

# Brivaracetam Monotherapy Patient Characteristics, Treatment Patterns, and Healthcare Resource Utilization Among Patients With Epilepsy: A Cohort Study Using US Claims Data

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P12-017

## Background

• Brivaracetam (BRV) is approved as adjunctive therapy and monotherapy for focal-onset seizures in the United States in patients ≥1 month of age,<sup>1</sup> as adjunctive therapy for focal-onset seizures in patients ≥2 years of age in Europe,<sup>2</sup> and as adjunctive therapy and monotherapy for focal-onset seizures with or without secondary generalization in patients ≥15 years of age in Japan<sup>3,4</sup>; however, BRV monotherapy real-world clinical data are limited.

## Objective

• To assess patient characteristics, treatment patterns, and epilepsy/seizure-related healthcare resource utilization (HCRU) in patients with epilepsy who initiated BRV monotherapy.

## Methods

- Retrospective analysis of de-identified data from Merative MarketScan (Commercial, Medicare, and Medicaid Supplemental databases) of patients with an epilepsy/seizure diagnosis (identified as ≥2 claims 30 days or more apart with *International Classification of Disease [ICD]-9/-10* codes 345.X/G40.X, or with *ICD-9/-10* codes 780.39/R56.9, during baseline; or ≥1 claim with *ICD-9/-10* codes 345.X/G40.X 30 days or more apart with the occurrence of ≥1 claim with *ICD-9/-10* codes 780.3X/R56.X during baseline) who received BRV monotherapy.
- Patients were included if they:
  - Had a BRV pharmacy claim (date of first BRV claim during the identification period [January 1, 2016 through December 31, 2020] = index date);
  - Were supplied BRV for ≥30 days;
  - Had made no claim for BRV within 365 days before the index date; and
  - Had medical/pharmacy benefits for ≥12 months before and ≥90 days after index (shorter pre-index period for patients <12 months of age).
- BRV monotherapy was defined as patients with (1) a BRV pharmacy claim, (2) antiseizure medications (ASMs) prescribed before BRV initiation discontinued <90 days after BRV initiation, and (3) no claim for another ASM within 90 days after BRV initiation.
- Outcomes included baseline characteristics, treatment patterns, and HCRU, and were assessed in all patients who initiated BRV monotherapy and in subgroups stratified by age (<16 years, 16-64 years, and ≥65 years of age).
  - Seizure/epilepsy-related HCRU (hospitalizations, intensive care unit visits, emergency department visits, and outpatient neurology visits) were captured 12 months before (baseline), and after first BRV prescription (follow-up; ranging from 3 to 12 months).
  - For BRV daily dose at 12 months, a prescription claim within 30 days before the 12-month timepoint was required.
  - Outcomes are reported for all patients who initiated BRV monotherapy at index, regardless of BRV treatment status at follow-up (ie, included patients who remained on BRV monotherapy and those who added ≥1 ASM at least 90 days after initiating BRV monotherapy).

## Results

- More than 365 days of follow-up was achieved by 81.3%, 85.7%, 80.9%, and 66.7% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.

### BASELINE CHARACTERISTICS

- Of 594 patients identified, 105 (17.7%), 471 (79.3%), and 18 (3.0%) patients were <16, 16-64, and ≥65 years of age, respectively.

### Baseline demographics

	ALL PATIENTS (N=594)	STRATIFIED BY AGE		
		<16 YEARS (n=105)	16-64 YEARS (n=471)	≥65 YEARS (n=18)
<b>Patient demographics</b>				
Age, mean (SD), years	32.9 (18.2)	9.0 (4.0)	36.6 (14.2)	74.7 (10.1)
Female, n (%)	338 (56.9)	55 (52.4)	274 (58.2)	9 (50.0)
<b>Seizure type during baseline, n (%)</b>				
Focal-onset <sup>a</sup>	288 (48.5)	52 (49.5)	225 (47.8)	11 (61.1)
Generalized-onset <sup>b</sup>	141 (23.7)	31 (29.5)	110 (23.4)	0
Undefined seizure type	165 (27.8)	22 (21.0)	136 (28.9)	7 (38.9)
<b>Psychiatric comorbidities in ≥20% of patients in any group during baseline,<sup>c</sup> n (%)</b>				
Other anxiety disorders	189 (31.8)	15 (14.3)	170 (36.1)	4 (22.2)
Mood disorders	170 (28.6)	9 (8.6)	158 (33.5)	3 (16.7)
Cognitive disorders	112 (18.9)	47 (44.8)	62 (13.2)	3 (16.7)
Attention deficit hyperactivity disorder	61 (10.3)	26 (24.8)	35 (7.4)	0
Autism and pervasive developmental disorders	57 (9.6)	26 (24.8)	30 (6.4)	1 (5.6)

<sup>a</sup>Included patients with an ICD code for focal seizures, with or without ICD codes for generalized seizures; <sup>b</sup>Included patients with an ICD code for generalized seizures only; <sup>c</sup>Patients could have had ≥1 psychiatric comorbidity during baseline. ICD, International Classification of Disease.

## Overview

### QUESTION

What are the patient characteristics, treatment patterns, and healthcare resource utilization (HCRU) among patients with epilepsy on brivaracetam (BRV) monotherapy?

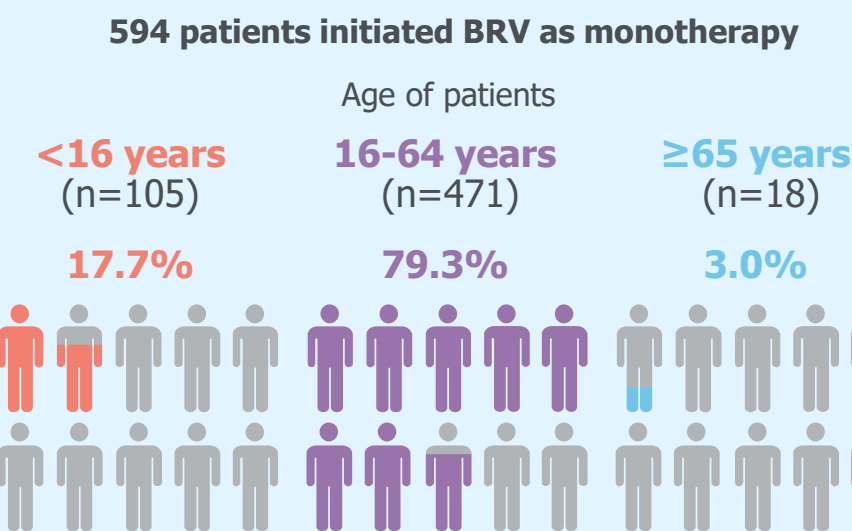


### INVESTIGATION

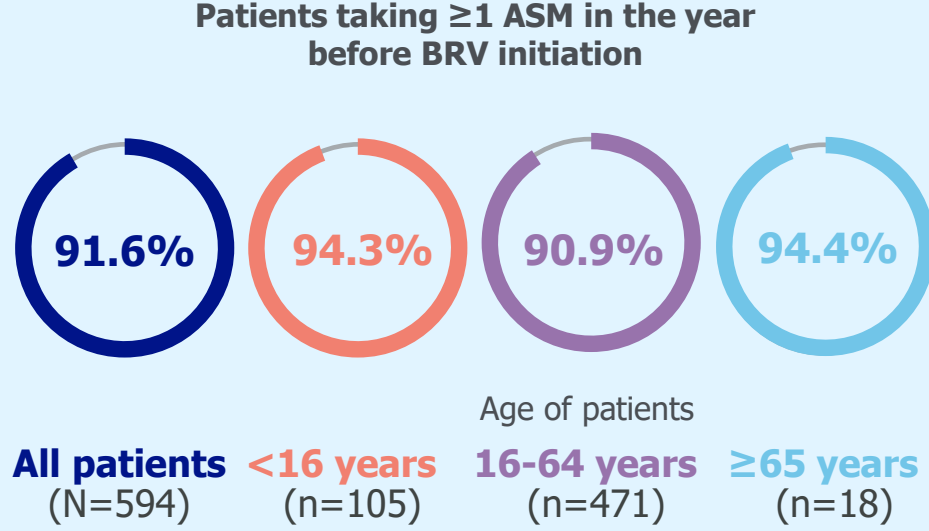
Retrospective analysis of de-identified data from Merative MarketScan of patients with an epilepsy/seizure diagnosis who were restricted to BRV monotherapy (patients with a BRV pharmacy claim [date of first BRV claim during the identification period (01/01/2016 through 12/31/2020) = index date] with antiseizure medications [ASMs] prescribed before BRV initiation discontinued <90 days after BRV initiation, and no claim for another ASM within 90 days after BRV initiation).

### RESULTS

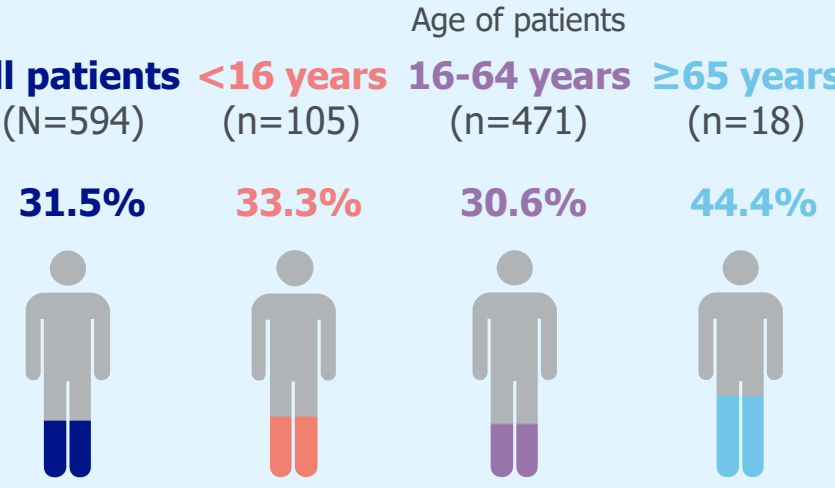
#### Patient characteristics



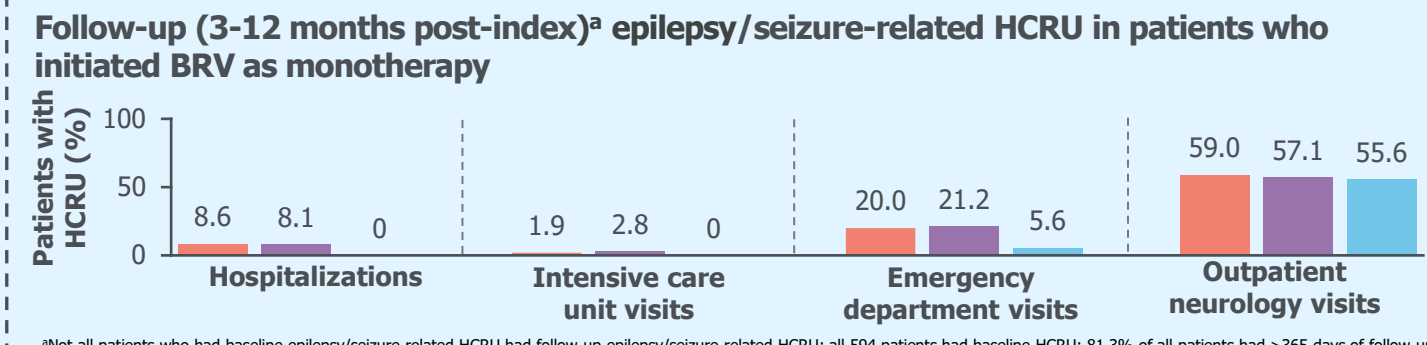
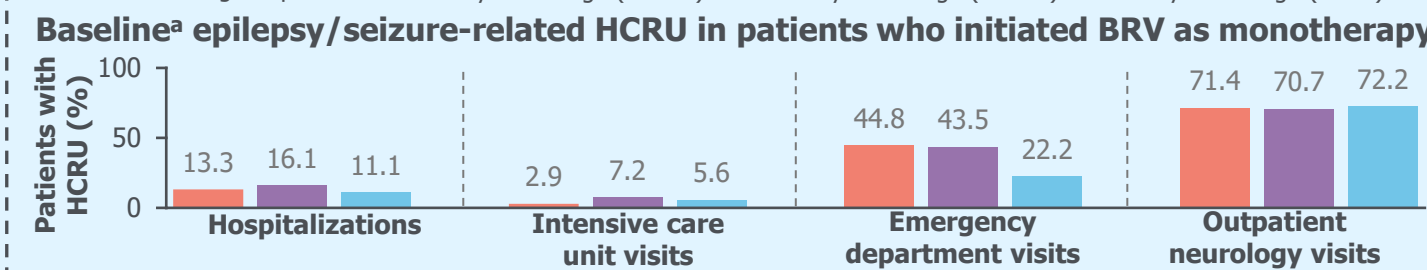
#### Treatment patterns



#### BRV retention as monotherapy at 12-month follow-up

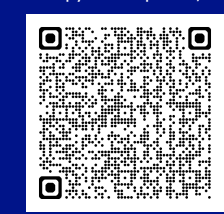


#### HCRU



<sup>a</sup>Not all patients who had baseline epilepsy/seizure-related HCRU had follow-up epilepsy/seizure-related HCRU: all 594 patients had baseline HCRU; 81.3% of all patients had >365 days of follow-up; HCRU, healthcare resource utilization.

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### CONCLUSIONS

Retention of BRV monotherapy was maintained by approximately 1 in every 3 patients for at least 12 months, and epilepsy/seizure-related HCRU decreased from baseline up to 12-month follow-up, regardless of age.

### TREATMENT PATTERNS

- More than 90% of patients, irrespective of age, were taking ≥1 ASM in the year before BRV initiation.
  - 91.6%, 94.3%, 90.9%, and 94.4% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively, were taking ≥1 ASM.
- Levetiracetam (LEV) was the most frequently initiated last ASM before BRV initiation in all groups.

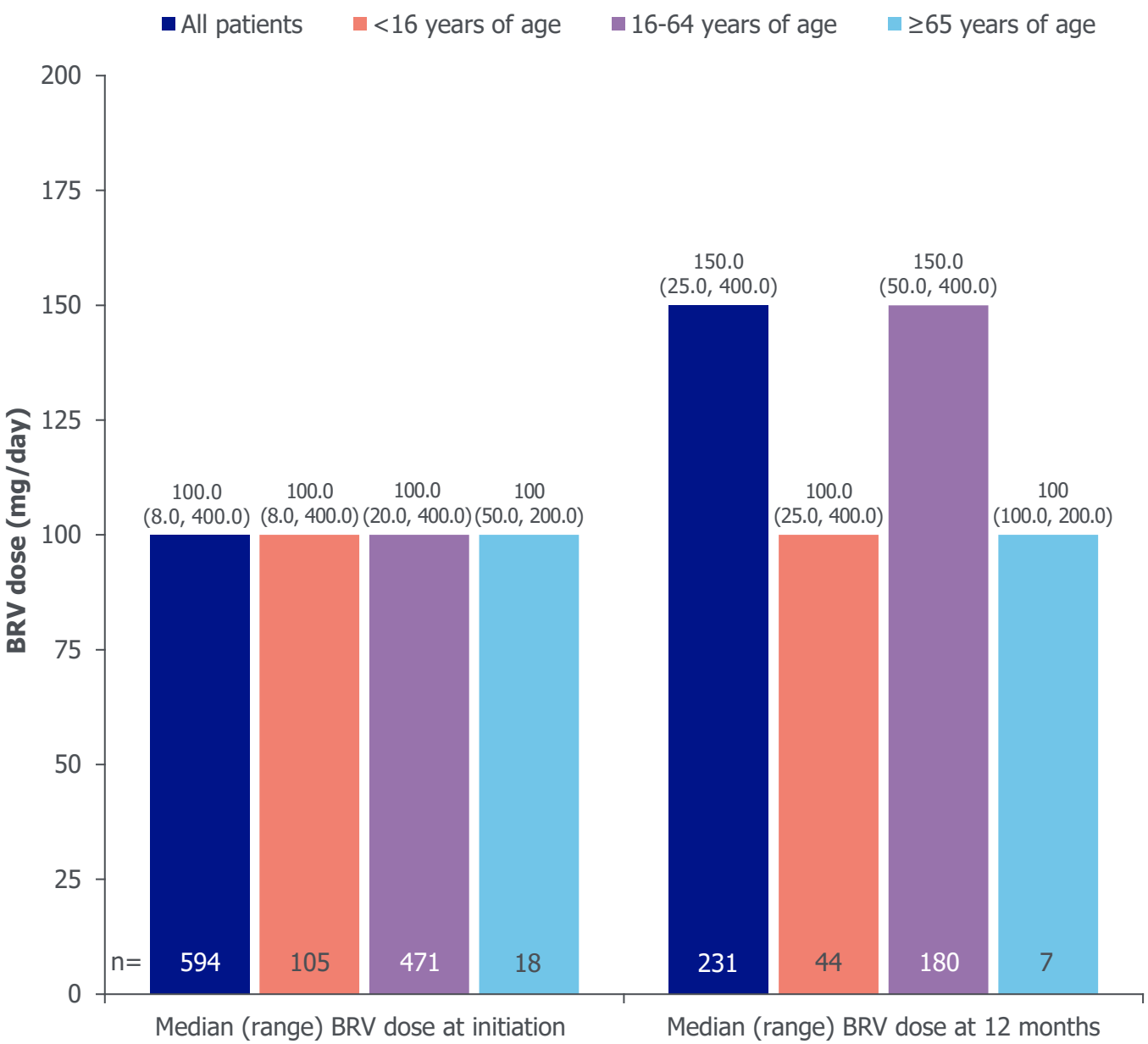
### ASMs before BRV initiation and at 12-month timepoint

	ALL PATIENTS (N=594)	STRATIFIED BY AGE		
		<16 YEARS (n=105)	16-64 YEARS (n=471)	≥65 YEARS (n=18)
<b>Last ASM initiated before BRV initiation<sup>a,b</sup> (at drug level)</b>				
Levetiracetam, n (%)	273 (49.2)	49 (49.0)	215 (49.1)	9 (52.9)
Lamotrigine, n (%)	36 (6.5)	1 (1.0)	32 (7.3)	3 (17.6)
Oxcarbazepine, n (%)	28 (5.0)	11 (11.0)	15 (3.4)	2 (11.8)
Clonazepam, n (%)	27 (4.9)	10 (10.0)	16 (3.7)	1 (5.9)
<b>BRV treatment status at 12-month timepoint</b>				
	N=594	n=105	n=471	n=18
BRV monotherapy, n (%)	187 (31.5)	35 (33.3)	144 (30.6)	8 (44.4)
Adjunctive therapy, <sup>c</sup> n (%)	49 (8.2)	11 (10.5)	38 (8.1)	0
BRV discontinued, n (%)	280 (47.1)	51 (48.6)	223 (47.3)	6 (33.3)
Lost to follow-up, n (%)	78 (13.1)	8 (7.6)	66 (14.0)	4 (22.2)
<b>ASMs at 12-month timepoint<sup>b,d,e,f</sup> (at drug level)</b>				
	n=53	n=11	n=42	n=0
Lamotrigine, n (%)	10 (18.9)	1 (9.1)	9 (21.4)	0
Topiramate, n (%)	7 (13.2)	2 (18.2)	5 (11.9)	0
Valproate, n (%)	5 (9.4)	0	5 (11.9)	0
Oxcarbazepine, n (%)	3 (5.7)	2 (18.2)	1 (2.4)	0

<sup>a</sup>Last ASM initiated before BRV initiation was calculated from the total number of last ASMs initiated before BRV initiation; <sup>b</sup>≥10% of ASMs in any group; <sup>c</sup>BRV treatment maintained with the addition of ≥1 other ASM; <sup>d</sup>ASMs at 12-month timepoint included ASMs started before 12 months and not stopped before the timepoint; <sup>e</sup>ASMs at 12-month timepoint were calculated from the total number of ASMs at the 12-month timepoint; <sup>f</sup>BRV was not included in the count. ASM, antiseizure medication.

### BRV DOSING

#### BRV dosing at BRV initiation and at 12 months

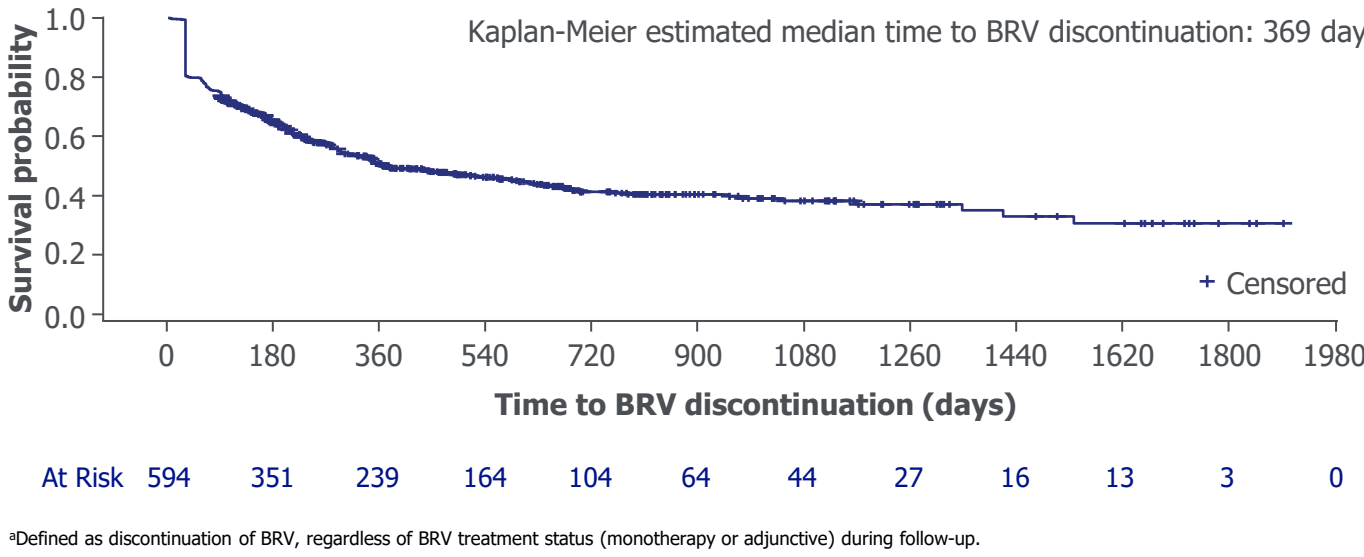


- At initiation, BRV daily dose was ≤200 mg for 99.3%, 99.0%, 99.4%, and 100.0% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.
  - At initiation, BRV daily dose was >200 mg for 0.7%, 1.0%, 0.6%, and 0%, respectively.
- At 12 months, BRV daily dose was ≤200 mg for 94.8%, 93.2%, 95.0%, and 100% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.
  - At 12 months, BRV daily dose was >200 mg for 5.2%, 6.8%, 5.0%, and 0%, respectively.

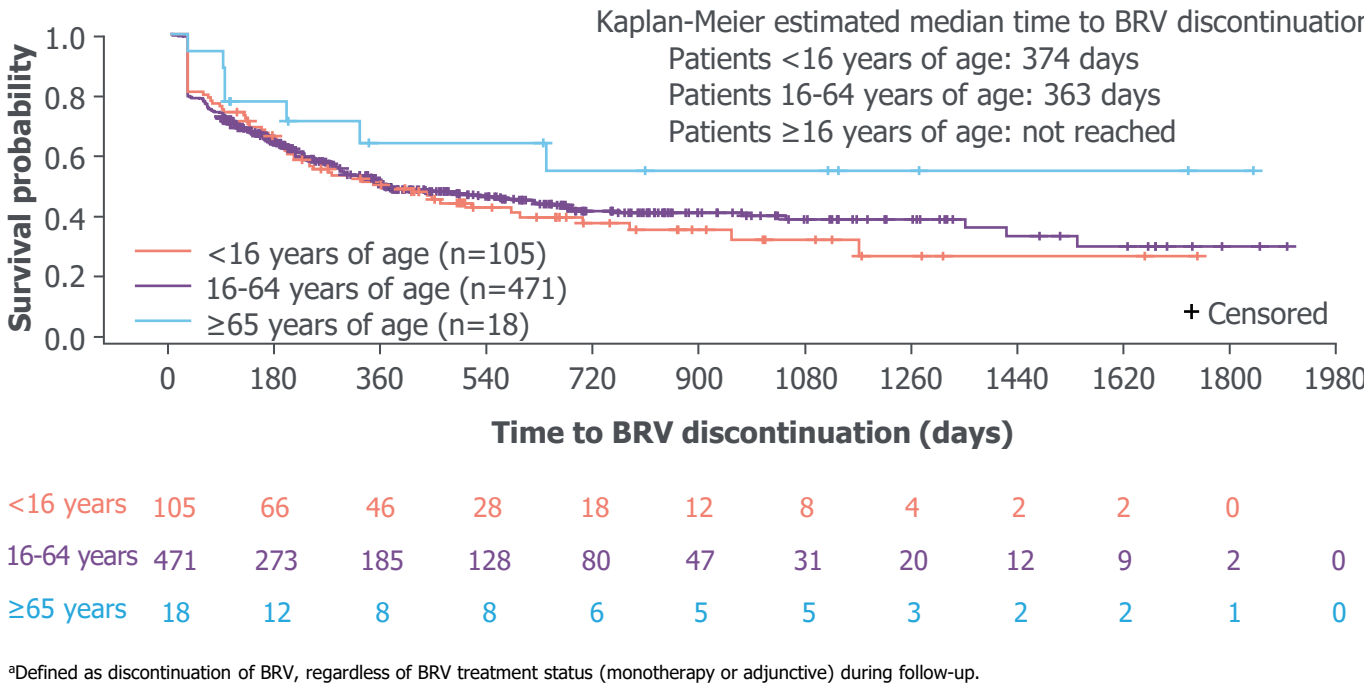
### BRV RETENTION

- Retention on BRV monotherapy at 12-month follow-up was achieved by 31.5%, 33.3%, 30.6%, and 44.4% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.

#### Kaplan-Meier estimated time to discontinuation of BRV,<sup>a</sup> among all patients who initiated BRV monotherapy

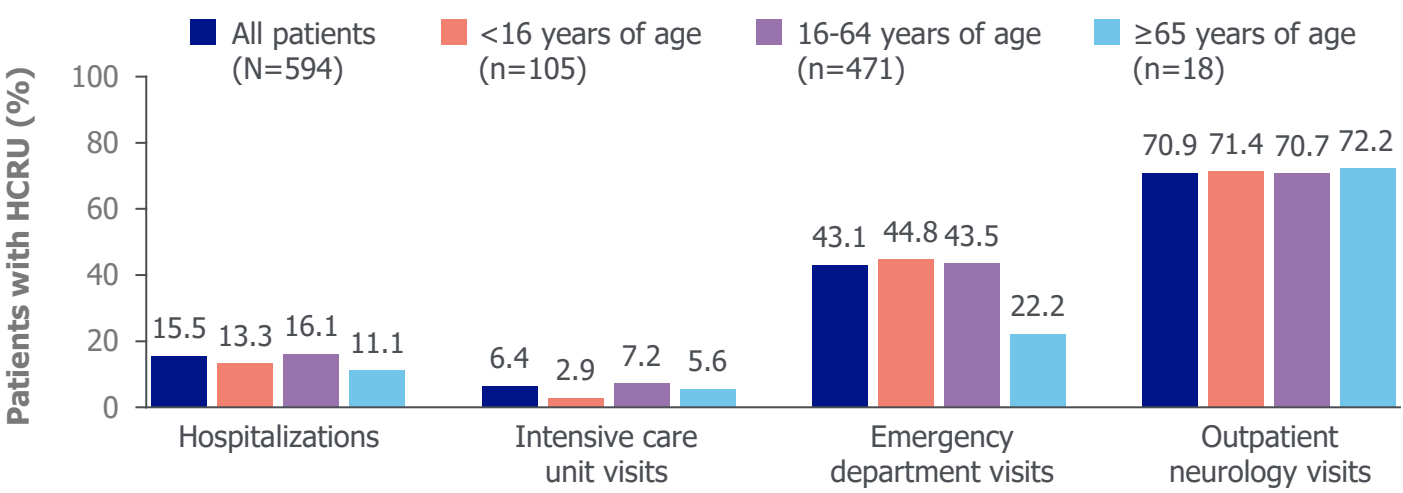


#### Kaplan-Meier estimated time to discontinuation of BRV,<sup>a</sup> among patients who initiated BRV monotherapy, by age group



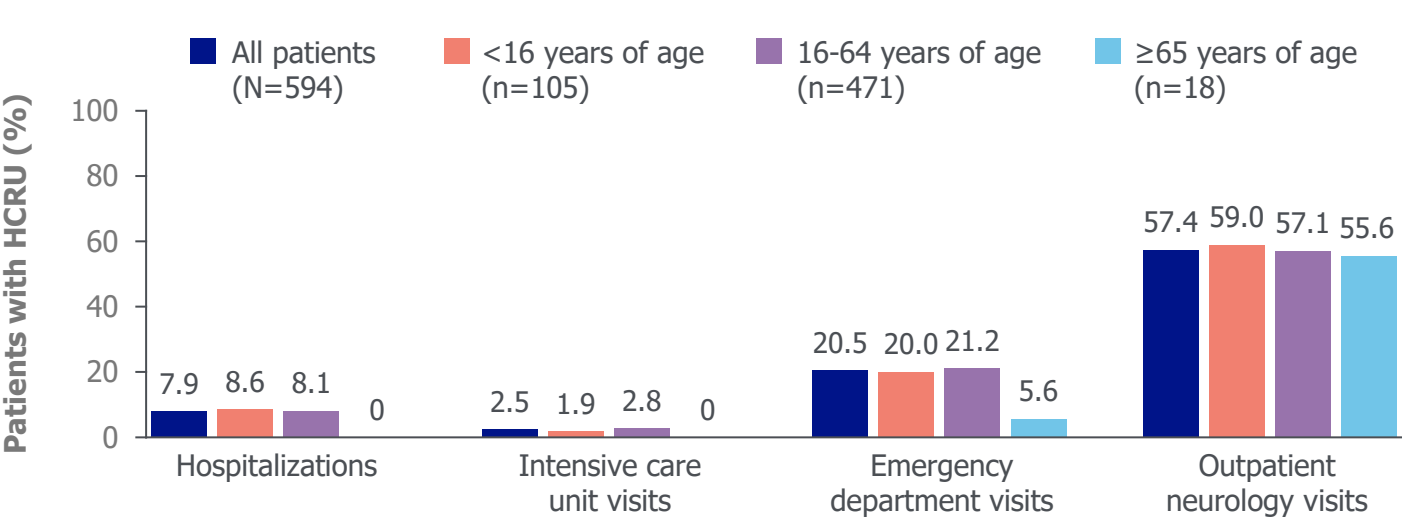
### HEALTHCARE RESOURCE UTILIZATION

#### Baseline<sup>a</sup> epilepsy/seizure-related HCRU in patients who initiated BRV as monotherapy



<sup>a</sup>All 594 patients had baseline HCRU. HCRU, healthcare resource utilization.

#### Follow-up (3-12 months post-index)<sup>a</sup> epilepsy/seizure-related HCRU in patients who initiated BRV as monotherapy



<sup>a</sup>81.3% of all patients had >365 days of follow-up; HCRU, healthcare resource utilization.

- Not all patients had 12-month follow-up epilepsy/seizure-related HCRU.
- From baseline to follow-up, there was a numerical reduction in epilepsy/seizure-related HCRU in all age groups, with the greatest reductions observed for emergency department visits.

## Limitations

- The study population was limited to patients with insurance coverage and, therefore, results may not be representative of the entire epilepsy population.
- There might be missing information, miscoding, or underreporting of information in the claims data.
- There was a small number of patients in the ≥65 years of age subgroup.
- The inclusion criterion of ≥90 days medical and pharmacy benefit coverage after index date may have created a selection bias; however, a sensitivity analysis revealed it had minimal impact on the results.
- Not all patients had 12 months of follow-up.

## Conclusions

- This retrospective data claims analysis demonstrated that approximately 1 in every 3 patients maintained BRV treatment as monotherapy for at least 12 months.
- Patients who initiated BRV as monotherapy had a decrease in epilepsy/ seizure-related HCRU from baseline up to 12-month follow-up, regardless of age.

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UCB-sponsored. UCB was involved in the design of the study, the collection, analysis, and interpretation of data, and review of the poster. The authors thank the patients and their caregivers in addition to the investigators and their teams who contributed to this trial. The authors acknowledge Bobby Jacob, PharmD, MPH (UCB, Smyrna, GA, USA) for managing the development of the poster, and Emma Budd, PhD (Evidence Scientific Solutions Ltd., Hordsham, UK) for writing assistance, which was funded by UCB. Author contributions: H Besson designed the study. B Numbere, H Besson, and A Kuba analyzed the data. All authors interpreted the data, critically reviewed the poster, and approved the final version for presentation. H Besson, B Moseley, K Pucylowski, and D Bourikas are employees of UCB. B Numbere was a contractor of UCB at the time of the study. A Kuba is a contractor of UCB. A Little was an employee of UCB at the time of the study.



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American Academy of Neurology 77th Annual Meeting  
San Diego, CA, USA | April 5–9, 2025

Previously presented at American Epilepsy Society 78th Annual Meeting, Los Angeles, CA, USA, December 6–10, 2024