Nourianz (Istradefylline oral tablet)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's Disease (PD) experiencing "off" episodes.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

A. Parkinson's Disease Adjunct to Levodopa/Carbidopa for patients experiencing "off" episodes

An authorization may be granted for 12 months when the following criteria are met:

- 1. Prescriber is a neurologist or being prescribed in consultation with a neurologist.
- 2. Member is at least 18 years of age.
- 3. Documentation of Parkinson's Disease diagnosis with "off" episodes lasting at least 2 hours in duration.
- 4. Member is currently taking Levodopa/Carbidopa and this is confirmed with prescription claims history.
- 5. Documentation of trial and failure or contraindication to at least 2 of the following classes of covered agents used as adjunctive treatment to levodopa/carbidopa:
 - a. Dopamine agonist (Ropinirole or Pramipexole)
 - b. COMT Inhibitor (Entacapone)
 - c. MAO-B Inhibitor (Selegiline)

III. QUANTITY LIMIT

Nourianz has a quantity limit of #30 tablets per 30 days for the 20mg and 40mg.

IV. REFERENCES

1. Nourianz (istradefylline). Kyowa Kirin. Bedminster, NJ. FDA Package Insert. November 2020.

