Bladder cancer is the sixth most common cancer and the tenth leading cause of cancer death in the United States (US), with over 83,000 new cases and 17,000 deaths in 2022. More than 90% of bladder cancers are urothelial carcinoma.

Patients diagnosed with regional or metastatic bladder cancer have poor prognosis. The 5-year relative survival is 39% for regional stage and only 5% for metastatic stage.

Pembrolizumab is a programmed death receptor-1 (PD-1)-blocking antibody. In the US, pembrolizumab is indicated for the treatment of adult patients with urothelial carcinoma who have previously received a PD-1 or PD-L1 inhibitor and platinum-containing chemotherapy or who are ineligible for platinum-containing chemotherapy. Encouraging efficacy was shown in KN-869/EV-103, a Phase III open-label, randomized, multi-center global study for the treatment of urothelial cancer (NCT03288545).

The total costs for a patient over the treatment course were $488,666 for Pem+EV, followed by $286,284 for pembrolizumab.

The inclusion of Pem+EV resulted in an annual budget increase of $364,817, $799,598, and $920,093 in year 1-3, and $1,111, $2,696, and $5,815 in year 4-5.

The budget impact was estimated by calculating the cost difference between two scenarios:

New drug scenario: Pem+EV is available for the treatment of la/mUC

Reference scenario: Pem+EV is not available for the treatment of la/mUC

The key parameters for model uncertainty were set as follows:

- Treatment duration for Pem+EV was derived from KN-869/EV-103, and the published literature for comparators and subsequent lines of therapy

- A hypothetical health plan of 1 million members was assumed. The size of the eligible population was calculated based on epidemiological inputs and RWE data (Figure 1)

- Comparators were selected based on NCCN guideline: gemcitabine plus cisplatin, gemcitabine plus paclitaxel, gemcitabine plus nab-paclitaxel. Specifically, proportion of receiving gemcitabine maintenance after GC was assumed to be 30%

- Subsequent treatments in second and further lines (2L) included pembrolizumab, EV, GC, etoifibatid, axolotumab, nivolumab, and abacitzumab based on NCCN guidelines

- Market shares were estimated from market research and claims data for comparators in 1L and 2L. For Pem+EV, it was assumed a constant 25% for over 3 years, and after progression, patients would receive GC given they already failed anti-PD-1/anti-PD-L1 therapy in combination in 1L (Table 1)

- Costs included drug acquisition, administration, monitoring, grade 3-5 adverse event (AE) management, and subsequent treatment costs. All costs are in 2022 US dollars

- Treatment duration for Pem+EV was derived from KN-869/EV-103, and the published literature for comparators and subsequent treatments

- One way sensitivity analyses (varying the parameters by +/-20%) and scenario analyses (varying key model assumptions) were conducted to assess model uncertainty.

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The table below shows the budget impact of adding Pem+EV in 1L treatment for bladder cancer will have a modest budget impact on US health plans.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>1L drug acquisition, administration</th>
<th>Subsequent drug acquisition, administration</th>
<th>Monitoring</th>
<th>All management</th>
<th>Total costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pem+EV</td>
<td>$476,304</td>
<td>$1,111</td>
<td>$1,967</td>
<td>$11,264</td>
<td>$489,889</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>$130,916</td>
<td>$78,652</td>
<td>$1,231</td>
<td>$1,695</td>
<td>$286,204</td>
</tr>
<tr>
<td>Atezolizumab</td>
<td>$165,632</td>
<td>$176,337</td>
<td>$1,844</td>
<td>$1,356</td>
<td>$1,591</td>
</tr>
<tr>
<td>Gemcitabine</td>
<td>$42,884</td>
<td>$181,594</td>
<td>$1,591</td>
<td>$1,265</td>
<td>$241,695</td>
</tr>
<tr>
<td>Gemcitabine plus paclitaxel</td>
<td>$1,454</td>
<td>$126,217</td>
<td>$493</td>
<td>$939</td>
<td>$1,331</td>
</tr>
<tr>
<td>Gemcitabine plus paclitaxel</td>
<td>$2,793</td>
<td>$268,626</td>
<td>$167</td>
<td>$117</td>
<td>$719</td>
</tr>
</tbody>
</table>

Note: the administration of IV drugs in 1L and subsequent lines (2L+) were accounted for in the costs.

The administration of IV drugs in 1L and subsequent lines (2L+) were accounted for in the costs.

The budget impact of adding Pem+EV in 1L treatment for bladder cancer will have modest budget impact on US health plans.

References: