

To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the indication of relapsed or progressed classical Hodgkin lymphoma (cHL) after autologous HSCT and post-transplantation brentuximab vedotin in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach based on available data and reasonable assumptions. Since exact figures for patient populations, pricing, and market penetration may not be publicly available, I will outline the methodology and provide illustrative calculations. Note that real-world data would be required for precise numbers.

Step 1: Define the Target Patient Population

The indication is for patients with cHL who have relapsed or progressed after autologous HSCT and post-transplantation brentuximab vedotin. This is a niche population within the broader Hodgkin lymphoma patient pool.

- **Prevalence of Hodgkin Lymphoma (HL):** HL has an incidence of approximately 2-3 per 100,000 people annually in Western countries. In the US, about 8,000-9,000 new cases are diagnosed yearly. In EU5, the combined incidence is roughly 10,000-12,000 new cases annually. In China and Japan, incidence is lower (around 0.5-1 per 100,000), leading to fewer cases (China: ~7,000-10,000; Japan: ~2,000-3,000 annually).
- **Relapsed/Refractory HL Post-HSCT and Brentuximab Vedotin:** Only a subset of HL patients relapse after first-line therapy, and an even smaller subset undergo autologous HSCT. Of those, a fraction fail brentuximab vedotin post-HSCT. Literature suggests that approximately 5-10% of HL patients may fall into this specific category of relapsed/refractory post-HSCT and post-brentuximab vedotin.
- **US:** ~8,500 new HL cases/year → ~850 patients (10%) may reach this stage annually.
- **EU5:** ~11,000 new HL cases/year → ~1,100 patients (10%) annually.
- **China:** ~8,500 new HL cases/year → ~850 patients (10%) annually.
- **Japan:** ~2,500 new HL cases/year → ~250 patients (10%) annually.
- **Total Eligible Patients (Annual Incident Cases):** ~3,050 across US, EU5, China, and Japan.

Since this is a chronic indication with potential for multiple years of treatment or follow-up, we can assume a **prevalent pool** of eligible patients that is 2-3x the annual incident cases (accounting for patients surviving and requiring ongoing or future treatment). Thus, the prevalent eligible population might be around **6,000-9,000 patients** across these geographies.

Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)

The problem assumes a 20%-30% share of treated patients for nivolumab. This means that of the eligible patients, 20%-30% will receive nivolumab for this indication.

- **Low End (20% Penetration):** 20% of 6,000-9,000 = **1,200-1,800 patients treated annually.**
- **High End (30% Penetration):** 30% of 6,000-9,000 = **1,800-2,700 patients treated annually.**

Step 3: Estimate Annual Cost of Treatment per Patient

Nivolumab is a high-cost immunotherapy. The annual cost of treatment varies by country due to pricing differences, discounts, and healthcare systems.

- **US:** Annual cost of nivolumab is approximately \$150,000-\$200,000 per patient (based on historical data for Opdivo in oncology indications).
- **EU5:** Pricing is typically 30-50% lower than the US due to negotiated pricing and health technology assessments. Assume ~\$100,000-\$120,000 per patient annually.
- **Japan:** Pricing is often aligned with EU levels, ~\$100,000-\$120,000 per patient annually.
- **China:** Pricing is significantly lower due to market access challenges and local pricing policies, ~\$50,000-\$70,000 per patient annually.

For simplicity, let's use weighted average costs considering patient distribution and pricing:

- US: ~40% of patients, \$175,000/patient.
- EU5: ~35% of patients, \$110,000/patient.
- Japan: ~10% of patients, \$110,000/patient.
- China: ~15% of patients, \$60,000/patient.

Weighted Average Annual Cost per Patient:

$(0.4 * 175,000) + (0.35 * 110,000) + (0.1 * 110,000) + (0.15 * 60,000) = \$70,000 + \$38,500 + \$11,000 + \$9,000 = \sim\$128,500$ per patient annually.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the average annual cost per patient.

- **Low End (1,200 patients at 20% penetration):**

$1,200 * \$128,500 = \sim\154 million annually.

- **High End (2,700 patients at 30% penetration):**

$2,700 * \$128,500 = \sim\347 million annually.

Thus, **Potential Peak Sales** for nivolumab in this indication across the US, EU5, China, and Japan range from **\$154 million to \$347 million annually**.

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

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

- Total eligible prevalent pool: 6,000-9,000 patients.
- 1% of treated patients: 1% of 6,000-9,000 = **60-90 patients**.
- Revenue from 1% share: 60-90 patients * \$128,500 = **\$7.7 million to \$11.6 million annually**.

Thus, the **\$ value of a 1% share of treated patients** is approximately **\$7.7 million to \$11.6 million annually**.

Final Answer

- **Potential Peak Sales for Nivolumab in this Indication (US, EU5, China, Japan):**
- Range: **\$154 million to \$347 million annually** (based on 20%-30% market penetration).
- **\$ Value of 1% Share of Treated Patients:**
- Range: **\$7.7 million to \$11.6 million annually**.

Caveats and Assumptions

1. Patient population estimates are based on general epidemiology data for HL and assumptions about relapse rates and treatment pathways. Real-world data may differ.
2. Pricing is approximated based on historical costs for nivolumab in oncology and may vary by country due to negotiations, rebates, or biosimilar competition.
3. Market penetration (20%-30%) is as per the query, but actual uptake depends on competition (e.g., other PD-1 inhibitors like pembrolizumab), clinical guidelines, and payer policies.
4. Peak sales assume steady-state adoption and do not account for ramp-up or decline phases.

For more accurate figures, detailed market research, payer data, and current pricing agreements would be necessary. If you have specific data or additional context, I can refine the calculations further.