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Kaftrio, AIFA committed to quickly concluding the assessment of reimbursement for new indications

The Italian Medicines Agency, aware of the importance of treating a serious and complex disease such as cystic fibrosis, is working to ensure that patients have the best treatment options while respecting the sustainability of the National Health Service.

The Agency is currently evaluating the reimbursement of new therapeutic indications for the medicine Kaftrio in combination with Kalydeco (ivacaftor), targeting all CFTR gene mutations underlying the different clinical manifestations of the disease. These mutations affect a large number of patients. This is a highly anticipated therapeutic extension, which at the same time has a significant impact on pharmaceutical expenditure.

The Scientific and Economic Committee for Medicines (CSE) of the Italian Medicines Agency (AIFA), which received the dossier from the pharmaceutical company that owns the medicine in July 2025, is working on the preliminary investigation for the extension of the indications covered by the National Health Service. The successful outcome of the procedure will depend on the willingness of the company that owns the medicine to reach a rapid conclusion to the reimbursement assessment process in the interests of patients.