DAT-SPECT

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

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

DaTscan is ioflupane iodine-123 injection, a radiopharmaceutical contrast agent used with DAT-SPECT. It has been investigated for detecting dopamine transporters (DaT) in suspected parkinsonian syndromes.
DAT-SPECT (cont.)

Criteria:

- Dopamine transporter imaging with single photon emission computed tomography (DAT-SPECT) for all indications is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, *but are not limited to*:

- Aiding in the diagnosis of individuals with clinically uncertain parkinsonian syndromes
- Essential tremor
- Dementia with Lewy bodies
- Monitoring of disease progression

Resources:

3. Medscape; Melville N. FDA Approves DaTscan for Imaging of Dopamine Transporters. 01/17/2011.

FDA Product Approval Information for DaTscan (Ioflupane I 123) Injection:

- FDA-approved indication: 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).