



DaTscan™ (Ioflupane I 123 Injection) is a radiopharmaceutical 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) and suspected dementia with Lewy bodies (DLB). In these patients, healthcare providers may use DaTscan imaging 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.

Coding Information

To receive appropriate reimbursement, physicians should report the appropriate HCPCS code for the product along with the appropriate CPT® code for the procedure. Some payers may require the National Drug Code (NDC) for DaTscan, which is 17156-210-01.

Code	Description
HCPCS: A9584	Iodine I-123 ioflupane, diagnostic, per-study dose, up to 5 millicuries
CPT®: 78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agents, (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day of imaging
CPT®: 78830	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed): tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/ detection of pathology, single area (eg, head, neck, chest, pelvis), single day imaging

CPT is a registered trademark of the American Medical Association.

HCPCS, Healthcare Common Procedure Coding System.

PRODUCT INDICATION AND USE: DATSCAN is indicated as an adjunct to other diagnostic evaluations for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging in adult patients with:

- suspected Parkinsonian syndromes (PS) or
- suspected dementia with Lewy bodies (DLB).

IMPORTANT SAFETY INFORMATION ABOUT DATSCAN

CONTRAINDICATIONS

- DaTscan is contraindicated in patients with known serious hypersensitivity to ioflupane I 123.

Please see additional Important Safety Information About DaTscan [here](#), and full Prescribing Information [here](#).



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IMPORTANT SAFETY INFORMATION ABOUT DATSCAN™ (IOFLUPANE I 123 INJECTION)

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WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including dyspnea, edema, rash, erythema, and pruritus, have been reported following DATSCAN administration.
- **Thyroid Accumulation:** DaTscan may contain up to 6% of free iodide (iodine-123). Thyroid uptake of iodine-123 may result in an increased long-term risk for thyroid neoplasia. To decrease thyroid accumulation of iodine-123, block the thyroid gland before administration of DaTscan.

ADVERSE REACTIONS

- In clinical trials, headache, nausea, vertigo, dry mouth, or dizziness of mild to moderate severity were reported. In postmarketing experience, hypersensitivity reactions and injection-site pain have been reported

DRUG INTERACTIONS

- Drugs that bind to the dopamine transporter with high affinity may interfere with the DaTscan image. The impact of dopamine agonists and antagonists on DaTscan imaging results has not been established

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. Administration of a thyroid blocking agent is recommended before the use of DaTscan in a pregnant woman. All radiopharmaceuticals have potential to cause fetal harm. There are no available data on DaTscan use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Advise pregnant woman of the potential risks of fetal exposure to radiation with the administration of DaTscan

- **Lactation:** Iodine 123 (I 123), the radionuclide in DaTscan, is present in human milk. There is no information on the effects on breastfed infants or on milk. Advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for at least 6 days after DaTscan administration to minimize radiation exposure to a breastfeeding infant
- **Pediatric Use:** The safety and efficacy of DaTscan have not been established in pediatric patients
- **Geriatric Use:** There were no differences in responses between elderly patients and younger patients that would require a dose adjustment observed in the parkinsonian syndrome studies.
- **Renal Impairment:** DaTscan is excreted by the kidney and patients with severe renal impairment may have increased radiation exposure and altered DaTscan images

OVERDOSAGE

- The risks of overdose relate predominantly to increased radiation exposure, with the long-term risks for neoplasia. In case of overdosage of radioactivity, frequent urination and defecation should be encouraged to minimize radiation exposure to the patient.

PROCEDURE — Radiation Safety

- DaTscan emits radiation and must be handled with safety measures to minimize radiation exposure to clinical personnel and patients

Prior to DaTscan administration, please read the full Prescribing Information, [here](#), for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

DaTscan™
Ioflupane I123 Injection

Common Diagnosis Codes*

Diagnosis and procedure coding are at the discretion of the physician based on the clinical condition of the patient, the nature of the physician's findings, and the procedural steps dictated in the patient's medical record. Only the physician can determine a diagnosis. Because policies vary, verification of covered diagnosis is recommended. Some examples could be:

ICD-10-CM	Description
G20	Parkinson's disease
G25.0	Essential tremor
G31.83	Dementia with Lewy Bodies

*Because coverage criteria vary by payer, providers are encouraged to check with the specific plan for specific, covered diagnosis codes. Individual benefit plans may vary.

Non-Medicare Claims for All Sites of Services

Medicaid programs and private payers may require different codes. Private payers will likely require preauthorization for the procedure; the patient's physician must establish the medical necessity for the procedure. The private payer will base payment for DaTscan and the procedure on the terms of each facility's contractual agreement.

Disclaimer

The information referenced and provided is based on coding experience and research of current general coding practices. The existence of codes does not guarantee coverage or payment for any procedure or contrast agent by any payer. The final decision for coding of any procedure must be made by the provider of care after considering the medical necessity of the services and supplies provided, as well as any regulations and local, state, or federal laws that may apply. The coding and payment data are furnished for general informational purposes only and should not be relied upon for the purposes of determining payer coverage and coding for a specific case or claim for payment. Providers should refer to authoritative coding sources such as the Common Procedural Terminology (CPT) Codes and Healthcare Common Procedure Coding System (HCPCS) Codes. GE Healthcare and its affiliates disclaim any liability associated with the use of this information and/or the reimbursement results in any particular instance, to the fullest extent permitted by law.

GE Healthcare Prior Authorization and Appeals Support Program



For questions or support related to reimbursement, coding, and coverage for DaTscan, please contact the DaTscan Support Line, 8AM-6PM ET. This support program is available to GE Healthcare customers who use SPECT imaging with DaTscan.

844 225 1595



GE Healthcare Reimbursement Hotline



GE Healthcare is pleased to offer toll-free customer support and documentation for coding and reimbursement related to our products. Please contact us at:

800 767 6664

GE Healthcare Medical Affairs for Clinical or Scientific Support



Please contact us at:

**800 654 0118 (option 2, then option 3) or
medical.affairs@ge.com**



GE Healthcare Website



For information regarding other GE Healthcare products, please visit our website at:

gehealthcare.com

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