

To estimate the **Potential Peak Sales** for **brexucabtagene autoleucel (Tecartus)** 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 based on available data and reasonable assumptions. Since exact patient numbers, pricing, and market penetration rates may not be publicly available in full detail, I will outline the methodology and use approximate figures based on industry standards, epidemiology data, and reported pricing for CAR-T therapies.

Step 1: Key Assumptions and Inputs

1. **Indication:** Relapsed or refractory mantle cell lymphoma (MCL).
2. **Target Population:** Adult patients with relapsed/refractory MCL who have failed prior therapies (anthracycline/bendamustine, anti-CD20 antibody, BTK inhibitor).
3. **Market Share:** Assuming 20% to 30% of treated patients in this indication.
4. **Pricing:** Brexucabtagene autoleucel is a CAR-T therapy, and pricing for similar therapies (e.g., Yescarta, Kymriah) is approximately \$373,000 per treatment in the US. Pricing in other regions may be lower due to healthcare system differences (e.g., ~70-80% of US price in EU5 and Japan, and significantly lower in China due to pricing negotiations).
5. **Epidemiology:** MCL is a rare subtype of non-Hodgkin lymphoma (NHL), accounting for ~6% of NHL cases. Incidence rates and eligible patient populations will vary by geography.
6. **Peak Sales Timing:** Peak sales are typically reached 5-7 years post-launch after market penetration stabilizes.

Step 2: Estimate Eligible Patient Population

MCL incidence and prevalence vary by region. Based on epidemiology data and literature:

- **US:** ~3,300 new MCL cases per year (incidence ~1 per 100,000). Assuming ~30-40% are relapsed/refractory and eligible for CAR-T (post prior therapies), ~1,000-1,300 patients per year.
- **EU5:** Combined population is ~1.5x the US, with similar incidence. Eligible patients ~1,500-2,000 per year.
- **Japan:** Incidence is lower (~0.5 per 100,000), with a population of ~125 million. Eligible patients ~200-300 per year.
- **China:** Much larger population (~1.4 billion), but lower incidence (~0.3-0.5 per 100,000) and lower access to advanced therapies. Eligible patients ~1,000-1,500 per year, though access and affordability limit uptake.

Total Eligible Patients (Annual Estimate):

- US: 1,200
- EU5: 1,750

- Japan: 250
- China: 1,250
- **Total:** ~4,450 patients annually (conservative estimate).

Step 3: Estimate Treated Patients and Market Share

Assuming brexucabtagene autoleucel captures **20%-30% of treated patients** in this indication:

- **US:** 240-360 patients (20-30% of 1,200)
- **EU5:** 350-525 patients (20-30% of 1,750)
- **Japan:** 50-75 patients (20-30% of 250)
- **China:** 250-375 patients (20-30% of 1,250, though uptake may be lower due to cost and access barriers)
- **Total Treated Patients:** 890-1,335 patients annually at 20-30% market share.

Step 4: Pricing per Patient

CAR-T therapies are expensive, with pricing varying by region:

- **US:** ~\$373,000 per patient (based on Yescarta/Tecartus pricing).
- **EU5:** ~\$300,000 per patient (assumed ~80% of US price due to negotiations and healthcare systems).
- **Japan:** ~\$300,000 per patient (similar to EU5).
- **China:** ~\$150,000 per patient (assumed significant discount due to pricing controls and affordability issues).

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as: **Number of Treated Patients × Price per Patient.**

At 20% Market Share:

- **US:** 240 patients × \$373,000 = **\$89.5 million**
- **EU5:** 350 patients × \$300,000 = **\$105 million**
- **Japan:** 50 patients × \$300,000 = **\$15 million**
- **China:** 250 patients × \$150,000 = **\$37.5 million**
- **Total Peak Sales (20%):** **\$247 million**

At 30% Market Share:

- **US:** 360 patients × \$373,000 = **\$134.3 million**
- **EU5:** 525 patients × \$300,000 = **\$157.5 million**
- **Japan:** 75 patients × \$300,000 = **\$22.5 million**
- **China:** 375 patients × \$150,000 = **\$56.3 million**
- **Total Peak Sales (30%): \$370.6 million**

Potential Peak Sales Range: \$247 million to \$370.6 million annually across the US, EU5, Japan, and China for this indication.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the eligible patient pool being treated with brexucabtagene autoleucel.

- **US:** 1% of 1,200 = 12 patients × \$373,000 = **\$4.48 million**
- **EU5:** 1% of 1,750 = 17.5 patients × \$300,000 = **\$5.25 million**
- **Japan:** 1% of 250 = 2.5 patients × \$300,000 = **\$0.75 million**
- **China:** 1% of 1,250 = 12.5 patients × \$150,000 = **\$1.88 million**
- **Total Value of 1% Share: \$12.36 million**

\$ Value of 1% Share of Treated Patients: \$12.36 million annually across these geographies.

Summary of Results

1. Potential Peak Sales for Brexucabtagene Autoleucel in Relapsed/Refractory MCL (20%-30% market share):

- US: \$89.5M - \$134.3M
- EU5: \$105M - \$157.5M
- Japan: \$15M - \$22.5M
- China: \$37.5M - \$56.3M
- **Total: \$247M - \$370.6M annually**

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

- US: \$4.48M
- EU5: \$5.25M

- Japan: \$0.75M
- China: \$1.88M
- **Total: \$12.36M annually**

Caveats and Limitations

- These estimates are based on assumptions for patient numbers, pricing, and market share, which may vary based on real-world data, competition (e.g., other CAR-T therapies or novel treatments), reimbursement policies, and access barriers, especially in China.
- Peak sales may be influenced by manufacturing capacity, patient access programs, and long-term outcomes data.
- The analysis assumes static pricing, though prices may decrease over time due to competition or negotiations.

If more specific data (e.g., exact patient numbers, regional pricing, or market share projections) is available, these estimates can be refined further.