Pharmacy Policy Bulletin: J-1459 Experimental and Investigational Products – Commercial and Healthcare Reform	
Number: J-1459	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Does not apply to Delaware Commercial Fully Insured or Delaware Healthcare Reform Plans
Version: J-1459-001	**Original Date:** 06/25/2025
Effective Date: 09/11/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Leqembi Iqlik (lecanemab-irmb)
FDA-Approved Indication(s):	• Treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Background:	• Leqembi Iqlik is considered experimental and investigational due to lack of sufficient clinical evidence supporting its use.

Approval Criteria

I. Approval Criteria
A. No exception will be made for experimental and investigational products.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

None

Automatic Approval Criteria

None

References:

1. Leqembi [package insert]. Nutley, NJ: Eisai Inc.; August 2025.