Corporate Medical Policy

Dopamine Transporter Imaging with Single Photon Emission Computed Tomography

File Name: dopamine_transporter_imaging_with_single_photon_emission_computed_tomography
Origination: 9/2012
Last CAP Review: 5/2018
Next CAP Review: 5/2019
Last Review: 5/2018

Description of Procedure or Service

Parkinsonian syndromes are a group of diseases that share similar cardinal signs, characterized by bradykinesia, rigidity, resting tremor and gait disturbance. Parkinson’s 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, 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 essential tremor who have been diagnosed with PD, may be erroneously treated. This has led to the development of additional tests and biomarkers to improve the accuracy of clinical diagnosis of PD and other parkinsonian syndromes. One recent approach is to evaluate the integrity of dopaminergic pathways in the brain with DAT-SPECT.

Dopamine transporter imaging with single-photon emission computed tomography (DaT-SPECT), using radiopharmaceutical ioflupane injection, is a neuro-imaging modality being evaluated to improve the differential diagnosis of parkinsonian syndromes from nonparkinsonian tremor, as well as dementia with Lewy bodies from Alzheimer disease. DaT-SPECT is based on the selective affinity of dopamine transporter ligands for dopamine synthesizing neurons, which allows visualization of deficits in the nigrostriatal dopaminergic pathway. Binding of ligands with affinity and specificity for dopamine transporter ligands in the striatum is, in general, reduced in PD, genetic parkinsonism, dementia with Lewy bodies, corticobasal degeneration, progressive supranuclear palsy, and multiple system atrophy. In contrast striatal DaT ligand binding is expected to be within the normal range in Alzheimer disease., essential tremor, dystonic tremor, orthostatic tremor, drug-induced parkinsonism, psychogenic parkinsonism, and vascular parkinsonism. There are, however, a significant percentage of patients with clinically diagnosed PD who do not show reduced DAT-SPECT binding. These are commonly referred to as scans without evidence of dopaminergic deficit, or SWEDD. Additional research may shed light on these cases.

Analysis of DAT-SPECT images can be visual or semi-quantitative or quantitative. Because patients typically do not become symptomatic before a substantial number of striatal synapses have degenerated, visual interpretation of the scan is thought to be sufficient for clinical evaluation. A variety of methods are being tested to improve the validity and reliability of ratings, including commercially available software to define the region of interest (ROI) for analysis and the development of an atlas for visual interpretation.

Regulatory Status
DaTscan™ (GE Healthcare) was approved by the U.S. Food and Drug Administration (FDA) in 2011 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. In these patients, DaTscan may be used to help
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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.”

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Dopamine transporter imaging with single photon emission computed tomography (DAT-SPECT) is investigational for all indications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Dopamine transporter imaging with single photon emission computed tomography is covered

Not applicable.

When Dopamine transporter imaging with single photon emission computed tomography is not covered

Dopamine transporter imaging with single photon emission computed tomography (DAT-SPECT) is investigational for all indications, including but not limited to:

- 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’s disease, OR
- monitoring of disease progression.

Policy Guidelines

For individuals who have clinically uncertain Parkinson disease who receive DaT-SPECT, the evidence includes randomized controlled trials, cohort studies, and case series studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Studies of technical validity have shown good interobserver reliability in interpreting images. In populations with clinically apparent Parkinson disease, studies of diagnostic accuracy have reported high sensitivity and specificity for Parkinson disease. Studies of clinical validity in the target population of clinically uncertain Parkinson disease have reported moderate sensitivity and high specificity. These findings are dependent on a reference standard (clinical diagnosis over time), and it is unknown whether DAT-SPECT would show greater sensitivity when assessed by the criterion standard (histopathologic diagnosis). Evidence on clinical utility in the target population includes a randomized controlled trial showing no significant difference in outcomes over time between patients who received a DaT-SPECT scan and those who did not. The evidence is insufficient to determine the effects of this technology on health outcomes.

For individuals who have clinically uncertain dementia with Lewy bodies who receive DaT-SPECT, the evidence includes randomized control trials, cohort studies, and case series studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Relative
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to the criterion end point of histopathology, DaT-SPECT has lower sensitivity and higher specificity than expert clinical diagnosis in patients with likely dementia with Lewy bodies. No such studies have been performed in the target population of clinically uncertain dementia with Lewy Bodies. No studies have directly evaluated the effect of DaT-SPECT imaging on health outcomes in the target population. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

The SPECT exam would be reported using CPT code 78607

There is a specific HCPCS code for DaTscan: A9584

Diagnoses that are subject to medical necessity review:

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


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10/16/12 New policy issued. Dopamine transporter imaging with single photon emission computed tomography (DAT-SPECT) is investigational for all indications, including but not limited to, aiding in the diagnosis of patients with clinically uncertain parkinsonian syndromes, essential tremor, or dementia with Lewy bodies, and for the monitoring of disease progression. Medical Director review 10/2012. Notification given 10/16/12 for policy effective date of 1/15/13. (sk)

2/12/13 Added diagnosis codes 331 – 333.99 to Billing/Coding section. (sk)

7/1/13 ICD-10 diagnosis codes added to Billing/Coding section. (sk)

9/10/13 Reference added. No change to Policy guideline. (sk)

8/12/14 Specialty Matched Consultant Advisory Panel review 7/29/14. Removed effective date 10/1/2014 from ICD-10 list. No change to Policy statement. (sk)

10/14/14 Reference added. No change to Policy statement. (sk)

3/10/15 Added diagnosis code 781.0; as well as ICD-10 diagnosis codes: R25.0, R25.1, R25.2, R25.3, R25.8, R25.9 to the Billing/Coding section. (lp)

7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lp)

1/26/16 Reference added. Added Alzheimer’s disease to list of “including but not limited to” investigational indications under “When Not Covered” section. Sr. Medical Director review 11/2015. (lp)

7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (an)

11/22/16 Reference added. (an)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. No change to policy statement. (an)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.