EE79

# Budget and Time Impact Analysis of Introducing Subcutaneous Pembrolizumab to Patients in the US: From Institution, Health Care Professional, and Patient Perspectives

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## Background

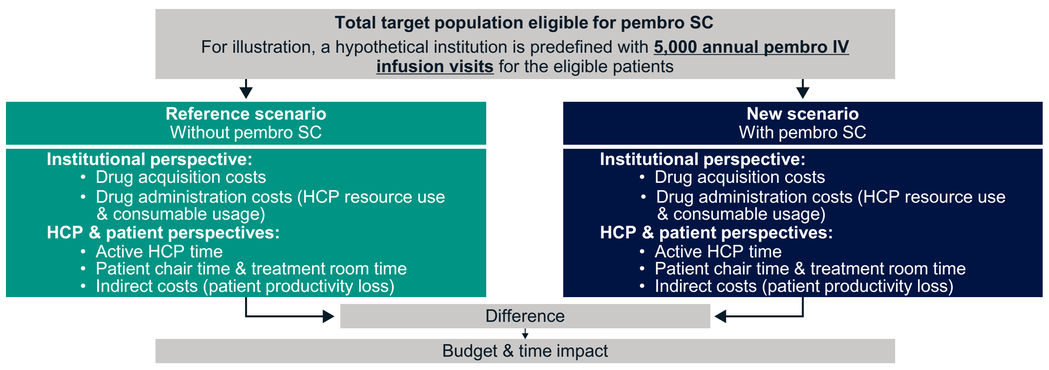
- KEYTRUDA® (pembrolizumab) has been approved globally for multiple indications as both a monotherapy and in combination with other agents across various lines of therapy. It is administered as an intravenous (IV) infusion of 200 mg every 3 weeks (Q3W) or 400 mg every 6 weeks (Q6W); at each infusion, intravenous pembrolizumab (pembro IV) is administered over the course of 30 minutes[1]
- Pembrolizumab and berahyaluronidase alfa (a variant of human hyaluronidase developed and manufactured by Alteogen Inc.) (KEYTRUDA QLEX™ in the US; hereafter pembro SC) demonstrated comparable pharmacokinetic exposure and showed consistent efficacy and safety results compared to pembro IV in the phase 3 3475A-D77 trial.[2] A time and motion (T&M) study conducted alongside the trial showed reduced time and resource use for health care professionals (HCPs), as well as shorter patient chair and treatment room time, with pembro SC preparation and administration compared with pembro IV[3]
- Pembro SC has been approved by the US Food and Drug Administration (FDA) for solid tumor indications approved for pembro IV and received a positive opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP).[4-5] The recommended doses are 395 mg Q3W or 790 mg Q6W; and the doses are administered subcutaneously in a single-dose vial over 1 minute (Q3W) or 2 minutes (Q6W)[4]
- The analysis' objective was to estimate the budget and time impact of introducing pembro SC to patients in the US, and evaluate its economic and societal value from institutional, HCP, and patient perspectives

## Methods

### Model structure

- A budget impact calculator (BIC) was constructed to evaluate the budget and time impact of adopting pembro SC in a hypothetical institution predefined with 5,000 annual pembro IV infusion visits for eligible patients. The base case setting is illustrative; the tool is adaptable to institutions with user-specific inputs (e.g., annual pembrolizumab administration volume, staffing structure)
- The model evaluated the budget and time impact of pembro SC over the first 3 years following its introduction as an alternative subcutaneous (SC) formulation of pembrolizumab in adult patients with indications eligible for pembrolizumab treatment (**Figure 1**)

### Figure 1. Model flow chart




### Model key attributes and parameters

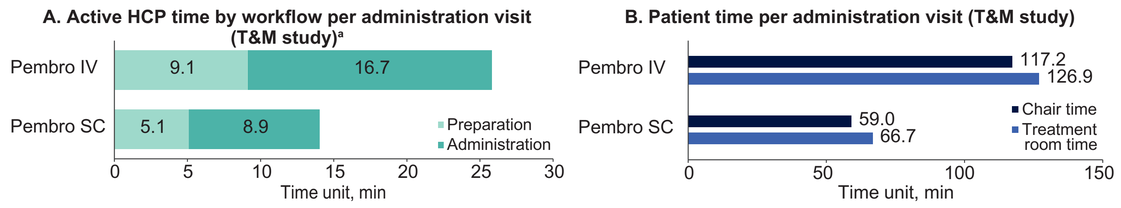
**Table 1** summarizes the model key attributes and parameters. Additional assumptions are listed below:

- For illustration, a hypothetical institution is defined with 5,000 annual pembro IV infusion visits, assuming a Q3W/Q6W patient distribution of 80%/20%, which corresponds to approximately 321 eligible patients per annum
- Administration was assumed to occur 100% in hospital- or community-based outpatient settings
- As the safety profiles of pembro SC and pembro IV were demonstrated to be similar in 3475A-D77, costs associated with adverse event management were not included in the model. Infusion- and injection-related reactions are generally mild (ie, grade 1 or 2), so are not expected to drive meaningful cost impact
- Indirect costs of patient productivity impairment were estimated based on:
  - Patient time spent in the treatment room including chair time, ie, 66.72 minutes for pembro SC compared to 126.86 minutes for pembro IV per administration visit, was derived from the T&M study.[3] Travel time associated with each administration visit was also considered and 50% of patients receiving SC injections were assumed to undergo treatment in a community-based setting
  - 40% of patients were under the retirement age, and for these patients a 100% productivity impairment was assumed during each administration visit due to convalescence

### Table 1. Key model attributes and parameters

| Parameter | Descriptions |
|---|---|
| Target population | Adult and pediatric (12 years and older) patients with solid tumor indications approved for IV formulation of pembrolizumab and among those who initiate therapy. The model takes a holistic view of pembrolizumab as a multi-indication therapy |
| Perspective | Institution, HCP, and patient perspectives (in the US) |
| Time horizon | 3-year |
| Pembrolizumab administration volume (for a hypothetical institution) | • Number of annual pembro IV infusion visits: 5,000 predefined for illustration<br>• Expected adoption of pembro SC (from IV): adoption increases over time, averaging 35% across the 3-year period |
| Time categories & inputs | The following time inputs were derived from the T&M study[3]<br>• Active HCP time associated with pembrolizumab administration (nursing, medical, and pharmacy staff), segmented by preparation and administration workflows and route (SC vs IV) (**Figure 2A**)<br>• Consumable usage required for pembrolizumab administration, by preparation and administration workflows and route (SC vs IV)<br>• Patient time associated with pembrolizumab administration, including chair time, treatment room time, and by route (SC vs IV) (**Figure 2B**)<br>Patient injection/infusion time was informed by the United States Prescribing Information (USPI)[1, 4] |
| Cost categories & inputs | The following cost categories were included in the model (costs were inflated to 2025 USD as needed):<br>• Drug acquisition costs: treatment costs for pembro SC and pembro IV were based on list price assuming parity; list price per vial for pembro IV was collected based on the wholesale acquisition cost from the US standard source[6]<br>• Drug administration costs: administration costs related to HCP resources and consumable usage required for pembrolizumab administration; Unit costs of HCP resources were derived using hourly wage data sourced from the US Bureau of Labor Statistics (BLS)[7] and unit costs for each consumable item were obtained from US General Services Administration (GSA).[8] Where unavailable, costs were estimated based on assumptions<br>• Indirect costs: costs associated with patient work-related productivity loss; The hourly productivity value was obtained from a national statistics database ($31.48/hour) and inflated to 2025 USD[9] |

### Figure 2. Time metrics (patient-level) per administration visit




[a]Active HCP time derived from the T&M study was calculated as a weighted average that assigns equal weight to each participating country.

## Results

- The assessment included the institutional-level budget impact, opportunity costs of care (ie, HCP resource utilization and consumable usage), active HCP time impact, patient time and capacity impacts (e.g., treatment room, chair, and during drug administration), and indirect costs from patient work-related productivity loss

### Institutional-level budget impact

- For an example institution with 5,000 pembro IV infusion visits annually and an average 35% adoption of pembro SC, the total budget impact is −$574,491 over a 3-year period compared with a scenario without pembro SC. **Table 2** presents detailed results from the base-case and scenario analyses
  - Assuming price parity, drug acquisition costs remain unchanged with the adoption of pembro SC from IV and have no budgetary impact
  - Costs of care related to HCP resource and consumable use are estimated to decrease by 54.7% per patient per administration and by 19.2% at the institutional level. Because the analysis included only direct hourly HCP wage costs and excluded other possible HCP labor expenses, estimated savings are likely to be conservative
  - One-way sensitivity analysis found that the largest drivers of cost impact were time horizon, institution size (ie, annual number of pembrolizumab administrations), pembro SC adoption rate, and consumable costs for IV and SC formulations

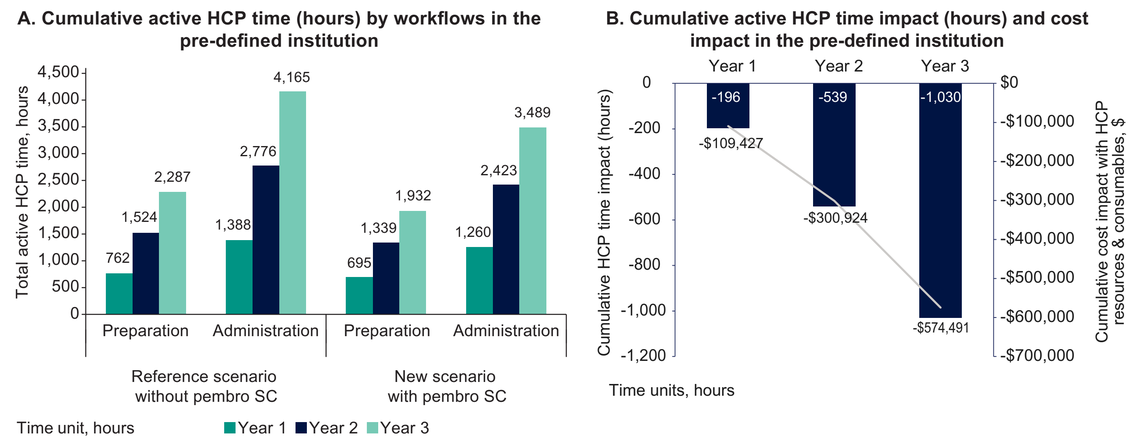
### Time and capacity impact

- Total active HCP time is reduced by 1,030 hours (−16.0%) over a 3-year horizon (**Table 2, Figure 3A, and 3B**), reflecting time savings across preparation and administration workflows for nursing, medical, and pharmacy staff in the predefined hypothetical institution
- Institutional-level total patient chair and treatment room time are reduced by 5,089 hours/212 days (−17.4%) and 5,263 hours/219 days (−16.6%), respectively, with capacity freed up for reallocation (**Table 2**, **Figure 4**)
  - Patient-level total chair time and treatment room time are reduced by 15.9 and 16.4 hours on average, respectively
  - Attributable to the reduced chair time per administration over a 3-year time horizon, institutional-level patient capacity is expected to increase by an additional of 332 patients or 5,172 visits for pembro SC administration, alternatively, 1,696 additional chemotherapy appointments. This offers an opportunity for the predefined institution to address unmet needs without additional medical resources and reduce patient waiting time for treatment
- Indirect costs from patient work-related productivity loss are expected to decrease by 42.6% per administration and by 14.9% at the institutional-level, primarily because patients spent less time in the treatment room and have shorter travel times when receiving pembro SC in community-based outpatient settings

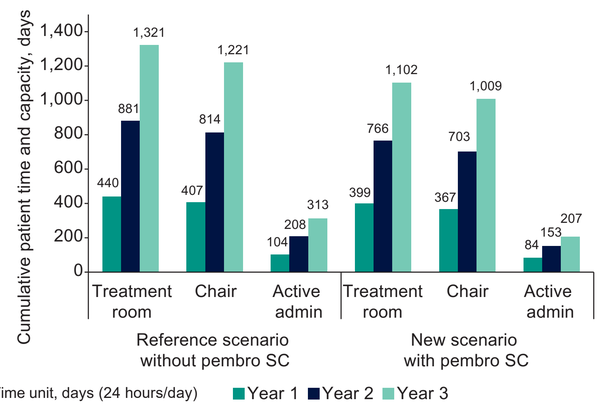
### Table 2. Institutional-level impact results

| Category | Scenario without pembro SC | Scenario with pembro SC | Impact (2025 USD; time unit: hours) | Impact, % |
|---|---|---|---|---|
| For illustrative purpose, the base-case analysis used a hypothetical institution with 5,000 annual pembro IV infusion visits and an average 35% adoption of pembro SC (from IV); results are reported over a 3-year time horizon | | | | |
| **Institutional-level budget impact** | | | | |
| **Total costs of care (base case)** | **$2,998,785** | **$2,424,294** | **-$574,491** | **-19.2%** |
| Administration costs: HCP resource use | $375,227 | $325,964 | -$49,263 | -13.1% |
| Administration costs: Consumable usage | $2,623,558 | $2,098,330 | -$525,228 | -20.0% |
| **Scenario analysis with alternative time horizon** | | | | |
| 5 year time horizon | $4,997,975 | $3,876,349 | -$1,121,626 | -22.4% |
| 1 year time horizon | $999,595 | $890,168 | -$109,427 | -10.9% |
| **Scenario analysis with alternative institutional size** | | | | |
| 6,000 annual pembro IV infusion visits | $3,598,542 | $2,909,153 | -$689,389 | -19.2% |
| 4,000 annual pembro IV infusion visits | $2,399,028 | $1,939,435 | -$459,593 | -19.2% |
| **Scenario analysis with higher adoption of pembro SC** | | | | |
| Average 40% adoption of pembro SC over 3 years | $2,998,785 | $2,342,224 | -$656,561 | -21.9% |
| **Institutional-level time and capacity impact** | | | | |
| **Institutional-level total active HCP time, hours** | 6,451 | 5,421 | -1,030 | -16.0% |
| **Institutional-level total patient time, hours** | | | | |
| Treatment room time | 31,716 | 26,453 | -5,263 | -16.6% |
| Chair time | 29,299 | 24,210 | -5,089 | -17.4% |
| Active administration time | 7,500 | 4,972 | -2,528 | -33.7% |

### Figure 3. Cumulative active HCP time (hours) by workflows and impact in the predefined institution




### Figure 4. Cumulative patient time and capacity (days) in the predefined institution




## Strengths and limitations

- The key strength of this study is that the time inputs were primarily derived from the T&M study alongside the pivotal 3475A-D77 trial.[3] To address confounding associated with chemotherapy administration, the T&M study excluded chemotherapy-related time from patient endpoints and captured only HCP time associated with pembrolizumab preparation and administration. Though it did not include US sites, its findings were validated with US external experts for generalizability
- The limitations of this study include the following:
  - The magnitude of the estimated budget and time savings may vary with institution size, projected adoption of pembro SC, and differences in administration workflows and staffing. The findings should be interpreted according to institution-specific assumptions
  - The pivotal 3475A-D77 trial and available observational evidence are based on a Q6W dosing schedule.[2,3] Due to the lack of data on the Q3W regimen, active HCP time and patient chair/treatment room time for Q3W was assumed to be the same as for Q6W

## Conclusion

Adoption of pembro SC as an alternative subcutaneous formulation of pembrolizumab is estimated to yield meaningful cost savings, primarily attributable to reductions in drug administration costs. Sensitivity analyses indicate these findings remain meaningful across a range of scenarios. In addition to direct cost savings, pembro SC is expected to improve immunotherapy drug administration and health care system efficiency by optimizing dosing, decreasing active HCP time and consumable use, and mitigating capacity constraints. Patients may benefit from shorter administration and travel times, with potential gains in productivity and lower indirect costs

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