**Access to Innovative Treatments Act**

**Overview:** On April 7, 2022, the Centers for Medicare & Medicaid Services (CMS) finalized a National Coverage Determination (NCD) that monoclonal antibodies directed against amyloid for the treatment of Alzheimer’s disease be covered for Medicare beneficiaries only under CMS’ Coverage with Evidence Development (CED) pathway. Under this CED any new Alzheimer’s treatment in this drug category will only be covered by Medicare if the Alzheimer’s patient is enrolled in a randomized control trial conducted in an outpatient hospital setting. CMS’s decision preemptively restricts access to an entire class of drugs and creates uncertainties and new regulatory hurdles that will make it harder for those living with Alzheimer's to access the care they deserve.

How the requirement for CMS-approved trials is limiting treatment access:

* Approximately 1.2 million people with Alzheimer’s are eligible and may benefit from this class of drugs. Yet, the average clinical trials enroll only around 3,000 people.
* Fewer than 1% of Alzheimer’s patients who would benefit would be able to access an Alzheimer’s treatment under the current CMS requirements.
* Underserved populations who are disproportionately impacted by Alzheimer’s and are underrepresented in clinical trials will have a harder time accessing new drugs.
* Only people who can pay out of their own pockets will have the latest drugs, while everyone else is denied access.

**Issue:** In the past, when CMS issued coverage rules that required CEDs, the CED continued for an average of 11 years. CMS has not shared a specific timeframe on how quickly they can reconsider Alzheimer’s drugs under this current CEDs program issued in April 2022. As a result, access to new and innovative therapies for the treatment of Alzheimer’s disease will be severely limited for an unknown and potentially long period of time. Uncertainty about when CMS will reconsider Alzheimer’s drugs under the current CEDs program denies access to drugs for many Medicare beneficiaries suffering from Alzheimer’s disease.

**Solution:** The “Access to Innovative Treatments Act,” would mandate a timeline for CMS to respond and reconsider Alzheimer’s drugs when enough data is collected on the drug's effectiveness. Specifically, the bill would require CMS to open reconsideration applications within 30 days of notification that a drug under CMS’ Coverage with Evidence Development (CED) program is effective & complete reconsideration within 90 days of this notification. Furthermore, the bill would restrict CMS from implementing limited coverage policies (ie CEDs) for an entire class of drugs in the future. This provision ensures that CMS makes a coverage determination for each individual drug brought before it based on the evidence collected on that specific drug.