July 23, 2019

Chasity Sennette, RN, BSN
Anthem, Inc.
Medical Policy Analyst Sr.
Office of Medical Policy and Technology Assessment

(Comments submitted electronically)


Dear Ms. Sennette:

The American College of Radiology (ACR)\(^1\) Commission on Nuclear Medicine and Molecular Imaging is writing to comment on a recent request received to review the RAD.00023 medical policy. We affirm that I-123 Ioflupane DaTscan single-photon emission computed tomography (SPECT) is not investigational and there is sufficient evidence to prove its value. DaTscan was approved by the US Food and Drug Administration (FDA) in 2011 to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS) to help differentiate essential tremor (ET) from PS. It is also approved by the FDA based on published results that indicate a high sensitivity and specificity of DaTscan for the detection of abnormalities of the substantia nigra associated with clinical disorders and is indicated for striatal dopamine transporter visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS) (idiopathic Parkinson's disease (PD), multiple system atrophy (MSA) and progressive supranuclear palsy (PSP)). In these patients, DaTscan may be used to help differentiate ET from tremor due to PS.

Although DaTscan is an adjunct to other diagnostic tools, it was not designed to distinguish among PD, MSA, and PSP. The effectiveness of the DaTscan as a screening test and for monitoring disease progression or response to therapy has not been established.\(^2\)

Moreover, the results from four large, multisite efficacy trials, entailing a total of 764 patients formed the scientific basis for the FDA’s approval of DaTscan. All four studies were open-label, non-randomized, phase 3 or 4 clinical trials to determine the sensitivity and specificity of DaTscan SPECT to detect or exclude participants with PS or ET and/or dementia with Lewy bodies (DLBD), Alzheimer disease (AD) or vascular dementia), compared with healthy volunteers, using clinical diagnosis as the

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1. The American College of Radiology (ACR) is a professional organization representing more than 38,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. The ACR, founded in 1924, is a professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science, and professions of radiologic care.

gold standard. A pooled analysis of the four studies in 2014 found that when images were assessed by on-site readers, DaTscan had a sensitivity of 92% and specificity of 84%.  

In addition, peer-reviewed literature shows that DaTscan leads to a change of diagnosis in 31–50% of patients and changes in care management for 52%-58% of patients. Effectiveness was expressed as the projected years on potentially beneficial therapy (PBTYs). The research suggests that over 5 years, the current clinical diagnostic pathway generated an average of 2.3 PBTYs/patient and the addition of DaTscan SPECT generated an average of 4.1 PBTYs/patient while decreasing the diagnostic costs by approximately 5%.  

A multidisciplinary panel of experts was convened to develop clinical criteria and algorithms to help guide clinicians and managed care organizations with the application of DaTscan. Based on the consensus of this expert panel, appropriate use of DaTscan includes cases where: (1) PD diagnosis is uncertain; (2) tremor of uncertain etiology is present; and (3) nonmotor and/or supportive symptoms and features associated with PD are present but the classical motor syndrome is absent or atypical.

According to the 2017 ACR-ACNM Practice Parameter for the Performance of Dopamine (DaT) Transporter SPECT Imaging for Movement Disorders, DaTscan was developed with SPECT to visualize the amount of DaT in the striatum. Therefore, DaTscan SPECT can be used not only for the objective confirmation of presynaptic nigrostriatal degeneration but also for the early differential diagnosis of PS from non-neurodegenerative disorders, such as essential tremor ET and drug-induced tremor. In addition, DaTscan is valuable to differentiate between Alzheimer disease AD and dementia with Lewy bodies (DLB), with normal uptake in AD and decreased DaT uptake in DLB. Additional, clinical indications for DaT SPECT imaging are included.

It is crucial that the appropriate therapeutic drugs are administered based on the patient's underlying condition. Some therapies may have unintended side effects, which can potentially be avoided when diagnostic agents, such as DaTscan, are appropriately used to further refine the patients’ diagnosis. These tests strengthen the physician's patient management and treatment choices, which allows the patient to receive the best care possible.

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We appreciate the opportunity to comment and look forward to working with you to update your medical policy. Please contact Alicia Blakey, Sr. Economic Policy Analyst at (703) 648-8923 or via email at ablakey@acr.org with any questions.

Sincerely,

[Signature]

Don C. Yoo, MD, FACR
Chair, ACR Commission on Nuclear Medicine and Molecular Imaging
American College of Radiology

[Signature]

William T. Thorwarth, Jr., MD, FACR
Chief Executive Officer
American College of Radiology

Enclosed: DaTscan Package Insert