

Life Molecular Imaging

August 2024 Hospital Outpatient Panel Meeting

Comments on HOPPS Proposed Rule on Separate Payment of Diagnostic Radiopharmaceuticals

Cindy Herring, MHA, BSNM, CPC

Head of Market Access

Florbetaben [F18]-Neuraceq®

- Neuraceq® is a radioactive diagnostic imaging agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline. Neuraceq® has historically been bundled into the diagnostic procedure since going off pass-through payment in 2019, resulting in very few procedures being done in the hospital outpatient setting.
- Neuraceq® is one of the 3 FDA approved imaging products used for beta-amyloid PET imaging:
 - Florbetaben [F18], Neuraceq® [HIGHLIGHTS OF PRESCRIBING INFORMATION \(neuraceq.com\)](https://www.neuraceq.com/HIGHLIGHTS-OF-PRESCRIBING-INFORMATION).
 - Florbetapir [F18], Amyvid® [amyvid-uspi.pdf \(lilly.com\)](https://www.lilly.com/amyvid-uspi.pdf)
 - Flutemetamol [F18], VizamyI™ [203137s005lbl.pdf \(fda.gov\)](https://www.fda.gov/oc/ohrt/203137s005lbl.pdf)

Florbetaben [F18]-Neuraceq®

- The FDA approved LMI's Neuraceq® product in 2014
- All three FDA approved beta-amyloid radiopharmaceuticals were used in CMS mandated NCA to NCD with CED programs from 2016-2023 in which Neuraceq® facilitated data supporting the necessity of beta-amyloid imaging in the identification of beta-amyloid plaques in the brain, a target for treatment in those with cognitive decline due to AD.
- Neuraceq® is one of three FDA approved beta-amyloid imaging agents subject to OPPS bundling after pass through ended.
- All three FDA approved products have the same indication as noted in their respective prescribing information however, two other agents have 2025 proposed allowable rates nearly 2x greater than Neuraceq®
 - APC 9458, Q9983 Neuraceq \$1154.70
 - APC 9459, Q9982 Vizamyl \$2255.50
 - APC 1664, A9586 Amyvid \$2148.39

Support of Proposed OPPS Decision

- Life Molecular Imaging (LMI) supports the OPPS decision for separate payment and the proposed payment threshold of greater than \$630.
- LMI supports using Mean Unit Cost (MUC) where there are enough hospital claims from 2023 to accurately reflect the selling price of the product.
- Where MUC claims are very low, and ASP is available, LMI proposes that CMS use 2024 Q2 and beyond ASP submitted by LMI for payment of product in the hospital outpatient setting.
- CMS seeks comment on the use ASP for all products eligible for future years. LMI encourages to use ASP where available starting as soon as possible and where ASP is not available to revert to MUC.

Assessment - 2025 and Beyond

- *Neuraceq® Q2 2024 ASP data has been submitted.*
- This 2024 data is likely more accurate than 2023 data as few hospitals were able to provide this service, and if they did, it was at a loss. More Independent Diagnostic Testing Facilities (IDTF) were able to image versus Hospital Outpatient Departments (HOPD) due to lack of OPPS payment.
- Only 10 Neuraceq® claims were included in the HOPPS analysis for the 2025.
- LMI is very concerned about the calculation of MUC when there are a lower number of claims and hospital cost adjustments that were used that may have inaccurately reflected the contracted and invoice amount of Neuraceq®.
- LMI requests that ASP data or pass-through pricing be used versus MUC due to the lack of hospital data used to calculate MUC.
- LMI is favor of using ASP as soon as possible and for future years, and where ASP is not available to then use MUC.