

**Sponsor**

Novartis Pharmaceuticals

**Generic Drug Name**

Brolucizumab

**Trial Indication(s)**

Age-related macular degeneration (AMD)

**Protocol Number**

CRTH258AUS18

**Protocol Title**

Characteristics of Patients with Neovascular Age-related Macular Degeneration Enrolled in the Brolucizumab Patient Support Services Program

**Clinical Trial Phase**

NA

**Phase of Drug Development**

NA

**Study Start/End Dates**

Study start date: 11 Aug 2020

Study Completion date: 25 Sep 2020

**Reason for Termination**

NA

**Study Design/Methodology**

The study was a retrospective, cross-sectional, descriptive study of patients with wet AMD who enrolled in the brolucizumab Patient Support Services (PSS) program. Evidence was generated to describe their baseline demographic and clinical characteristics.

- Identification period of the index period: 10/10/2019 to 04/30/2020
- Index date: Date of enrollment into the PSS program
- Study Period: 10/10/2019 to 04/30/2020

**Centers**

The patient support services (PSS) program, sponsored by Novartis, is designed to help patients who are considering treatment with BEOVU® (brolucizumab). Patients can voluntarily enroll in the program based on their specific needs. Through the program, patients with neovascular (wet) age-related macular degeneration (AMD) are provided 1-on-1 personalized support through a dedicated “Care Champion.” Care Champions can answer questions about brolucizumab, provide transportation support options, and assist patients in understanding their insurance coverage (Beovu® Reimbursement Support, 2021).

Patient data are captured through an online or physical enrollment form. Data forms include patient demographic and insurance information as self-identified by patients, as well as a section to be filled out by a representative of the provider that details provider information. Limited clinical data such as visual acuity (VA), status of wet AMD, and whether the patient has started treatment can also be captured on the enrollment form.

**Primary objective(s)**

The primary objective of the study was to describe the primary plan type for patients with wet AMD enrolled in the brolucizumab patient support services program.

**Secondary objective(s)**

The secondary objective was to describe the demographic and clinical characteristics of patients with wet AMD enrolled in the brolucizumab patient support services program.

### **Test Product (s), Dose(s), and Mode(s) of Administration**

Not applicable

### **Statistical Methods**

All analyses for the primary and secondary objectives were descriptive. Descriptive statistics were tabulated for the baseline demographic and clinical characteristics.

### **Study Population: Key Inclusion/Exclusion Criteria**

#### **Inclusion criteria**

- Patients were enrolled in the brolocizumab PSS program
- $\geq 19$  years old

#### **Exclusion criteria**

None

**Participant Flow**

The study cohort includes 18,457 patients enrolled in the brolocizumab PSS program, aged  $\geq 19$  years and with complete data for age, gender, and insurance.

## **Baseline Characteristics**

Refer to Secondary Outcomes section for baseline characteristics.

**Primary Outcome Result(s)****Number of patients with primary insurance (Primary plan type)**

Most patients had primary insurance (17,839; 97%).

Insurance Coverage	Patient Count	% Patient
<b>Primary Insurance Yes/No</b>		
Insurance- Yes	17,839	97
Insurance- Not Available	618	3
Total	18,457	100

## Secondary Outcome Result(s)

### Age and gender characteristics

The population was predominantly female (58%) and were aged 65 years or older (95%).

Age Groups (Years)	Male	Female	Total Percentage (%)
19–25	1	4	0.03
26–35	6	2	0.0
36–45	13	11	0.13
46–55	74	43	0.63
56–64	293	413	3.80
65+	7,352	10,420	95.40
<b>Total Number N, (%)</b>	<b>7,739</b>	<b>10,893</b>	<b>100.00</b>
<b>Percentage (%)</b>	<b>41.54</b>	<b>58.46</b>	

### Number of patients enrolled according to US state and Provider (by state)

The largest proportion of patients were enrolled in Ohio and Texas (both 7%), followed by Florida and Arizona (both 6%).

Distribution of patients among the other states ranged from 0-5%. Florida had the highest number of providers with 116 (8%), followed by 107 in California (7%), 95 in Texas (6%), and 90 in New York (6%).

State	Patient region (by state)		Provider region (by state)	
	Patient Enrollment Count	Patient Enrollment Count Distribution (%)	Provider Count of Patient Enrolled	Provider Count Distribution (%) of Patient Enrolled
AK	1	0	1	0
AL	142	1	18	1
AR	201	1	11	1
AZ	1,072	6	36	2
CA	981	5	107	7
CO	495	3	32	2
CT	759	4	30	2
DC	11	0	4	0
DE	82	0	8	1
FL	1,185	6	116	8
GA	597	3	36	2
HI	45	0	8	1
IA	240	1	17	1
ID	63	0	8	1
IL	739	4	65	4
IN	397	2	37	2
KS	268	1	15	1



KY	174	1	21	1
LA	272	1	30	2
MA	609	3	37	2
MD	373	2	49	3
ME	82	0	10	1
MI	565	3	48	3
MN	146	1	13	1
MO	322	2	37	2
MS	64	0	4	0
MT	23	0	5	0
NC	703	4	39	3
ND	59	0	8	1
NE	47	0	11	1
NH	84	0	11	1
NJ	723	4	57	4
NM	84	0	11	1
NV	172	1	13	1
NY	980	5	90	6
OH	1,330	7	63	4
OK	142	1	15	1
OR	287	2	23	2
PA	464	3	58	4
RI	122	1	6	0
SC	191	1	26	2
SD	36	0	2	0
TN	120	1	26	2
TX	1,309	7	95	6

UT	443	2	13	1
VA	649	4	48	3
VT	1	0	1	0
WA	34	0	13	1
WI	225	1	27	2
WV	214	1	10	1
WY	2	0	2	0
Null	128	1	55	4

#### Type of primary insurance coverage

Most commonly primary insurance was government insurance (16,525 patients; 90%), followed by commercial (1,507; 8%).

<b>Insurance Coverage Insurance Plan Type</b>	<b>Patient Count</b>	<b>% Patient</b>
Commercial Insurance	1,507	8
Government	16,525	90
Other/NA	425	2
<b>Total</b>	<b>18,457</b>	<b>100</b>

#### Type of Secondary plan type

Secondary insurance types were most commonly government plans (8,344 patients; 45%) while 2,486 patients (13%) had commercial secondary insurance plan. Secondary insurance plan type was listed as Other or was not available for large proportion of patients (7,627; 41%).

<b>Insurance Coverage Secondary Plan Type</b>	<b>Patient Count</b>	<b>% Patient</b>
Commercial Insurance	2,486	13
Government	8,344	45
Other/NA	7,627	41
<b>Total</b>	<b>18,457</b>	<b>100</b>

#### Disease status

The largest proportion of patients (7,365, 40%) had right eye disease, followed by 6,149 patients (33%) with left eye disease, and 4,805 patients (26%) with bilateral disease.

<b>Disease status</b>	<b>Patient Count</b>	<b>% Patient</b>
Bilateral	4,805	26
Left Eye	6,149	33
Right Eye	7,365	40
Incomplete Data	138	1
<b>Total</b>	<b>18,457</b>	<b>100</b>

#### **Safety Results**

No safety data was collected or analyzed as part of this retrospective study.

**Other Relevant Findings**

None

**Conclusion**

A cohort of 18,457 patients with wet AMD was identified from the brolucizumab PSS program. Most of these patients had a primary insurance plan (97%). The insurance plan type was mainly government (90%) followed by commercial (8%). Furthermore, a large proportion of patients had government insurance (45%) as their secondary plan, compared with commercial insurance (13%). Benefit verification was completed for 98% of patients, most of whom were covered (96%).

The secondary objective describes the demographic and clinical characteristics of the cohort. The cohort was predominantly female (58 %), and a majority (95%) of patients were aged 65 years or older. The largest proportion of patients were enrolled in Ohio and Texas (both 7%), followed by Florida and Arizona (both 6%). Distribution of patients among the other states ranged from 0-5%. Right eye disease was reported for 40% of patients, left eye disease for 33%, and bilateral disease 26%. The most common diagnosis description was active choroidal neovascularization occurring in the right eye (6,249), left eye (5,353) or bilaterally (4,201).

**Date of Clinical Study Report**

09 March 2021