LECANEMAB (Leqembi) Fact Sheet

Bottom Line:
Lecanemab, like aducanumab, is an antibody that attacks and dissolves the amyloid protein that is thought to contribute to Alzheimer's dementia. It is the first monoclonal agent to receive traditional approval from the FDA. Although the trial data with this agent are more rigorous and positive, it is still marginally effective at best, requires twice-monthly IV infusion, has cumbersome monitoring requirements, and carries potentially significant side effects, all at very high cost. We can't recommend it until we see more positive data.

FDA Indications:
Mild cognitive impairment or mild dementia due to Alzheimer's.

Dosage Forms:
Injection: 200 mg/5 mL, 500 mg/2 mL.

Dosage Guidance:
Start and continue recommended dose of 10 mg/kg IV, infused over one hour, Q2 weeks.

Monitoring: Baseline brain magnetic resonance imaging (MRI); repeat MRI prior to the fifth, seventh, and 14th infusions. Patients who develop amyloid-related imaging abnormalities (ARIAs) may require dosing suspensions depending upon severity on MRI and symptomatology.

Cost: $$$$$

Side Effects:
- Most common: ARIAs in 26% of patients, edema, headache, cough, diarrhea, infusion-related reactions (fever, flu-like symptoms, nausea, vomiting, hypotension, hypertension, oxygen desaturation, decreased lymphocytes, increased neutrophils).
- Serious but rare: Atrial fibrillation (4%).

Mechanism, Pharmacokinetics, and Drug Interactions:
- Recombinant human immunoglobulin gamma-1 (IgG1) anti-amyloid beta monoclonal antibody.
- Degraded into small peptides and amino acids through catabolic pathways, similar to endogenous IgG; t ½: 5–7 days.
- No drug interactions known.

Clinical Pearls:
- Lecanemab was initially granted accelerated approval based on reduction in amyloid beta plaques as well as some reduction (27%) in cognitive decline; in July 2023, it received full FDA approval.
- Lecanemab, if used, should only be used in patients with mild cognitive impairment. There are no data on its effects in earlier or later stages.
- ARIAs are common but less than what was shown with aducanumab.

Fun Fact:
Both the Veterans Administration and Medicare announced they would provide the $26,000-per-year drug for qualifying enrollees. Clinicians will need to participate in a registry, which will collect additional "real world" evidence.