

BRIVIACT® (brivaracetam) CV – Testimony

Good morning/afternoon. My name is _____ and I am the _____ for UCB.

This Testimony will discuss Briviacet, a unique SV2A anticonvulsant.

For more than 2 decades, UCB has been focused on developing new medicines and solutions for people with epilepsy.

- In the U.S., 3.4 million Americans are living with epilepsy.^{1,2}
- **NEVADA** has **31,600** residents currently living with epilepsy.³
- Epilepsy is a complex and heterogeneous disease with numerous causes, seizure types, and serious comorbidities^{4,5} which result in substantial socioeconomic and cost burden.⁶
- Estimated direct costs of epilepsy are approximately \$28 billion per year in the U.S.⁷⁻⁹
- Healthcare costs can be influenced by type of AED selected for treatment as well as titration periods.^{10,11} One recent retrospective U.S. chart review analysis found the time to reach an AED maintenance dose (**the titration period**) may increase healthcare costs. Epilepsy resource use cost was increased by 47% during the titration phase compared to the 6 month post-maintenance period.¹¹

Despite the availability of over 25 antiepileptic drugs (AEDs), more than 30% of patients continue to experience seizures and are considered refractory.¹²

- Treatment of refractory epilepsy relies on combining numerous AED options with diverse mechanisms of action (MOAs) to target various pathways in tandem. Further, AEDs within the same mechanistic class may be needed to optimize seizure control in any given patient.¹³⁻¹⁶
- Many common AEDs may take 7-126 days to reach a target dose.¹⁷⁻²³

Gradual dose escalation is not required with BRIVIACT.²⁴ A therapeutic dose can be initiated on the first day of treatment.

- 100% of BRIVIACT utilization is in patients with epilepsy.²⁵

BRIVIACT is indicated for the treatment of partial-onset seizures in patients 4 years of age and older and is a Schedule V controlled substance. As the safety of BRIVIACT injection has not been established in pediatric patients, BRIVIACT injection is indicated for the treatment of partial-onset seizures in adults (16 years of age and older).²⁴

- *In vitro* studies have shown that BRIVIACT has a 15- to 30-fold higher affinity to SV2A compared to levetiracetam (LEV) and that BRIVIACT lacks activity at high voltage activated calcium channels and AMPA receptors.²⁶⁻²⁹ The clinical significance of these *in vitro* data is unknown.
- Positron Emission Tomography (PET) studies in healthy human volunteers have shown that BRIVIACT enters the brain faster than levetiracetam.³⁰

BRIVIACT has demonstrated efficacy in reducing seizure frequency in three placebo-controlled adjunctive studies of 1,550 adult patients with uncontrolled partial-onset seizures.²⁴

- All three studies included patients with prior LEV exposure. In Study 3, a pre-specified analysis examined efficacy in the 54% of patients who had prior LEV exposure, with BRIVIACT demonstrating efficacy over placebo among those patients.²⁵

For detailed information on BRIVIACT's safety profile, including important warnings and precautions, please refer to the Package Insert. The most common adverse reactions are somnolence and sedation, dizziness, fatigue, and nausea and vomiting.²⁴

Please consider providing open access to all AEDs, including BRIVIACT for appropriate Medicaid patients with partial-onset seizures.

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