hivma
hiv medicine association

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October 31, 2011

Jeffrey Kelman, MD
Chief Medical Officer, Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-1850

Re: CMS Proposal to Improve Part D Drug Utilization Controls for Antiretrovirals

Dear Dr. Kelman:

The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposal to control payment under Medicare Part D for overutilization of certain drugs, including antiretrovirals. HIVMA represents more than 4,700 clinicians working on the frontlines of the HIV epidemic in communities across the country. One of our primary activities is to partner with IDSA on developing nationally recognized clinical practice guidelines and quality measures to promote high quality HIV care.

Antiretrovirals are the cornerstone of effective management of HIV and in conjunction with expert HIV care have led to remarkable improvements in outcomes and life expectancy for patients with HIV disease. While highly effective, HIV treatment continues to be complex and requires a combination of at least three potent agents that are prescribed according to factors unique to the individual patient, including drug resistance profiles, interactions with treatments for co-occurring conditions and medication tolerability.

In recognition of the complexity of HIV treatment and the evolving science informing it -- the National Institutes of Health convenes the Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents to maintain federal treatment recommendations reflecting the latest state of knowledge on HIV treatment.[1] These recommendations along with those maintained by the IAS-USA are widely recognized by HIV clinicians as setting the standard for HIV treatment in the U.S.[2]

We support appropriate prescribing of antiretrovirals and appreciate the need to reduce inappropriate utilization of these medications. However, it is imperative that in implementing new controls over antiretroviral drug utilization, access to treatment is not delayed or impeded in any way for patients who rely on daily access to antiretroviral therapy to maintain suppression of HIV.

[1] Available at: http://aidsinfo.nih.gov.
[2] Available at: http://www.iasusa.org/guidelines/.

CMS instituted protections for antiretrovirals in 2006 when Medicare Part D was first implemented that have been critical to our HIV patients. As one of six "classes of clinical concern" plans have been required to cover all of the drugs within the antiretroviral drug class, and in recognition of the health risks for HIV patients posed by delayed access to antiretrovirals, plans have been barred from applying any utilization management techniques, such as prior authorization or step therapy, to this drug class. We are greatly concerned by the possibility that our patients' access to antiretrovirals could be subject to the delays that they experience in accessing their non-antiretroviral medications, delays caused by the complex and lengthy prior authorization requirements and other utilization management techniques employed by Medicare Part D plan sponsors to control costs.

Implementation of beneficiary-level controls under Medicare Part D is troubling in part because a majority of Medicare Part D plans do not have a financial incentive to support appropriate management of HIV therapy since they are not responsible for costs incurred by other parts of the health care system if a beneficiary's antiretroviral therapy is poorly managed. We urge you to proceed with caution in implementing beneficiary-level controls for antiretrovirals under Medicare Part D and to consider the recommendations offered below.

1) **Set a national standard for controls rather than leaving it to the discretion of plan sponsors**. This is critical to ensure that all Medicare beneficiaries with HIV have access to the same standard of care and to ensure that the standard of care is grounded in the best available evidence on effective HIV treatment. A secondary concern with regard to allowing plan sponsors to develop utilization controls is the confusion and inefficiencies that this would create at the HIV clinic or health system level, where providers often manage Medicare beneficiaries from multiple plans.

2) **Adhere to the federal HIV treatment guidelines for adults and adolescents.** The DHHS National Institutes of Health panel maintains the guidelines as a living document because of the challenges clinicians face in staying up-to-date on advances in HIV treatment. Federal programs should support the standard of care recommended in the treatment guidelines, which recommend when to start therapy, identify preferred treatment regimens and include dosage levels.

3) **Convene an advisory group of HIV expert clinicians and scientists with representatives from the guidelines panel and national HIV medical provider associations, such as HIVMA, to review any plan guidance related to utilization control for antiretrovirals.** To avoid implementation challenges that could potentially harm Medicare beneficiaries, we strongly urge you to consult with HIV experts who care for Medicare patients for input on the potential consequences of the policy prior to finalizing plan guidance on this issue.

4) **At the plan sponsor level, ensure that any questionable HIV prescriber patterns are reviewed by HIV expert physicians.** There are many issues that can be perceived as over-utilization but are not, including complex regimens due to repeated previous virologic failure and the considerations of multiple co-morbidities. These very real extenuating circumstances can only be effectively considered by an HIV expert. HIVMA developed the following criteria for identifying qualified HIV physicians in the absence of recognition of HIV expertise by the formal bodies that govern medical board certification. The definition is supported by a significant body of evidence demonstrating that HIV treatment health outcomes and cost effectiveness is directly linked to the HIV-related experience and expertise of the medical provider.

HIVMA Definition of a Qualified HIV Physician

HIV physicians should demonstrate continuous professional development by meeting the following qualifications:

- In the immediately preceding 36 months, provided continuous and direct medical care, or direct supervision of medical care, to a minimum of 25 patients with HIV;

- In the immediately preceding 36 months has successfully completed a minimum of 40 hours of Category 1 continuing medical education addressing diagnosis of HIV infection, treatment for HIV disease and co-morbidities, and/or the epidemiology of HIV disease, and earning a minimum of 10 hours per year;

  AND

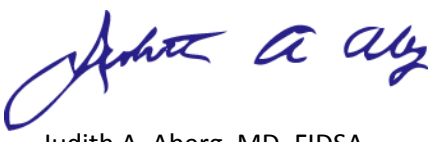
- Be board certified or equivalent in one or more medical specialties or subspecialties recognized by the American Board of Medical Specialties or the American Osteopathic Association.

  OR

- In the immediately preceding 12 months, completed recertification in the subspecialty of infectious diseases with self-evaluation activities focused on HIV or initial board certification in infectious diseases. In the 36 months immediately following certification, newly certified infectious diseases fellows should be managing a minimum of 25 patients with HIV and earning a minimum of 10 hours of category 1 HIV-related CME per year.

The Medicare programs offers lifesaving health coverage to some of our most vulnerable patients who, with advances in HIV treatment, may have lifespans approximating those of the general population but who generally qualify for coverage only after becoming disabled by AIDS. Interrupting HIV therapy not only poses serious risk for the patients themselves but also increases the risk of HIV transmissions to others. We would very much appreciate the opportunity to meet with you to discuss solutions to this issue that do not jeopardize their health. Finding a solution that does no harm is important given that the population of Medicare beneficiaries with HIV will grow as greater numbers of our patients benefiting from earlier HIV treatment qualify for Medicare based on age rather than disability. Please contact the HIV Medicine Association executive director Andrea Weddle at aweddle@hivma.org to schedule a meeting or to discuss this issue further.

Sincerely,



Judith A. Aberg, MD, FIDSA
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