

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma 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 dynamics may vary and are not fully provided, I will outline the methodology and assumptions to arrive at an estimate. Please note that actual figures may differ based on real-world data, and I will use reasonable approximations based on publicly available information and market research norms.

Step 1: Define the Target Patient Population

The indication is for **first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma**. We need to estimate the number of eligible patients in each geography.

Incidence and Prevalence of Gastric/GEJ Cancer

- **Gastric cancer** is one of the leading causes of cancer deaths worldwide, with high incidence in East Asia (e.g., China, Japan), and significant burden in the US and Europe.
- Approximately **60-70% of gastric/GEJ cancers are HER2-negative**, based on clinical studies.
- We focus on **locally advanced unresectable or metastatic cases**, which account for roughly **40-50% of diagnosed cases** at presentation.

Estimated Annual Incidence of Eligible Patients (First-Line Setting)

Using approximate annual incidence data for gastric/GEJ cancer and adjusting for HER2-negative status and advanced/metastatic stage:

- **US**: ~27,000 new gastric cancer cases/year; ~60% HER2-negative and ~45% advanced/metastatic = ~7,300 eligible patients.
- **EU5**: ~60,000 new cases/year; ~60% HER2-negative and ~45% advanced/metastatic = ~16,200 eligible patients.
- **China**: ~400,000 new cases/year; ~60% HER2-negative and ~45% advanced/metastatic = ~108,000 eligible patients.
- **Japan**: ~130,000 new cases/year; ~60% HER2-negative and ~45% advanced/metastatic = ~35,100 eligible patients.
- **Total Across Geographies**: ~166,600 eligible patients annually.

These are rough estimates based on data from sources like the American Cancer Society, GLOBOCAN, and regional cancer registries.

Step 2: Estimate Market Share of Treated Patients

The problem states a **20% to 30% share of treated patients** for pembrolizumab in this indication. This accounts for competition from other therapies (e.g., chemotherapy alone, other immunotherapies) and market penetration challenges.

- For simplicity, we'll calculate using both ends of the range (20% and 30%) to provide a range for peak sales.

- **Treated Patients at 20% Share:**

- US: $7,300 \times 0.2 = 1,460$ patients

- EU5: $16,200 \times 0.2 = 3,240$ patients

- China: $108,000 \times 0.2 = 21,600$ patients

- Japan: $35,100 \times 0.2 = 7,020$ patients

- Total: ~33,320 patients

- **Treated Patients at 30% Share:**

- US: $7,300 \times 0.3 = 2,190$ patients

- EU5: $16,200 \times 0.3 = 4,860$ patients

- China: $108,000 \times 0.3 = 32,400$ patients

- Japan: $35,100 \times 0.3 = 10,530$ patients

- Total: ~49,980 patients

Step 3: Estimate Annual Cost of Pembrolizumab per Patient

Pembrolizumab is typically priced based on a per-dose or per-cycle basis, and treatment duration for metastatic cancers can last several months to a year or more until disease progression or toxicity.

- **US Pricing:** Pembrolizumab's list price is approximately \$10,000 per dose (every 3 weeks). Assuming ~17-18 cycles per year (based on a Q3W schedule), the annual cost per patient is ~\$170,000–\$180,000. We'll use \$175,000 for simplicity.

- **EU5 Pricing:** Pricing in Europe is typically 30-50% lower due to healthcare negotiations. Assume ~\$100,000 per patient annually.

- **China Pricing:** Pricing in China is significantly lower due to market access agreements and local pricing policies. Assume ~\$40,000 per patient annually.

- **Japan Pricing:** Pricing in Japan is closer to EU levels, ~\$100,000 per patient annually.

These are rough estimates based on historical pricing trends for Keytruda and other oncology drugs.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each geography.

At 20% Market Share:

- **US:** 1,460 patients × \$175,000 = **\$255.5 million**
- **EU5:** 3,240 patients × \$100,000 = **\$324.0 million**
- **China:** 21,600 patients × \$40,000 = **\$864.0 million**
- **Japan:** 7,020 patients × \$100,000 = **\$702.0 million**
- **Total Peak Sales at 20% Share:** **\$2,145.5 million (or ~\$2.15 billion)**

At 30% Market Share:

- **US:** 2,190 patients × \$175,000 = **\$383.3 million**
- **EU5:** 4,860 patients × \$100,000 = **\$486.0 million**
- **China:** 32,400 patients × \$40,000 = **\$1,296.0 million**
- **Japan:** 10,530 patients × \$100,000 = **\$1,053.0 million**
- **Total Peak Sales at 30% Share:** **\$3,218.3 million (or ~\$3.22 billion)**

Thus, the **Potential Peak Sales** range for pembrolizumab in this indication across the specified geographies is approximately **\$2.15 billion to \$3.22 billion annually**, depending on market share.

Step 5: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total eligible patient population in each geography. We calculate the number of patients and multiply by the annual cost per patient.

- **US:** 7,300 patients × 0.01 = 73 patients; 73 × \$175,000 = **\$12.8 million**
- **EU5:** 16,200 patients × 0.01 = 162 patients; 162 × \$100,000 = **\$16.2 million**
- **China:** 108,000 patients × 0.01 = 1,080 patients; 1,080 × \$40,000 = **\$43.2 million**
- **Japan:** 35,100 patients × 0.01 = 351 patients; 351 × \$100,000 = **\$35.1 million**
- **Total \$ Value of 1% Share Across Geographies:** **\$107.3 million**

Thus, the **\$ value of a 1% share of treated patients** across the US, EU5, China, and Japan is approximately **\$107.3 million annually**.

Final Answer:

1. **Potential Peak Sales for Pembrolizumab** in the indication of first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma (assuming 20% to 30% market share):

- **Range: \$2.15 billion to \$3.22 billion annually** across the US, EU5, China, and Japan.

- Breakdown by geography (at 20% and 30% share):

- US: \$255.5M to \$383.3M

- EU5: \$324.0M to \$486.0M

- China: \$864.0M to \$1,296.0M

- Japan: \$702.0M to \$1,053.0M

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

- **Total: \$107.3 million annually** across all geographies.

- Breakdown by geography:

- US: \$12.8M

- EU5: \$16.2M

- China: \$43.2M

- Japan: \$35.1M

Notes and Assumptions:

- Patient population estimates are based on approximate incidence data and may vary with updated epidemiology studies.

- Pricing assumptions are based on historical data for pembrolizumab and may differ due to regional negotiations, discounts, or reimbursement policies.

- Market share (20-30%) is assumed as per the query, but actual penetration depends on competition, clinical adoption, and payer dynamics.

- Peak sales assume steady-state market penetration and do not account for ramp-up or decline phases.

If you have access to more precise data (e.g., exact patient numbers, pricing, or market forecasts), these calculations can be refined further.