

To estimate the **Potential Peak Sales** for lisocabtagene maraleucel (Breyanzi) in the indication of relapsed or refractory mantle cell lymphoma (MCL) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data on patient numbers, pricing, and market penetration may not be publicly available in real-time, I will outline a methodology based on reasonable assumptions and general market data. If you have specific data or figures (e.g., exact patient numbers or pricing), I can refine the calculations.

Lisocabtagene maraleucel (Breyanzi) is a CAR-T cell therapy approved for adult patients with relapsed or refractory MCL who have received at least two prior lines of systemic therapy, including a BTKi. This is a niche indication with a relatively small patient population, but CAR-T therapies command high prices due to their personalized nature and clinical efficacy.

Step 1: Estimate the Target Patient Population

Mantle cell lymphoma (MCL) is a rare subtype of non-Hodgkin lymphoma (NHL), accounting for approximately 6% of NHL cases. The relapsed or refractory (R/R) population after two lines of therapy, including a BTKi, is a subset of this group.

Incidence and Prevalence of MCL:

- **US:** MCL incidence is ~0.5-1 per 100,000 people annually. With a population of ~330 million, this translates to ~1,650-3,300 new cases per year. Approximately 20-30% of patients may reach R/R status after 2 lines of therapy, so ~330-990 eligible patients annually.
- **EU5:** Combined population of ~260 million. Using a similar incidence rate, ~1,300-2,600 new cases per year. R/R after 2 lines: ~260-780 eligible patients.
- **Japan:** Population of ~125 million. Incidence: ~625-1,250 new cases per year. R/R after 2 lines: ~125-375 eligible patients.
- **China:** Population of ~1.4 billion. Incidence may be slightly lower due to regional differences (~0.3-0.5 per 100,000), so ~4,200-7,000 new cases per year. R/R after 2 lines: ~840-2,100 eligible patients.

Total eligible patients (R/R MCL after 2 lines of therapy):

- US: ~330-990
- EU5: ~260-780
- Japan: ~125-375
- China: ~840-2,100
- **Total across geographies:** ~1,555-4,245 patients annually.

Treated Population:

Not all eligible patients will receive CAR-T therapy due to factors like access, cost, health status, and logistics. Assuming a **20-30% treatment rate** (as per the query's assumption of share of treated patients), the treated population is:

- US: ~66-297 patients

- EU5: ~52-234 patients
- Japan: ~25-113 patients
- China: ~168-630 patients
- **Total treated patients:** ~311-1,274 patients annually.

Step 2: Pricing of Lisocabtagene Maraleucel (Breyanzi)

CAR-T therapies are expensive due to their personalized manufacturing process. The list price for Breyanzi in the US for other indications (e.g., large B-cell lymphoma) is approximately **\$410,000 per patient** (based on available data as of 2023). Pricing may vary by region due to healthcare system differences:

- **US:** ~\$410,000 per patient
- **EU5:** ~\$350,000-\$400,000 (slight discount due to price negotiations)
- **Japan:** ~\$350,000-\$400,000 (similar to EU5)
- **China:** ~\$200,000-\$300,000 (lower due to pricing pressures and local reimbursement policies)

For simplicity, we'll use an average price across regions with a range:

- US: \$410,000
- EU5: \$375,000
- Japan: \$375,000
- China: \$250,000

Step 3: Calculate Potential Peak Sales (20%-30% Share of Treated Patients)

Peak sales are calculated as:

Peak Sales = Number of Treated Patients x Price per Patient

Low-End Estimate (20% share):

- US: 66 patients x \$410,000 = **\$27.1 million**
- EU5: 52 patients x \$375,000 = **\$19.5 million**
- Japan: 25 patients x \$375,000 = **\$9.4 million**
- China: 168 patients x \$250,000 = **\$42.0 million**
- **Total Low-End Peak Sales: \$98.0 million**

High-End Estimate (30% share):

- US: 297 patients x \$410,000 = **\$121.8 million**
- EU5: 234 patients x \$375,000 = **\$87.8 million**
- Japan: 113 patients x \$375,000 = **\$42.4 million**
- China: 630 patients x \$250,000 = **\$157.5 million**
- **Total High-End Peak Sales: \$409.5 million**

Potential Peak Sales Range: \$98 million to \$410 million annually across the US, EU5, Japan, and China for this indication.

Step 4: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated patient population in each region. Using the treated patient range (311-1,274):

- 1% of treated patients = ~3.1 to 12.7 patients annually across all regions.

Now, calculate the revenue for 1% share using the regional pricing:

Low-End (based on lower patient numbers, ~3.1 total patients):

- US: 1% of 66 = 0.66 patients x \$410,000 = **\$0.27 million**
- EU5: 1% of 52 = 0.52 patients x \$375,000 = **\$0.20 million**
- Japan: 1% of 25 = 0.25 patients x \$375,000 = **\$0.09 million**
- China: 1% of 168 = 1.68 patients x \$250,000 = **\$0.42 million**
- **Total Low-End Value of 1% Share: \$0.98 million**

High-End (based on higher patient numbers, ~12.7 total patients):

- US: 1% of 297 = 2.97 patients x \$410,000 = **\$1.22 million**
- EU5: 1% of 234 = 2.34 patients x \$375,000 = **\$0.88 million**
- Japan: 1% of 113 = 1.13 patients x \$375,000 = **\$0.42 million**
- China: 1% of 630 = 6.3 patients x \$250,000 = **\$1.58 million**
- **Total High-End Value of 1% Share: \$4.10 million**

\$ Value of 1% Share of Treated Patients: \$0.98 million to \$4.10 million annually across the US, EU5, Japan, and China.

Summary of Results

1. **Potential Peak Sales for Lisocabtagene Maraleucel (20%-30% share of treated patients):**

- Range: **\$98 million to \$410 million annually** across US, EU5, Japan, and China for R/R MCL.

2. \$ Value of 1% Share of Treated Patients:

- Range: **\$0.98 million to \$4.10 million annually** across the same geographies.

Key Assumptions and Caveats

- Patient population estimates are based on general epidemiology data for MCL and assumptions about R/R rates after two lines of therapy.

- Pricing is assumed based on publicly available data for CAR-T therapies and adjusted for regional differences.

- The 20%-30% treatment rate is as per the query; actual market penetration may vary based on competition, access, and reimbursement.

- These figures represent peak sales potential and do not account for ramp-up time, manufacturing constraints, or payer negotiations.

- China's pricing and uptake are more speculative due to limited CAR-T adoption and pricing transparency.

If you have access to more precise data (e.g., exact patient numbers, local pricing, or market share projections), I can refine these estimates further. Let me know!