

To estimate the **Potential Peak Sales** for isatuximab-irfc (Sarclisa) in the indication of newly diagnosed multiple myeloma (NDMM) patients ineligible for autologous stem cell transplant (ASCT) 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 exact data on patient populations, pricing, and market dynamics may not be publicly available in real-time, I will outline the methodology and provide reasonable assumptions based on publicly available information, market trends, and typical oncology drug sales patterns. The final numbers should be validated with primary market research or proprietary data sources.

Step 1: Define the Target Patient Population

- **Indication:** Newly diagnosed multiple myeloma (NDMM) patients ineligible for ASCT.
- **Geographies:** US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan.
- **Epidemiology:** Multiple myeloma incidence and the proportion of NDMM patients ineligible for ASCT vary by region due to differences in age demographics, healthcare systems, and treatment guidelines.
- Approximately 30-40% of NDMM patients are ineligible for ASCT due to age (>65-70 years) or comorbidities.
- Incidence of multiple myeloma (per 100,000 population) is roughly:
 - US: ~7-8
 - EU5: ~5-7
 - Japan: ~2-3
 - China: ~1-2
- Population estimates (2023):
 - US: ~330 million
 - EU5: ~260 million (combined)
 - China: ~1,400 million
 - Japan: ~125 million

Using these figures, we can estimate the annual incident NDMM cases and the proportion ineligible for ASCT:

- **US:** ~25,000-30,000 NDMM cases/year; ~10,000-12,000 ineligible for ASCT.
- **EU5:** ~15,000-20,000 NDMM cases/year; ~6,000-8,000 ineligible for ASCT.
- **China:** ~15,000-25,000 NDMM cases/year; ~6,000-10,000 ineligible for ASCT.
- **Japan:** ~2,500-3,500 NDMM cases/year; ~1,000-1,500 ineligible for ASCT.

Total Target Population (ineligible for ASCT):

- US: ~11,000
- EU5: ~7,000
- China: ~8,000

- Japan: ~1,250
- **Global Total (these geographies):** ~27,250 patients/year.

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

- Assuming isatuximab-irfc (Sarclisa) captures 20%-30% of the treated NDMM patients ineligible for ASCT:
- **US:** 2,200-3,300 patients
- **EU5:** 1,400-2,100 patients
- **China:** 1,600-2,400 patients
- **Japan:** 250-375 patients
- **Total Treated Patients with Sarclisa:** ~5,450-8,175 patients/year across these geographies at peak penetration.

Step 3: Pricing Assumptions

- Sarclisa is a monoclonal antibody, and pricing for such drugs in multiple myeloma is high, especially in combination regimens.
- Annual cost per patient (based on similar drugs like daratumumab and typical US pricing):
- **US:** ~\$150,000-\$200,000 per patient/year
- **EU5:** ~\$80,000-\$120,000 per patient/year (lower due to pricing negotiations and healthcare systems)
- **Japan:** ~\$100,000-\$150,000 per patient/year
- **China:** ~\$30,000-\$50,000 per patient/year (significant discounts due to market access challenges and local pricing policies)
- For simplicity, we'll use midpoint estimates:
- US: \$175,000
- EU5: \$100,000
- China: \$40,000
- Japan: \$125,000

Step 4: Calculate Potential Peak Sales

Using the number of treated patients (20%-30% share) and pricing per region:

At 20% Market Share:

- **US:** 2,200 patients * \$175,000 = **\$385 million**
- **EU5:** 1,400 patients * \$100,000 = **\$140 million**
- **China:** 1,600 patients * \$40,000 = **\$64 million**

- **Japan:** 250 patients * \$125,000 = **\$31.25 million**

- **Total Peak Sales (20%):** **\$620.25 million**

At 30% Market Share:

- **US:** 3,300 patients * \$175,000 = **\$577.5 million**

- **EU5:** 2,100 patients * \$100,000 = **\$210 million**

- **China:** 2,400 patients * \$40,000 = **\$96 million**

- **Japan:** 375 patients * \$125,000 = **\$46.875 million**

- **Total Peak Sales (30%):** **\$930.375 million**

Potential Peak Sales Range: **\$620 million to \$930 million annually** across the US, EU5, China, and Japan for this indication.

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

A 1% share corresponds to 1% of the total target population (27,250 patients) = ~272.5 patients.

- **US:** 1% = 110 patients * \$175,000 = **\$19.25 million**

- **EU5:** 1% = 70 patients * \$100,000 = **\$7 million**

- **China:** 1% = 80 patients * \$40,000 = **\$3.2 million**

- **Japan:** 1% = 12.5 patients * \$125,000 = **\$1.5625 million**

- **Total \$ Value of 1% Share:** **\$31.0125 million**

Final Answer

- **Potential Peak Sales for isatuximab-irfc (Sarclisa)** in NDMM patients ineligible for ASCT (20%-30% market share): **\$620 million to \$930 million annually** across the US, EU5, China, and Japan.

- **\$ Value of 1% Share of Treated Patients:** **~\$31 million annually** across these geographies.

Caveats and Assumptions

1. **Epidemiology Data:** Patient numbers are estimates based on incidence rates and population data. Exact numbers may vary.

2. **Pricing:** Pricing is assumed based on similar drugs and regional differences. Actual pricing may differ due to negotiations, reimbursement policies, and competition.

3. **Market Share:** A 20%-30% share assumes moderate to strong uptake, but competition from other drugs (e.g., daratumumab) and future entrants could impact this.

4. **Treatment Duration:** Assumes annual cost per patient; actual duration of therapy may vary.

5. **Market Access:** Assumes successful reimbursement and access in all regions, which may not be guaranteed, especially in China.

For more precise figures, primary market research, payer insights, and updated epidemiology data are recommended.