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OVERVIEW

Dopamine transporter imaging with single-photon emission computed tomography (DAT-SPECT) is being evaluated to improve the differential diagnosis of parkinsonian syndromes from non parkinsonian tremor and of dementia with Lewy bodies (DLB) from Alzheimer disease.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

not applicable

POLICY STATEMENT

Dopamine transporter imaging with single photon emission computed tomography (DAT-SPECT) is not medically necessary for all indications, including but not limited to the following as the evidence is insufficient to determine the effects of the technology on health outcomes:

- aiding in the diagnosis of patients with clinically uncertain parkinsonian syndromes; OR
- distinguishing between parkinsonian syndromes and essential tremor; OR
- distinguishing between dementia with Lewy bodies and Alzheimer disease; OR
- monitoring of disease progression

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

Parkinsonian syndromes (PS) are a group of diseases that share similar cardinal signs, characterized by bradykinesia, rigidity, resting tremor, and gait disturbance. Parkinson disease (PD) is the most common cause of parkinsonism; however, diagnosing PD in the early stage of the disease can be difficult. In addition, other etiologies such as essential tremor (ET), corticobasal degeneration, multisystem atrophy, progressive supranuclear palsy, vascular parkinsonism, and drug-induced parkinsonism can lead to a similar set of symptoms. Even in specialized movement disorders centers, up to 25% of patients may be misclassified, and some patients, such as those with ET who have been diagnosed with PD, may be erroneously treated. This has led to the development of additional tests to improve the accuracy of clinical diagnosis of PD and other PSs. One recent approach is to evaluate the integrity of dopaminergic pathways in the brain using dopamine transporter single-photon emission computed tomography (DAT-SPECT).

In 2011, the FDA approved the diagnostic radiopharmaceutical I-123 ioflupane (DaTscan, GE Healthcare) for dopamine transporter imaging. The main use for the radiopharmaceutical is to allow for better separation of patients with essential tremor from those with pre-synaptic Parkinsonian syndromes, as well as differentiating between some causes of parkinsonism

For individuals who have clinically uncertain Parkinson disease who receive DAT-SPECT, the evidence includes a number of studies from Europe, where a ligand has been available for over a decade. Relevant outcomes are test accuracy, symptoms, and functional outcomes. In terms of technical performance, the ligand is specific for the striatal dopamine transporter, and studies indicate reliability in assessment of the images when performed by experienced readers. Studies of diagnostic accuracy report good specificity for confirming nigrostriatal degeneration, with less sensitivity for ruling out disease; these findings are dependent, however, on a reference standard (clinical diagnosis), which may be flawed, and it is unknown whether DAT-SPECT would show greater sensitivity when compared to the criterion standard of histopathologic diagnosis. Evidence on clinical utility includes a randomized controlled trial (RCT) that showed more patients evaluated with DAT-SPECT have changes in diagnosis and management than controls without imaging; however, there is limited evidence to evaluate whether these changes improve health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have clinically uncertain dementia with DLB who receive DAT-SPECT, the evidence includes studies on diagnostic accuracy and its effect on diagnosis and confidence in diagnosis. Relevant outcomes are test accuracy, symptoms, and functional outcomes. For discriminating between DLB and Alzheimer disease, the sensitivity and specificity of DAT-SPECT is somewhat lower than for parkinsonian syndromes, although the comparison standard used in the available studies may be flawed. There are few patients who have been evaluated with histopathology as the reference standard. Evidence on clinical utility includes an RCT that indicates that DAT-SPECT can influence diagnosis of DLB, particularly when the scan is abnormal. It cannot be determined from this study whether the revised diagnosis was more accurate or resulted in a beneficial change in patient management. The evidence is insufficient to determine the effects of the technology on health outcomes.

DaTscan™ (GE Healthcare) has been in use in Europe since 2000 with a diagnostic indication for use in parkinsonian patients and with expanded use since 2006 in patients suspected of DLB. In 2011, DaTscan™ was approved by the U.S. Food Drug Administration (FDA) through a new drug application and is “indicated for striatal dopamine transporter visualization using single-photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected parkinsonian syndromes (PS). In these patients, DaTscan™ may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease, multiple system atrophy and progressive supranuclear palsy). DaTscan™ is an adjunct to other diagnostic evaluations.”⁴ FDA product code: KPS.

CODING

The following code is not medically necessary as this radiopharmaceutical is used for DaTscan:
A9584 – Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries.

RELATED POLICIES

None

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