Corporate Medical Policy

Dopamine Transporter Imaging with Single Photon Emission Computed Tomography

File Name: dopamine_transporter_imaging_with_singlePhoton_emission_computed_tomography
Origination: 9/2012
Last CAP Review: 5/2017
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Description of Procedure or Service

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

Background

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 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.

DAT-SPECT detects presynaptic dopaminergic deficit by measuring dopamine transporter (DAT) binding. In general, striatal DAT binding is reduced in PD, genetic parkinsonism, dementia with Lewy bodies (DLB), corticobasal degeneration, progressive supranuclear palsy, and multiple system atrophy, while striatal DAT binding is in the normal range in Alzheimer’s disease, essential tremor, dystonic tremor, orthostatic tremor, drug-induced parkinsonism, psychogenic parkinsonism, and vascular parkinsonism. It is proposed that an abnormal DAT-SPECT supports the diagnosis of PD or other neurodegenerative parkinsonian syndrome (multisystem atrophy, progressive supranuclear palsy), while a normal DAT-SPECT in a symptomatic patient increases the likelihood of a disease not affecting the nigrostriatal dopaminergic pathway. 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.

Due to the degeneration of nigrostriatal neurons in DLB, DAT-SPECT is also proposed to differentiate DLB from Alzheimer’s disease. Some note a severe sensitivity to neuroleptics (potentially life-threatening) in patients with DLB. However, newer agents are usually well-tolerated, and patients with DLB may also respond to the cholinesterase inhibitors that are more commonly used to treat Alzheimer’s disease.

Analysis of DAT-SPECT images can be visual or semi-quantitative or quantitative. Since 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.
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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. Quantitative interpretation may aid visual interpretation and, if performed rigorously, may increase diagnostic accuracy; however, interobserver variability tends to be high with manual ROI based semi-quantification. Semi-quantitative analysis also requires normal control values and varies across imaging systems.

Dopamine transporter ligands include $^{123}$I-β-CIT, $^{123}$I-FP-CIT, and $^{99m}$Tc-TRODAT-1. $^{123}$I-β-CIT requires a delay between injection and scan of about 24 hours. $^{123}$I-FP-CIT (DaTscan) is a fluoropropyl derivate of β-CIT that can be injected 3-6 hours before the scan.

**Regulatory Status**
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. DaTscan was approved by the U.S. Food and Drug Administration (FDA) in 2011 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.”

**Related Guidelines**
Deep Brain Stimulation

***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
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- distinguishing between dementia with Lewy bodies and Alzheimer’s disease, OR
- monitoring of disease progression.

**Policy Guidelines**

DAT-SPECT is being evaluated to improve the differential diagnosis of PS from non-parkinsonian tremor and of DLB from Alzheimer’s disease. Most of the available literature is from Europe, where a ligand has been available for over a decade. 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.

For diagnosing Parkinson’s disease in patients with parkinsonian symptoms, 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 with the criterion standard of histopathological diagnosis. Evidence on clinical utility includes a randomized controlled trial that showed more patients evaluated with DAT-SPECT have changes in diagnosis and management compared to controls without imaging, however, no improvement in quality of life was observed within the 1-year follow-up. In other studies, DAT-SPECT findings are consistent with about 90% of diagnoses made by specialists in movement disorders and that in a relatively small proportion of patients, the diagnosis has been altered based on DAT-SPECT.

For discriminating between DLB and Alzheimer’s disease, the sensitivity and specificity of DAT-SPECT is somewhat lower than for PS, although the comparison standard used in the available studies may be flawed. One retrospective community-based study suggests that DAT-SPECT may influence the clinical diagnosis and management of a large proportion of patients with possible DLB.

Overall, the evidence available at this time is insufficient to determine with certainty the effect of this technology on health outcomes. Therefore, DAT-SPECT is considered investigational.

**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: 331 – 333.99, 781.0*


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.
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**Scientific Background and Reference Sources**

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**Policy Implementation/Update Information**

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