206U: Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease

Public Comment	**Rationale**
Gapfill	No comparable existing clinical diagnostic laboratory test for Alzheimer's disease

207U: Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)

Public Comment	**Rationale**
Gapfill	No comparable existing clinical diagnostic laboratory test for Alzheimer's disease

Test Purpose: 206U+207U (Discern™)

- There are ~500K new cases of dementia each year in the U.S.
  - 25-30% of these patients do not have AD
  - There is no accurate test to definitively diagnose AD

- The Discern™ test uses a non-invasive skin punch biopsy for lab testing that identifies AD versus other forms of dementia
  - 206U – primary test
  - 207U – confirmatory test

- Unlike other AD tests, Discern™ is autopsy-validated and highly accurate (> 95% specificity, sensitivity) for diagnosing early AD; and does not measure amyloid or tau.

- Discern™ has received “Breakthrough Status” from the FDA and is currently under FDA review

Recommendation: 206U+207U (Discern™)

- **Gapfill 206U and 207U**

- **Rationale**
  - No other existing comparable clinical tests on the CLFS for Alzheimer's disease for crosswalking

  - Discern™ provides new clinical diagnostic information