Complera Receives “Alternative” U.S. Treatment Guidelines Status

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The once-daily fixed-dose combination tablet Complera (rilpivirine plus tenofovir and emtricitabine) has been added to the U.S. Department of Health and Human Service’s antiretroviral treatment guidelines as a second-tier “alternative” option for people living with HIV starting therapy for the first time, according to an update released Friday, October 14. Other changes include the removal of both Viramune (nevirapine) and Combivir (zidovudine plus lamivudine) as alternative treatment options—both are now considered third-tier “acceptable” options—by the DHHS guidelines committee.

The DHHS’s Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents makes recommendations about the best time to start or switch therapy, the best treatments to use in various situations, ways to monitor treatment and deal with side effects and certain opportunistic infections (OIs), and a host of other issues related to ARV treatment. The guidelines were last updated in January 2011.

The addition of Complera, the second fixed-dose combination tablet containing a complete regimen active against HIV—along with Edurant, the stand-alone tablet containing rilpivirine, to be combined with other agents—is among the most notable changes in the October 2011 update. Both are listed as alternative options. Atripla is still the only first-tier “preferred” non-nucleoside reverse transcriptase inhibitor (NNRTI)–based regimen for first-time HIV treatment takers.

The reason for Complera’s listing as an alternative, as opposed to a preferred, regimen is its history of effectiveness in clinical trials. Compared with study volunteers who used Sustiva plus Truvada (often used together as Atripla), those using Edurant plus Truvada who had pre-treatment viral loads in excess of 100,000 copies were more likely to see their viral loads rebound while on therapy. Clinical trial participants using Edurant plus Truvada were also more likely to develop drug resistance to other NNRTIs—including Sustiva (efavirenz), Intelence (etravirine) and Viramune (nevirapine)—and Truvada, compared with those using Sustiva plus Truvada.

“Based on limited data on durability of treatment responses (48 weeks) and the lower virologic response compared with [Sustiva] in patients with high pretreatment viral loads, the [guidelines] panel recommends [Complera] as an alternative regimen for initial therapy,” the authors state. “Caution should be exercised when using [rilpivirine] in patients with [viral loads greater than] 100,000 copies/mL, given the higher [rilpivirine] virologic failure rates and the greater probability

of [etravirine] resistance at the time of failure observed in this population during clinical trials."

Across the board, however, Edurant plus Truvada was comparable to Sustiva plus Truvada in terms of maintaining viral loads below the level of detection, all the while causing fewer serious side effects, notably central nervous system problems.

Other changes in NNRTI recommendations include all Viramune-based regimens being reclassified as acceptable options for people starting HIV treatment for the first time, despite the fact that a new formulation of nevirapine called Viramune XR allows for once-daily dosing. Previously, Viramune plus Combivir was classified as an alternative regimen.

Combivir, the first approved tablet containing two nucleoside reverse transcriptase inhibitors (NRTIs), has been reclassified from an alternative dual-NRTI option to an acceptable option because the combination has greater toxicities compared with Truvada and Epzicom (abacavir plus lamivudine) and requires twice-daily dosing. However, Combivir remains the preferred dual-NRTI for pregnant women receiving ARV therapy.

Other key recommendations, such as when to start or switch HIV treatment, remain unchanged.

For a complete review of these recommendations, see our updated "When to Start and What to Start With" lesson page.

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