increasingly becoming eligible for Medicare coverage. **We**

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[4] AASLD and IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Available online at: http://www.hcvguidelines.org.
[5] CDC. Hepatitis C: Why People Born Between 1945 and 1965 should get tested. Available online at: https://www.cdc.gov/knowmorehepatitis/media/pdfs/factsheet-boomers.pdf.

urge for the antiviral anti-hepatitis drug classes to be updated as follows:

- **Anti-hepatitis B Oral Agents**
- **Anti-hepatitis B Other**
- **Anti-hepatitis C Oral Agents**
- **Anti-hepatitis C Other**

We also strongly recommend that all of the anti-hepatitis oral agents are included on the example drug list and urge the addition of the following:

- **Ombitasvir, paritaprevir, and ritonavir (Technivie)**

We strongly recommend recognizing these new classes of drugs to treat viral hepatitis by creating anti-hepatitis B oral agents and anti-hepatitis C oral agents drug classes in addition to maintaining anti-hepatitis B and C other drug classes.

Thank you for the opportunity to comment on the USP Model Formulary Guidelines 7.0. Please contact Amy Killelea with the National Alliance of State & Territorial AIDS Directors (akillelea@nastad.org), Andrea Weddle with the HIV Medicine Association (aweddle@hivma.org) or Robert Greenwald with the Treatment Access Expansion Project (rgreenwald@law.harvard.edu) if we can be of assistance.

Respectfully submitted by the HIV Health Care Access Steering Committee:

AIDS Action Baltimore | AIDS Action Committee of MA | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | The AIDS Institute | APLA Health | AIDS Treatment Data Network | AIDS United | American Academy of HIV Medicine | Association of Nurses in AIDS Care | Community Access National Network | Communities Advocating Emergency AIDS Relief (CAEAR) Coalition | Gay Men's Health Crisis | Georgia AIDS Coalition | Harlem United | Health and Disability Advocates | HealthHIV | HIVictorious, Inc. | HIV Medicine Association | HIV Prevention Justice Alliance | Housing Works | Los Angeles LGBT Center | Moveable Feast | National Alliance of State and Territorial AIDS Directors | National Minority AIDS Council | The National Working Positive Coalition | Project Inform | San Francisco AIDS Foundation | South Carolina Campaign to End AIDS | Treatment Access Expansion Project | Treatment Action Group | VillageCare