Prescribing Policy for Monoclonal Antibodies for Alzheimer's Disease and Plans for Future Implementation: Challenges and Opportunities

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VA Characteristics

- Staff Model HMO → This model allows for VA to very quickly institute changes related to formulary decisions, safety concerns, etc. and enforce those changes throughout the system
  - Comprehensive health care system
  - Direct provider of care
  - Providers are employees
  - Own and operate infrastructure
  - Prescription drug benefit is integrated, not added on or contracted out

New Molecular Entity Review Process

- NME approved by FDA
- Literature search and draft clinical review completed
- Presented to select National Formulary Committee SME's and changes incorporated
- Disseminated widely to clinical staff in the field for comment
- Presented to National Formulary Committee and changes incorporated
- VA National Formulary decision
- National criteria for use developed when indicated
- National decisions and documents disseminated to local facilities for implementation

VA Coverage for Aducanumab and Lecanemab

- Misleading press releases and media coverage has caused stakeholder (internal and external) confusion related to formulary status/place in therapy of monoclonal antibodies for Alzheimer's Disease within VA system

- In the media, the VA decision has often been portrayed as being radically different than the CMS decision on coverage, but in fact, the decisions of the two organizations are aligned

VA Coverage for Lecanemab

- Formulary status
  - Non-formulary with place in therapy outlined in monograph (aducanumab) (https://www.pbm.va.gov/PBM/clinicalguidance/drugmonographs/Aducanumab_ADUHELM_monograph_508.pdf)
  - Non-formulary with criteria for use (lecanemab) (https://dvagov.sharepoint.com/:b:/r/sites/VHAPBM/Formulary/Clinical Guidance/Criteria For Use/Lecanemab-irmb LEQEMBI CFU.pdf?csf=1&web=1&e=dsR8YU)
  - Prospective medication use evaluation required with EACH dose administered (coverage with evidence)
    - Data will be used to assess safety and appropriateness of use
  - Non-promotable status for both drugs across VA facilities

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VA Monoclonal Antibody Select Inclusion Criteria

- Prescriber must be a VA neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia
- Patient must meet criteria for mild cognitive impairment or mild Alzheimer's Disease dementia
- Amyloid PET imaging or CSF analysis consistent with Alzheimer's Disease
- Functional Assessment Staging Test (FAST) stage score meeting criteria for MCI or Mild AD dementia
- Mini-mental State Examination (MMSE) score or equivalent scale in mild dementia/cognitive disorder range
- Neuroradiology must be available to review serial MRI scans

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VA Monoclonal Antibody Select Exclusion Criteria

- Any condition other than Alzheimer's that may be contributing cause of cognitive impairment
- Contraindication to brain MRI
- Transient ischemic attack, stroke, or seizures within the past year
- MRI abnormalities related to edema or hemorrhages
- Untreated bleeding disorders

VA Real Time Prospective MUE

- Mandatory Real-Time Medication Use Evaluation assesses the safe and appropriateness of use of the agents
  - Appropriate Patients and Providers
    - Confirm specialty providers designated to administer
    - Confirm appropriate patient diagnoses
  - Infrastructure
    - Confirm SOP in place for patient infusion and monitoring
  - Confirm inclusion and exclusion criteria prior to administration
  - Track and monitor infusion and dosing
  - Identify concomitant therapy
  - Track and monitor safety
    - ADEs (during infusion and in-between doses)
  - General efficacy assessment
  - Track and assess reason for discontinuation
- Ongoing monitoring and reports to SMEs and Formulary Group

Additional Considerations

- Need for standardized operating procedure that can be tailored at local facility level
  - Appropriate infrastructure needed at local facility level to assure safe infusion of drug
  - Access to baseline and ongoing testing monitoring
    - MRI, ApoE e4 testing, amyloid PET imaging, CSF analysis
  - Access to neuroradiology providers with knowledge base to interpret neuroimaging findings
    - Local providers, teleradiology, contract providers
- Need for centralized education and training
  - Drug infusion procedures
  - Appropriate baseline and ongoing screening/monitoring
  - Interpretation of tests/labs
  - Medication Use Evaluation completion

Questions??