Blind to the Cost

Oral ganciclovir to prevent CMV

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Preliminary results of a recent study sponsored by Syntex Corporation show that preventative treatment with an oral formulation of ganciclovir reduces the incidence of cytomegalovirus (CMV) by about 50 percent among people with AIDS and may prolong their survival. Infection with CMV—a herpesvirus that is frequently present in people with HIV—most commonly strikes the eye, where it can cause blindness, the colon, where it can cause debilitating diarrhea and the esophagus. In the study of people with less than 50 CD4 cells (or less than 100 CD4 cells and a previous AIDS-defining infection), an interim analysis showed that 16 percent of those taking oral ganciclovir developed some CMV disease compared to 30 percent of those on placebo. Due to the significant benefit noted, an independent review board halted the trial and ganciclovir was offered to all participants.

Syntex, which was recently purchased by Hoffmann-La Roche, has an application before the Food and Drug Administration (FDA) to use oral ganciclovir as maintenance therapy for people who have already been treated for an episode of CMV retinitis. Once the oral formulation is approved for maintenance therapy, doctors could prescribe it for prophylaxis as well, but insurers usually will not reimburse patients for such “off-label” use of a drug. This is significant because CMV prophylaxis with the oral formulation of ganciclovir is expected to cost $24,000 a year. *AIDS Alert* reports that the high cost (and fear of creating resistance to the drug) recently kept officials at the Centers for Disease Control and Prevention (CDC) from recommending oral ganciclovir for prevention of CMV as part of new guidelines for prophylaxis against opportunistic infections. Instead they encourage people with AIDS to monitor any changes in their field of vision and see their ophthalmologists regularly.

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