Feinstein announces submission of new drug application for diagnosing parkinsonian syndromes

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The Feinstein Institute for Medical Research announced today the submission of a New Drug Application to the US Food and Drug Administration (FDA) for the Fluorodopa F 18 positron emission tomography (PET) scan used to diagnose parkinsonian syndromes. Earlier this year, the Feinstein Institute received FDA approval under an Expanded Access Investigational New Drug (IND) program, permitting the Feinstein Institute to receive reimbursement for the use of the diagnostic tool in clinical research studies. This was the first time the FDA approved payment for Fluorodopa F 18 PET studies in parkinsonian syndromes.

The Fluorodopa F 18 PET scan, also known as FDOPA PET scan, is a simple yet powerful, noninvasive diagnostic tool that allows for the early diagnosis and proper medical management of patients with symptoms of Parkinson's disease. Parkinsonian syndromes, such as decreased body movements, stiffness or rigidity, tremors or shaking of hands, are either caused by Parkinson's disease or by some other medical conditions, including Huntington's disease or drug use. It is important to differentiate if a patient has parkinsonian syndromes or Parkinson's disease because the symptoms are identical, but non-Parkinson's disease patients will not respond to typical Parkinson's disease medications. Many patients who do not have Parkinson's disease but do have parkinsonian syndromes endure unnecessary, potentially harmful treatment that ultimately doesn't alleviate their symptoms long term.

Patients with Parkinson's disease have demonstrated a low level of the neurotransmitter dopamine in the brain. The drug Fluorodopa F 18, a sterile solution, is used with PET to visualize the distribution of dopamine in the brain, and therefore may be used to confirm the diagnosis of Parkinson's disease and to follow the rate of disease progression.

The Feinstein Institute has been using Fluorodopa F 18 PET scan for the last 20 years under the leadership of David Eidelberg, MD, Thomas Chaly, PhD, and Vijay Dhawan, PhD. It is under the leadership of Dr. Chaly that the Feinstein Institute achieved the FDA approval of the Expanded Access IND with payment and the submission of a NDA for Fluorodopa F 18 Injection. The Feinstein Institute is the first and only research institute to receive approval from the FDA to use FDOPA PET scan under an Expanded Access IND program, allowing Feinstein Institute researchers and doctors to use the diagnostic tool in clinical research studies and receive reimbursement.

"We submitted a full New Drug Application for FDOPA PET scan, as we believe this will provide national recognition for an important diagnostic," said Dr. Chaly. "The FDOPA PET scan, if approved, has the potential to improve the quality of life for patients with parkinsonian symptoms by thwarting unnecessary costs and side effects from treatments."

Provided by North Shore-Long Island Jewish Health System