MASSACHUSETTS

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Medical Policy

Dopamine Transporter Imaging with Single Photon Emission Computed Tomography

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Policy Number: 918

BCBSA Reference Number: 6.01.54 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Deep Brain Stimulation, #473

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Dopamine transporter imaging with single-photon emission computed tomography may be considered **MEDICALLY NECESSARY** when used for individuals with:

- clinically uncertain Parkinson disease; or
- clinically uncertain dementia with Lewy bodies.

Use of dopamine transporter imaging with single-photon emission computed tomography is considered **INVESTIGATIONAL** for all other indications not included above.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS code above if medical necessity criteria are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance
F02.811	Dementia in other diseases classified elsewhere, unspecified severity, with agitation
F02.818	Dementia in other diseases classified elsewhere, unspecified severity, with other behavioral disturbance
G20.A1	Parkinson's disease without dyskinesia, without mention of fluctuations
G20.A2	Parkinson's disease without dyskinesia, with fluctuations
G20.B1	Parkinson's disease with dyskinesia, without mention of fluctuations
G20.B2	Parkinson's disease with dyskinesia, with fluctuations
G20.C	Parkinsonism, unspecified
G21.9	Secondary parkinsonism, unspecified
G31.83	Dementia with Lewy bodies
R25.0	Abnormal head movements
R25.1	Tremor, unspecified
R25.8	Other abnormal involuntary movements
R25.9	Unspecified abnormal involuntary movements
R26.0	Ataxic gait
R26.2	Difficulty in walking, not elsewhere classified
R26.89	Other abnormalities of gait and mobility
R26.9	Unspecified abnormalities of gait and mobility
R41.89	Other symptoms and signs involving cognitive functions and awareness
R41.9	Unspecified symptoms and signs involving cognitive functions and awareness

Description

Parkinsonian Syndromes

Parkinsonian syndromes 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.

Despite the well-known symptoms of PD, diagnosis is challenging even for experienced clinicians, particularly in the early stages of the disease. In addition, other etiologies such as essential tremor, corticobasal degeneration, multiple system atrophy, progressive supranuclear palsy, vascular parkinsonism, and drug-induced parkinsonism can lead to a similar set of symptoms. One recent approach to improve the accuracy of clinical diagnosis of PD and other parkinsonian syndromes is to evaluate the integrity of dopaminergic pathways in the brain using dopamine transporter imaging with single-photon emission computed tomography (DaT-SPECT) imaging.

Dementia with Lewy Bodies

Dementia with Lewy bodies is a type of dementia characterized by parkinsonism, visual hallucinations, cognitive fluctuation, sleep disorders, and severe neuroleptic sensitivity. Dementia with Lewy bodies is the second most common form of degenerative dementia; Alzheimer disease, which can have similar symptoms at onset, is the most common.

Diagnosis can be challenging, particularly when patients have multiple comorbidities including cerebrovascular disease and/or Alzheimer disease.[1] As with PD, dementia with Lewy bodies is characterized by the degeneration of nigrostriatal neurons; as such, DaT-SPECT is also proposed to differentiate dementia with Lewy bodies from Alzheimer disease.

DaT-SPECT

DaT-SPECT is based on the selective affinity of dopamine transporter (DaT) ligands for dopamine-synthesizing neurons, which allows visualization of deficits in the nigrostriatal dopaminergic pathway.

DaT ligands include iodine 123I-2β-carbomethoxy-3β-(4-iodophenyl) tropane (^{123}I-β-CIT), which is a cocaine analogue with an affinity for both dopamine and serotonin transporters. Intravenous ^{123}I-β-CIT requires a delay between injection and scan of about 24 hours. Iodine-123 N-(3-fluoropropyl)-2β-carbomethoxy-3β-(4-iodophenyl) nortropane (^{123}I-FP-CIT) is a fluoropropyl derivate of β-CIT that is selective for brain striatal DaT but can also bind to the serotonin transporter. Intravenous ^{123}I-FP-CIT can be injected 3 to 6 hours before the scan (DaTscan). Other SPECT ligands with affinity for dopamine transporter include technetium 99m (2β((N,N¢-bis(2-mercaptoethyl) ethylene diamino)methyl) and 3β-(4-chlorophenyl) tropane (^{99m}Tc-TRODAT-1).[2,3]

Binding of ligands with an affinity for DaT 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 of Alzheimer disease, essential tremor, dystonic tremor, orthostatic tremor, drug-induced parkinsonism, and psychogenic parkinsonism.[2]

Visualization of striatal dopamine transporter binding, through DaT-SPECT, permits assessment of presynaptic dopaminergic deficit. It is proposed that an abnormal DaT-SPECT scan supports the diagnosis of PD, dementia with Lewy bodies, or other neurodegenerative parkinsonian syndromes, while a normal DaT-SPECT scan in a symptomatic patient supports the diagnosis of a disease not affecting the nigrostriatal dopaminergic pathway.

Analysis of DaT-SPECT images can be visual, semiquantitative, or quantitative. In patients with PD, physical symptoms start after 30% to 50% of dopaminergic neurons have degenerated.[4,5] Symptomatic patients with PD would be thus expected to have sufficient abnormality on DaT-SPECT for visual analysis to be adequate for interpretation. 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 for analysis and the development of an atlas for visual interpretation. Several research centers are developing quantitative and semiquantitative classification methods for the evaluation of DaT-SPECT images.[6,7,8,9]

Anatomic variation in the brain, including vascular lesions, may interfere with the distribution of the iodine-123 tracer and could result in an abnormal scan.[10] Dopamine agonists and levodopa may also affect DaT expression, which could influence the ability of DaT-SPECT to monitor the progression of disease unless these agents are discontinued prior to imaging. Patients with clinically diagnosed PD or dementia with

Lewy bodies, who present with a normal DaT-SPECT scan, are referred to in the literature as having "scans without evidence of dopaminergic deficit." While many of these patients are ultimately diagnosed with non-PD syndromes, a portion of patients with normal DaT-SPECT imaging are confirmed to have PD or dementia with Lewy bodies by the reference standard. In studies where clinical diagnosis is used as an endpoint, scans without evidence of dopaminergic deficit are present in 3% to 20% of PD patients.[11,] In a study of patients clinically diagnosed with dementia with Lewy bodies, van der Zande et al (2016) found that 10% of these patients had normal scans.[12,] Further research may shed light on these cases.

Summary

Dopamine transporter imaging with single-photon emission computed tomography (DaT-SPECT), using radiopharmaceutical ioflupane injection, is a neuroimaging modality being evaluated to improve the differential diagnosis of parkinsonian syndromes from nonparkinsonian tremor, as well as dementia with Lewy bodies from Alzheimer disease.

Summary of Evidence

For individuals who have clinically uncertain Parkinson disease (PD) who receive dopamine transporter imaging with single-photon emission computed tomography (DaT-SPECT) , the published evidence includes randomized controlled trials (RCTs) , cohort studies, and case series studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. In populations with clinically apparent PD, studies of diagnostic accuracy have reported high sensitivity and specificity for PD. Studies of clinical validity in the target population of clinically uncertain PD are limited by gaps in study design, conduct, and relevance. Evidence on clinical utility in the target population includes an RCT 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 that the technology results in an improvement in the net health outcome.

For individuals who have clinically uncertain dementia with Lewy bodies who receive DaT-SPECT, the published evidence includes RCTs, cohort studies, and case series studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. No studies with the optimal reference standard to assess clinical validity have been performed in the target population of clinically uncertain dementia with Lewy bodies. No studies have directly evaluated the effect of DaT-SPECT on health outcomes in the target population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
12/2023	Annual policy review. No references added. Policy statements unchanged.
10/2023	Clarified coding information.
12/2022	Annual policy review. No references added. Policy statements unchanged.
10/2022	Clarified coding information.
12/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Clarified coding information.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. New medically necessary indications described for clinically uncertain Parkinson disease and clinically uncertain dementia with Lewy bodies. Clarified coding information. Effective 4/1/2019.
11/2017	Annual policy review. New references added.
10/2016	Annual policy review. New references added.
1/2016	Annual policy review. New references added.
12/2015	Added coding information.
9/2014	Annual policy review. New references added.

10/2013	Annual policy review. New references added.
2/2013	New policy describing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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