

DaTscan (123I-Ioflupane) for Diagnosis of Parkinson's Disease

Policy Number: **M20140521032**
Effective Date: **7/1/2014**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: Internal External

Data Classification: Confidential Restricted Public

Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s): MediSource; MediSource Connect; Child Health Plus; Essential Plan
- Medicare, if yes, which plan(s): MAPD; PDP; ISNP; CSNP
- Commercial, if yes, which type: Large Group; Small Group; Individual
- Self-Funded Services (*Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.*)

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes No

Purpose and Applicability:

To set forth the the criteria for the use of DaTscan testing in individuals with suspected Parkinson's Disease (PD).

Policy:

Commercial, Self-Funded and Medicare Advantage:

DaTscan is covered to evaluate adult members with suspected Parkinson Syndromes (PS) to differentiate essential tremor from tremor due to PD. The DaTscan ordering provider is required to be a neurologist.

The member is required:

1. To complete a thorough neurologic exam by a neurologist prior to DaTscan testing; and
2. To complete and fail a trial of appropriate medications for PD or for essential tremor prior to DaTscan testing.

Indications:

1. To differentiate essential tremor from tremor due to PD.
2. DaTscan is considered an adjunct to other diagnostic evaluations.

Contraindications:

1. Pregnancy.
2. Inability to cooperate with SPECT or SPECT/CT brain imaging.
3. A known hypersensitivity to ¹²³I-ioflupane or any of its excipients.
4. Breastfeeding is considered a relative contraindication as it is not known if ¹²³I-ioflupane is excreted into human breast milk.

DaTscan is not covered to monitor disease progression or response to therapy.

MediSource, MediSource Connect and Essential Plan:

MediSource, MediSource Connect and Essential Plan cover DaTscan utilizing the criteria above.

Child Health Plus:

DaTscan is intended for use in adults, therefore it would not be utilized for a Child Health Plus member.

Background:

DaTscan is used to detect the loss of nerve cells in area of the brain that releases dopamine. It assists in the diagnosis of movement disorders such as Parkinson's disease where the loss of nerve cells leads to tremor, gait disturbance and muscle stiffness. Because tremor may also occur in essential tremor, DaTscan is used to distinguish between essential tremor and diseases related to Parkinson's disease.

The active substance in DaTscan, ¹²³I-ioflupane, is a radiopharmaceutical which, when injected into the body, attaches to the structures that transport dopamine. The scan is then viewed using single photon emission computed tomography (SPECT), detecting the radioactive ¹²³I-ioflupane. In Parkinson's disease, the amount of dopamine containing nerve cells is reduced, which may then be viewed on the scan. Parkinson's disease may be difficult to diagnose due to its progression and characteristics shared by numerous disorders. Misdiagnosis may result in inappropriate therapies with consequent adverse effects, inappropriate testing, and diagnosis delays.

In the UpToDate report titled Diagnosis and differential diagnosis of Parkinson disease it states "Striatal dopamine transporter imaging using 123I-FP-CIT single-photon emission computed tomography

(DaTscan) can reliably distinguish patients with PD and other parkinsonian syndromes associated with nigrostriatal degeneration (i.e., MSA, PSP, and corticobasal degeneration [CBD]) from controls or patients with essential tremor (ET), but it cannot differentiate PD and the other parkinsonian syndromes from one another.”

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes No

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

DaTscan is a diagnostic radiopharmaceutical containing the active substance 123I-N-3-fluoropropyl-2 β -carbomethoxy-3 β -(4-iodophenyl) nortropine, also referred to as 123I-ioflupane. Ioflupane has a high binding affinity to the dopamine transporter (DAT) protein located on presynaptic dopaminergic neurons, particularly in the nigrostriatal region of the brain. Radioiodination of ioflupane with the isotope 123I permits visualization of the product using a gamma camera capable of single photon emission computed tomography (SPECT). The pattern of reabsorption can help differentiate essential tremor from tremor due to PD.

Parkinson’s Disease (PD), one of several movement disorders referred to as Parkinson syndrome (PS) or Parkinsonism, is a progressive neurological disease characterized by tremor, hypokinesia, rigidity, and postural instability.

Parkinson Syndrome (PS), also known as Parkinson Plus Syndrome, is movement disorders where atypical variants may be present. These conditions are more serious and less treatable than classic PD, and include multiple system atrophy (MSA), progressive supranuclear palsy (PSP), corticobasal degeneration (CBD), and Lewy body dementia (LBD).

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Bega D, Kuo PH, Chalkidou A, Grzeda MT, Macmillan T, Brand C, Sheikh ZH, Antonini A. Clinical utility of DaTscan in patients with suspected Parkinsonian syndrome: a systematic review and meta-analysis. NPJ Parkinsons Dis. 2021 May 24;7(1):43.

Chou KL. Diagnosis and differential diagnosis of Parkinson disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 20, 2023)

Djang DS, Janssen MJ, Bohnen N, et al. SNM practice guideline for dopamine transporter imaging with 123I-ioflupane SPECT 1.0. J Nucl Med. 2012 Jan;53(1):154-63.

Hayes, Inc., Medical Technology Directory Report DaTscan (123I-Ioflupane; GE Healthcare) for Diagnosis and Management of Parkinson Disease; Lansdale PA: March 7, 2019.

Park E. A new era of clinical dopamine transporter imaging using 123I-FP-CIT. J Nucl Med Technol. 2012 Dec;40(4):222-8.

Parkinson’s Disease Foundation (PDF) [web site]. Understanding Parkinsonism. Available at: <http://parkinson.org/Understanding-Parkinsons/What-is-Parkinsons/Types-of-Parkinsonisms> Accessed December 20, 2023.

Regulatory References

New York State Department of Health [web site] New York State Medicaid Program Physician Procedure Codes Section 4 Radiology. April 2023. Available at: <https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect4.pdf> Accessed December 20, 2023.

United States Food and Drug Administration (FDA) [web site]. New drug approval letter. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022454s000ltr.pdf Accessed December 20, 2023.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member’s contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes No

Revision Date	Owner	Notes
3/1/2024	Health Care Services	Revised
1/1/2024	Health Care Services	Revised
3/1/2023	Health Care Services	Reviewed
3/1/2022	Health Care Services	Reviewed
4/1/2021	Health Care Services	Reviewed
5/1/2020	Health Care Services	Reviewed
6/1/2019	Medical Management	Revised
6/1/2018	Medical Management	Reviewed
6/1/2017	Medical Management	Revised
7/1/2016	Medical Management	Revised
7/1/2015	Medical Management	Revised

