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AIFA approves reimbursability of drugs for pre-exposure prophylaxis to HIV-1 (PrEP)

With Resolution of the BoD No. 15 of 26 April 2023, the Italian Medicines Agency admits the reimbursability of the association Emtricitabine/Tenofovir Disoproxil for "Pre-exposure prophylaxis (PrEP) and with a view to reducing the risk of sexually transmitted HIV-1 infection in adults and adolescents at high risk". It is an additional prevention tool for HIV-negative people with high-risk sexual behaviours and a measure of significant impact on public health.

The Agency has therefore accepted the proposal made by the Section for the fight against AIDS of the Technical Health Committee of the Italian Ministry of Health, sharing its general approach, the criteria for patient selection and the overall strategy of taking charge.

The infectious disease specialist can prescribe the therapy, after filling in a prescription form containing the inclusion and exclusion criteria to the treatment and the main characteristics of the taking charge and monitoring programme. The treatment is only distributed by hospital pharmacies.

The measure will enter into force on the day following its publication in the Official Gazette.