

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>9-24-12</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>100084</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Keck, Singleton</i>	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____
	<input type="checkbox"/> FOIA DATE DUE _____
	<input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			



PROJECT
INFORM

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SEP 24 2012

Department of Health & Human Services
OFFICE OF THE DIRECTOR

September 18, 2012

Tony Keck
State of South Carolina
Department of Health & Human Services
1801 Main Street, PO Box 8206
Columbia, SC 29201-8206

Dear Mr. Keck,

I write regarding the recent FDA approval of Stribild, a product of Gilead Sciences, for the treatment of HIV infection and to oppose a request by the AIDS Healthcare Foundation that you require prior authorization for the use of this medication.

Project Inform is a national organization with 27 years of respected service representing the interests of people with HIV and AIDS in the drug discovery and delivery process; supporting patient education regarding HIV disease and its treatment; and advocating for unfettered access to quality, affordable health care for this population.

Project Inform is the founder of the Fair Pricing Coalition (FPC), which continues to meet with pharmaceutical companies to achieve the lowest possible pricing for newly approved HIV medications. FPC also works to ensure affordable access to HIV treatments by advocating for generous patient assistance and co-payment assistance programs. We were an active participant in FPC discussions with Gilead regarding Stribild pricing because we view it as an important addition to treatment options available to people with HIV. For many patients, Stribild offers a more effective and more easily tolerated HIV treatment regimen than other currently available single or multi-drug options. Adherence to a lifelong daily medication regimen is challenging but also key to achieving optimum health outcomes. We view Stribild as potentially very helpful to current efforts to gain further control of the epidemic by encouraging greater numbers of people with HIV and AIDS to engage in and adhere successfully to effective treatment.

Project Inform was therefore disappointed with the AWP price established by Gilead for Stribild. To be certain, other multi-drug regimens are costlier, but the price of this newly approved medication is appreciably greater than the fixed-dose regimen, Atripla. We know that state Medicaid feel the burden of all high-cost drugs, not just those that treat HIV infection, and support all efforts by Medicaid to secure the best possible price for brand and generic drugs. Nevertheless, we strongly oppose any effort to restrict beneficiary access to this medication based on its pricing.

You may recently have been contacted by the AIDS Healthcare Foundation (AHF), which is encouraging state Medicaid Directors nationally to place Stribild on prior authorization. We wish to make clear that AHF does not represent the position of the larger HIV/AIDS advocacy community on this issue. We view their request as an attack on Gilead that ignores the best interest of patients with HIV and AIDS. AHF's position is antithetical to some of the most important principles we have fought to protect through our advocacy for unfettered access to approved HIV therapies. We believe that:

- Effective treatment for HIV infection requires an individualized approach based on the person's virus type, previous treatment history, and potential for drug interactions and side effects;
- Some studies have indicated that adherence and health outcomes are improved by single fixed-dose regimens;
- Prescribers are best suited to determine which of many currently available HIV treatment regimens are best for their patients;
- Cost should not be the deciding factor in which HIV treatment regimen a patient takes. Efficacy and ability to adhere should be the determining factors;
- Access to prescribed medications should not be delayed by administrative processes;
- The cost of reviewing requests for prior authorization places its own costly administrative burden on public payers; and
- Once again, the cost of other comparably effective HIV treatment regimens that the Department of Health & Human Services has designated as 'preferred regimens' can easily be higher than Stribild.

We encourage states to use all of the mechanisms provided under the law to negotiate discounts for prescription medications, including Stribild, but to reject calls for prior authorization of this much needed medication. If you are considering AHF's request, we would ask for the opportunity to discuss this question with you.

Thank you very much for your consideration, and for your service on behalf of people living with HIV and AIDS.

Sincerely,



Dana Van Gorder
Executive Director



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