KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Single Photon Emission Computed Tomography (SPECT)

- DaT-SPECT (Dopamine Transporter-Single Photon Emission Computed Tomography)
- Evaluation of Behavior Problems
- Imaging with (123I)Ioflupane, DaTscan, or (123I)FP-CIT
- SPECT for Amyloid Mediated Cardiomyopathy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Single Photon Emission Computed Tomography (SPECT) (220.12). *Medical necessity review no longer required
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Service	Criteria
Evaluation of Origin of Behavior Problems	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
DaT-Spect for evaluation of movement disorders (e.g., Parkinson's, essential tremor, etc.)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
SPECT for Amyloid Mediated Cardiomyopathy	Known genetic mutation putting the patient at risk for cardiac amyloidosis; **OR** • Prior cardiac testing suggestive for cardiomyopathy (Echo or Cardiac MRI) and other causes of cardiomyopathy have been ruled out by **ONE** of the following: ▪ Laboratory evaluation for Monoclonal protein is negative ▪ Hematology consultation has excluded significant monoclonal protein abnormalities (either with bone marrow biopsy, or explanation of insignificant abnormalities in laboratory evaluation for monoclonal protein)
SPECT for all other indications	No Review Required

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The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Single Photon Emission Computed Tomography (SPECT) is a nuclear medicine technique that can be used to image almost any organ system. SPECT imaging is performed by acquiring multiple images (aka projections) with a gamma camera. A topographic reconstruction algorithm is then applied to the multiple two-dimensional projections, resulting in a three-dimensional dataset. To acquire the images, the gamma camera is rotated around the patient. The camera typically moves 3-6o each time until a 360 rotation is achieved. Each image takes approximately 15-20 seconds, for a total scanning time of approximately 15-20 minutes.

Brain imaging with SPECT is generally performed with the radiopharmaceutical hexamethylpropylene amine oxime (99mTC-HMPAO). 99mTC emits gamma rays that are detectable by a gamma camera. When attached to HMPAO, it can be taken up by brain tissue at a rate proportional to brain metabolism. Brain blood flow is highly correlated to local brain metabolism and energy use. Areas of the brain that are undergoing increased neuronal activity consume greater amounts of oxygen and energy and are perfused more, and areas of the brain that area less functionally active are perfused less. The SPECT image thus indirectly reflects cerebral metabolism. Patients undergoing brain SPECT are exposed to approximately 2-8 mSv of radioactivity, a level comparable to a CT scan. 99mTC-HMPAO SPECT brain scanning provides similar information about local brain function to FDG PET scans and functional MRI. Although PET has a higher resolution, the SPECT equipment is less expensive and may be more widely available. While MRI and PET are limited to hospitals due to their cost, SPECT equipment can be installed in physicians' offices (Overmeyer & Taylor, 2001).

A report contracted by the American Psychiatric Association (APA) in 2005 concluded that SPECT is useful for research on psychiatric disorders, and for diagnosing cerebral trauma, seizure disorders and brain tumors for which there are detectible patterns of perfusion abnormalities. However, the authors found insufficient evidence to support the use of SPECT for the diagnosis and treatment of psychiatric disorders in the pediatric population. The APA report stated that there is a lack of evidence linking a particular structural or functional brain abnormality to a single psychiatric disorder. In addition, the authors cautioned that the long-terms effects of using the radioactive nucleotides associated with SPECT imaging in children and adolescents are not known.

A group of SPECT practitioners have criticized the APA report as being flawed and misleading (Wu et al, unpublished manuscript). They counter the APA claim that SPECT cannot yet diagnose psychiatric illness with the statement that clinicians do not rely on SPECT to make psychiatric diagnoses. Instead, SPECT practitioners use brain imaging as another source of data, along with clinical presentation, to help them make informed decisions about diagnosis. They also state that it is unfair to single out the possible danger associated with radioactive nucleotides used with SPECT imaging since children are treated with other nuclear medicine procedures such as studies for cardiovascular, cerebrovascular and orthopedic disease. They report that the average radiation exposure for one SPECT scan is similar to the exposure from a bone scan, brain CT scan or abdominal x-ray.

Medical Technology Assessment Committee (MTAC)

Single Photon Emission Computed Tomography

10/02/2006: MTAC REVIEW

Evidence Conclusion: In order to demonstrate that SPECT brain imaging is able to accurately diagnose behavior problems, there needs to be sufficient evidence that particular SPECT findings correlate with specific behavioral conditions, and that SPECT is sensitive and specific at diagnosing these conditions compared to a gold standard diagnostic tool. Most of the published studies on the first topic, SPECT findings associated with a clinical behavior problem are too small to produce reliable estimates. The largest study was by Amen and colleagues (1997). They compared SPECT scans of children with and without ADHD both at rest and while performing an intellectual stress task. The study found significantly decreased prefrontal activity during the intellectual stress activity in the ADHD group, but not the non-ADHD group. The Amen study is inconclusive due to the small sample size and lack of adjustment for confounding variables. Moreover, since only 65% of the participants with ADHD had decreased prefrontal activity during intellectual stress, it is not clear how the SPECT

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information would be used to help diagnose ADHD. In addition, Dr. Amen has a private clinic that performs SPECT which may bias the study's methods and conclusions. Gustafsson and colleagues performed a variety of tests on 28 children with ADHD, including brain SPECT and EEG. The investigators did not find a significant association between EEG and SPECT findings. They found several statistically significant correlations between regional cerebral blood flow detected by SPECT and several instruments, particularly the number of Minor Physical Abnormalities (MPA). The vast majority of statistical comparisons were not statistically significant, and since such a large number of comparisons were performed at $p<0.05$, some significant findings would be expected by chance alone. No empirical evidence was identified on the effectiveness of brain SPECT at assisting practitioners in making a clinical diagnosis, e.g. of ADHD. Such a study would compare the diagnosis made by practitioners with and without information from SPECT, with the diagnosis confirmed by a qualified objective third party. In addition, there was no empirical evidence on the long-term safety of SPECT brain imaging in children. In conclusion, there is insufficient evidence in the published literature on the ability of SPECT brain imaging to diagnose behavior problems or assist clinicians in making a diagnosis, and insufficient evidence on the safety of brain SPECT in the pediatric population.
Articles: Objective 1a: The ideal study design is a comparison of brain function or structure as assessed by SPECT among individuals with and without behavioral problems. Methodological features include sufficient sample size, appropriate selection of controls, matching or controlling for confounding variables, objective confirmation of diagnosis and appropriate statistical analysis. Several studies were identified that compared brain activity using SPECT among children with ADHD and healthy controls. The studies were generally limited by small sample sizes. Most included 20 or fewer children with ADHD and 7 or fewer controls. The largest study (n=54 ADHD, n=18 non-ADHD) was conducted by a prominent SPECT practitioner (Dr. Amen)—this study was critically appraised. Objective 1b: The ideal study of diagnostic accuracy would report the sensitivity and specificity of SPECT imaging and include an independent blinded comparison to a "gold standard" diagnosis. No studies that met the above criteria were identified. Only one study compared SPECT findings to another imaging technique, EEG (Gustafasson et al., 2000) and this study was critically appraised
Objective 2: A strong study would compare the accuracy of the diagnosis made with and without information from SPECT imaging, with the diagnosis confirmed by an objective expert such as experienced psychiatrist blinded to diagnosis. No relevant studies were identified. Objective 3: No studies were identified on the long-term safety of SPECT brain imaging in children. *The studies that were critically appraised were:*
Amen DG, Carmichael BD. High-resolution brain SPECT imaging in ADHD. Ann Clin Psychiatry 1997; 9: 81-86. See Evidence Table**.** Gustafsson P, Thernlund G, Ryding E et al. Associations between cerebral blood flow measured by single photon emission computed tomography (SPECT), electro-encephalogram (EEG), behavior symptoms, cognition and neurological soft signs in children with attention-deficit hyperactivity disorder (ADHD). Acta Pediatr 2000; 89: 830-835. See Evidence Table.

The use of Single Photon Emission Computed Tomography in the evaluation of origin of behavior problems does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

DaT-SPECT

Movement disorders are neurological conditions that affect the speed, fluency, quality, and ease of movement. They include a wide range of disorders including, but not limited to, Parkinsonian syndromes (PS) and essential tremor (ET). ET, the most common movement disorder, typically involves involuntary shaking movement with no cause. PS, on the other hand, is a group of neurodegenerative disorders that have similar features and symptoms, of which, the most frequent form is idiopathic Parkinson's disease (PD) accounting for 80% of all PS. Although ET and PS have different underlying etiologies, they present with similar clinical features, especially in the early stages of disease progression, thus complicating diagnostic differentiation. Accurate diagnosis of patients with suspected PS is critical for patient management because the disease course, therapy and prognosis greatly differ from non-degenerative diseases (Dauer and Przedborski 2003; de Lau and Breteler 2006).

Currently, the gold standard for the diagnosis of PS is post-mortem neuropathological examination. In practice, however, diagnosis is based on the presence of two or more classical motor features including bradykinesia, rigidity, tremor, and postural instability which can be atypical or mild in the early stages of the disease. Long-term clinical follow-up and good response to dopaminergic drugs have also been used to support clinical diagnosis (de la Fuente-Fernández 2012). Pathologic studies have shown that the lack of an objective diagnostic tool has resulted in an error rate of 10-30% (Rajput, Rozdilsky et al. 1991). Misdiagnosis can lead to unnecessary disability if effective treatment options are not initiated, and inappropriate therapies may unnecessarily expose patients to the potential side effects thus warranting an early and accurate diagnostic tool to ensure appropriate management.

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DaTscan™ is a recent advance in imaging technology that supports the clinician in the differential diagnosis of PS and ET. While there is limited knowledge on the etiology of ET, the main pathological hallmark of PS is the loss of dopaminergic neurons in the substantia nigra, leading to striatal dopamine depletion (Dauer and Przedborski 2003). The DaTscan™ technology is able to determine the location and measure the amount of dopamine transporter (DaT) in the brain. More specifically, through small amounts of a contrast agent called (^{123}I)ioflupane and using a single photon emission computerized tomography (SPECT) scanner, DaTscan™ is able to demonstrate reduced striatal uptake of DaT where PS is present and, in contrast, normal striatal uptake in patients with ET. The results of DaTscan™ are not intended to differentiate between different PS disorders, but instead, should be used when diagnosis is inconclusive to rule out other movement disorders with similar presenting symptoms.

In January 2011, the U.S. Food and Drug Administration (FDA) approved the DaTscan™ for striatal dopamine transporter (DaT) visualization using SPECT brain imaging to assist in the evaluation of adult patients presenting with symptoms or signs suggestive of dopaminergic neurodegeneration. In these patients, DaTscan may be used to help differentiate ET from tremor due to PS and is intended for use as an adjunct to other diagnostic evaluations.

Medical Technology Assessment Committee (MTAC)

DaT-SPECT
02/10/2014: MTAC REVIEW
Evidence Conclusion: The evidence supports high sensitivity and specificity, but the lack of a gold standard limits the value of these numbers. There is evidence to indicate that the use of DaTscan™ can sometimes result in changes in diagnosis and treatment, however, there is no evidence to support that these changes result in improved health outcomes.
Articles: The literature search for studies on the accuracy of DaTscan in patients with suspected PS revealed almost 200 articles that assessed the DaTscan in a variety of differential diagnostic situations. This search was further narrowed down to include studies that specifically addressed diagnostic differentiation between PS and ET. For the most part, the literature was comprised of studies that were small with limited methodology due to a lack of gold standard for diagnosis.

The following articles were selected for critical appraisal:
Marshall VL, Reininger CB, Marquardt M et al. Parkinson's Disease is overdiagnosed clinically at baseline in diagnostically uncertain cases: A 3-year European multicenter study with repeat [^{123}I]-FP-CIT SPECT. *Movement Disorders*. 2009;24(4):500-508. See Evidence Table. Vlaar AM, van Kroonenburgh MJ, Kessles AG, et al. Meta-analysis of the literature on diagnostic accuracy of SPECT in parkinsonian syndromes. BMC Neurol 2007; 7:27. See Evidence Table. Kupsch AR, Bajaj N, Weiland F, et al. Impact of DaTscan SPECT imaging on clinical management, diagnosis, confidence of diagnosis, quality of life, health resource use and safety in patients with clinically uncertain parkinsonian syndromes: a prospective 1-year follow-up of an open-label controlled study. *J Neurol Neurosurg Psychiatry*. 2012; 83:620-628. See Evidence Table.

The use of DaT-SPECT does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

SPECT – for Evaluation of Behavior Problems
Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging
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) or acquisition, single day imaging

DaT-SPECT- for evaluation of movement disorders (e.g., Parkinson's, essential tremor, etc.)
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Medicare – Medical Necessity review not required
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging
A9584	Iodine I-123 Ioflupane, diagnostic, per study dose, up to 5 mCi

SPECT—for Amyloid Mediated Cardiomyopathy

CPT® or HCPC Codes	Description
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging
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) or acquisition, single day imaging

SPECT – for other indications
No Review Required

CPT® or HCPC Codes	Description
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging
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) or acquisition, single day imaging

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/26/2006	04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC, 05/07/2024MPC, 05/06/2025MPC	02/03/2025

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/25/2023	Merged DaT-Spect criteria with SPECT criteria set.

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11/05/2024	MPC approved clinical criteria for SPECT for Amyloid Mediated Cardiomyopathy. Requires 60-day notice; effective April 1, 2025.
02/03/2025	Updated codes section to align with the upcoming 4/1/2025 changes.

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