Cost of care and budget impact of first-line treatments in patients with locally advanced or metastatic urothelial carcinoma from the Mexican public payer perspective

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CONCLUSIONS

- **This study estimated costs of the first year of treatment with platinum-based chemotherapy (CT) → avelumab maintenance and best supportive care (BSC), CT → BSC, enfortumab vedotin + pembrolizumab (EV + PEM), and nivolumab (NIV) + CT in patients with locally advanced or metastatic urothelial carcinoma (la/mUC) in Mexico using a 1-year cost-of-care model and a 5-year budget impact analysis (BIA) from the national payer's perspective**
- **In the first year of treatment, CT → BSC was associated with the lowest total direct medical costs ($588,428 MXN), followed by CT → avelumab + BSC ($1,221,271 MXN); higher costs were observed for NIV + CT ($1,431,290 MXN) and EV + PEM ($3,124,243 MXN)**
- **Based on acquisition costs, for each patient treated with EV + PEM, approximately 3 patients could be treated with CT → avelumab + BSC, whereas acquisition costs were similar for NIV + CT and CT → avelumab + BSC**
- **In the 5-year BIA, the treatment scenario of EV + PEM resulted in the largest budget increase (+141%) while CT → avelumab + BSC showed a cumulative budget impact of 11.4%**
- **This exploratory economic analysis showed that the introduction of EV + PEM and NIV + CT as 1L treatment options would likely result in higher overall direct healthcare costs; CT → avelumab + BSC showed the lowest projected budget impact increase among the evaluated regimens over a five year period**

PLAIN LANGUAGE SUMMARY

- **This study estimated the costs of the first year of treatment of patients with advanced urothelial cancer in Mexico for:**
  - **Platinum-based chemotherapy followed by avelumab maintenance**
  - **Platinum-based chemotherapy followed by best supportive care**
  - **Enfortumab vedotin + pembrolizumab**
  - **Nivolumab + platinum-based chemotherapy**
- **The cost of buying treatments was lowest for platinum-based chemotherapy followed by best supportive care or avelumab, and highest for nivolumab + platinum-based chemotherapy and enfortumab vedotin + pembrolizumab**
- **For the total cost of treating 1 patient with enfortumab vedotin + pembrolizumab, 3 patients could be treated with platinum-based chemotherapy followed by avelumab maintenance**
- **Overall, costs in the first year of treatment were lower with platinum-based chemotherapy followed by best supportive care or avelumab maintenance treatment compared with enfortumab vedotin + pembrolizumab and nivolumab + platinum-based chemotherapy**
- **Over a 5-year period, increased use of enfortumab vedotin + pembrolizumab would result in the largest budget increase**
- **This exploratory economic analysis showed that the introduction of EV + PEM and NIV + CT as 1L treatment options would likely result in higher overall direct healthcare costs; CT → avelumab + BSC showed the lowest projected budget impact increase among the evaluated regimens over a five year period**

BACKGROUND

- UC is the most common cancer of the bladder[1]
  - In Mexico, an estimated 3,745 new bladder cancer cases were diagnosed in 2022[2]
  - Incidence rates of bladder cancer were 1.7 and 35.3 per 100,000 in male patients and 0.6 and 9.9 in female patients aged <65 and ≥65 years, respectively[2]
- Systemic treatment is recommended for la/mUC and aims to prolong survival and manage symptoms[3]
- Historically, CT was the first-line (1L) standard of care, but most patients have disease progression within the first year[3]
  - This reality has driven the development of new strategies such as immunotherapy, antibody-drug conjugates, and other targeted therapies that have transformed disease management
- Results from the JAVELIN Bladder 100, EV-302, and CheckMate 901 phase 3 trials have led to the use of avelumab 1L maintenance, EV + PEM, and NIV + CT, respectively, as treatments for la/mUC, significantly altering the treatment landscape[4-6]
  - In Mexico, avelumab is approved by regulatory authorities, and included in the National Compendium of Health Supplies (2023),[7] supporting public sector access
  - NIV- and PEM-based regimens are reimbursed in the public market, whereas EV-based regimens are not reimbursed and are mainly available in the private sector[8]

METHODS

Cost-of-care model

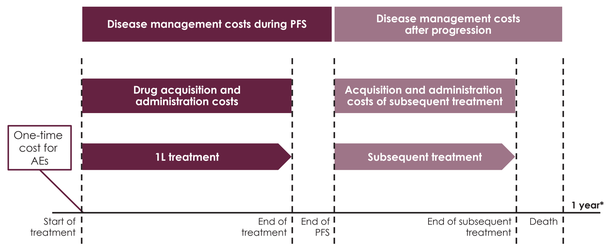
- A cost-of-care model was developed to estimate the direct medical costs associated with the treatment of patients with la/mUC during the first year of therapy; the model captures the full 1L setting, in which the analysis starts at the beginning of the induction treatment phase followed by maintenance treatment phase, and includes other relevant 1L treatments
- The cost-of-care model compared CT → avelumab + BSC, CT → BSC, EV + PEM, and NIV + CT in patients with la/mUC
- Clinical inputs were informed by data from JAVELIN Bladder 100,[4] EV-302,[5] and CheckMate 901,[6] including overall survival (OS), progression-free survival (PFS), and treatment duration (**Table 1**)
- Costs included drug acquisition, administration, adverse event (AE) management, disease management, and subsequent treatments from the payer's perspective (**Figure 1**)
  - Follow-up, disease management, and AE costs were estimated through a microcosting approach validated by local clinical experts
  - Drug prices were obtained from CompraNet (2024)[9]
  - Subsequent treatments were modeled as a weighted basket by 1L regimen, using expert-informed distributions, while the percentage of patients receiving any second-line treatment was derived from clinical trial data (**Supplementary Table 1**)

Table 1. Effectiveness of 1L treatments

	CT → BSC[4]	CT → ave + BSC[4]	EV + PEM[5]	NIV + CT[6]	CT (non-responders)[10]
Median treatment duration, months	CT: 3.7 BSC: 3.0	CT: 3.7 Ave + BSC: 5.8	EV: 7.0 PEM: 8.5	NIV: 7.4 CT: 4.1	5.2*
Median PFS, months	CT → BSC: 7.4† BSC: 2.1	CT → ave + BSC: 10.8† Ave + BSC: 5.5	12.5	7.9	7.0†
Median OS, months	20.5	29.7	31.5	21.7	11.0§

1L, first line; **Ave**, avelumab; **BSC**, best supportive care; **CT**, platinum-based chemotherapy; **EV**, enfortumab vedotin; **NIV**, nivolumab; **OS**, overall survival; **PEM**, pembrolizumab; **PFS**, progression-free survival.
*Calculated as the median treatment duration of the induction phase (3.7 months) plus the median treatment duration from KEYNOTE-045 (1.5 months). †Calculated as the duration from the start of induction CT to the first day of maintenance treatment (5.3 months) plus median PFS with BSC (2.1 months) or avelumab + BSC (5.5 months). ‡Calculated as the median treatment duration of the induction phase (3.7 months) plus median PFS from KEYNOTE-045 (3.3 months).§Calculated as the median treatment duration of the induction phase (3.7 months) plus median OS from KEYNOTE-045 (7.3 months).

Figure 1. Cost-of-care model

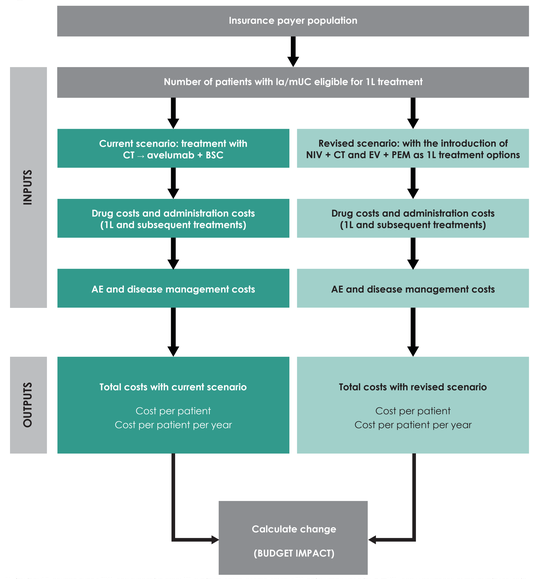


1L, first line; **AE**, adverse event; **OS**, overall survival; **PFS**, progression-free survival.
*This figure illustrates treatment with OS of <1 year.

5-year BIA

- The BIA compared current practice (CT → avelumab + BSC) with an adoption scenario introducing EV + PEM and NIV + CT into 1L treatment
- The target population for the BIA was estimated based on bladder cancer incidence in Mexico, stratified by age and sex, from which UC cases were derived and adjusted by stage distribution and progression rates[2]
  - Applying eligibility criteria for 1L treatment resulted in an estimated 539 patients in Mexico in year 1 who were diagnosed with la/mUC and were platinum-eligible (**Supplementary Figure 1**)
- Three alternative scenarios were evaluated: EV + PEM, NIV + PBC, and CT → avelumab + BSC, each representing the regimen with the largest market share
- Costs included drug acquisition, administration, AE management, disease management, and subsequent treatments, estimated via microcosting with local expert input (**Figure 2**)
- Annual and total costs were calculated for each scenario, and incremental budget impact was estimated based on projected market uptake over time

Figure 2. BIA



1L, first line; **AE**, adverse event; **BSC**, best supportive care; **CT**, platinum-based chemotherapy; **EV**, enfortumab vedotin; **la/mUC**, locally advanced or metastatic urothelial carcinoma; **NIV**, nivolumab; **PEM**, pembrolizumab.

RESULTS

Cost-of-care model

Medication acquisition costs in the first year of treatment

- CT → BSC had the lowest acquisition cost in the first year of treatment ($10,910 MXN); the acquisition cost of CT → avelumab + BSC was $911,948 MXN, which was 68% lower than EV + PEM ($2,850,827 MXN) and 19% lower than NIV + CT ($1,119,812 MXN)(**Supplementary Figure 2**)
- Based on acquisition costs, for each patient treated with EV + PEM or NIV + CT, 3 patients and 1 patient, respectively, could be treated with CT → avelumab + BSC

Total direct healthcare costs for the first year of treatment

- The total costs of care for each 1L regimen in the first year of treatment were:
  - CT → avelumab + BSC: $1,221,271 MXN
  - CT → BSC: $588,428 MXN
  - EV + PEM: $3,124,243 MXN
  - NIV + CT: $1,431,290 MXN
- CT → BSC had the lowest total direct healthcare costs in the first year of treatment (52% lower than CT → avelumab + BSC); CT → avelumab + BSC had 61% lower total direct healthcare costs than EV + PEM and 15% lower costs than NIV + CT (**Table 2**)

Table 2. Total direct healthcare costs for the first year of treatment per treated patient (MXN $)

Costs, MXN $	CT → BSC	CT → avelumab + BSC	EV + PEM	NIV + CT
Drug acquisition	10,910	911,948	2,850,827	1,119,812
Drug administration	87,703	148,222	170,559	134,119
AE management*	20,192	21,091†	5,027	11,463
Disease management	56,314	96,244	97,830	76,932
Acquisition and administration of subsequent treatment	315,376	7,021	0†	21,656
Disease management for subsequent treatment	97,933	36,745	0†	67,309
Total cost	588,428	1,221,271	3,124,243	1,431,290

Costs were calculated by multiplying the monthly cost by the median treatment duration reported in the respective clinical trials.
AE, adverse event; **BSC**, best supportive care; **CT**, platinum-based chemotherapy; **EV**, enfortumab vedotin; **NIV**, nivolumab; **PEM**, pembrolizumab.
*Included grade ≥3 AEs occurring in ≥2% of patients in any of the treatments considered, based on clinical and economic relevance criteria. AE frequencies were obtained from published clinical trials and prescribing information. †AE management cost includes the induction CT phase and avelumab maintenance. AE management cost was lower for avelumab alone compared with EV + PEM and NIV + CT. In the EV-302 trial, patients treated with EV + P were progression free during the first 12 months.[5] Given that the model estimates costs for the first year of treatment, no second-line treatment costs are incurred within this period.

5-year BIA

Market scenario

- Current scenario: all patients receive CT as induction; after 4–6 cycles, approximately 80% remain progression-free and are eligible for maintenance, of whom 100% receive avelumab + BSC
- Alternate scenario: EV + PEM and NIV + CT are included as new 1L options, partially displacing the exclusive use of CT and reducing the number of patients who receive avelumab maintenance (**Table 3**)

Table 3. Alternative market share scenarios (%) for 1L treatment over 5 years

Treatment, %	Year 1	Year 2	Year 3	Year 4	Year 5
Scenario 1: EV + PEM					
EV + PEM	70	80	80	80	80
NIV + CT	15	10	10	10	10
CT → avelumab + BSC	15	10	10	10	10
Scenario 2: NIV + CT					
EV + PEM	7	8	9	10	11
NIV + CT	33	42	51	60	69
CT → avelumab + BSC	60	50	40	30	20
Scenario 3: CT → avelumab + BSC					
EV + PEM	7	6	5	5	5
NIV + CT	7	6	5	5	5
CT → avelumab + BSC	86	88	90	90	90

Scenarios are defined based on the regimen with the projected highest market share in each case.
1L, first line; **BSC**, best supportive care; **CT**, platinum-based chemotherapy; **EV**, enfortumab vedotin; **NIV**, nivolumab; **PEM**, pembrolizumab.

Cumulative budget impact over 5 years

- Estimated patients numbers per scenario are shown in **Supplementary Table 2**
- The cumulative cost of the current scenario (CT → avelumab + BSC) was $3,182,594,278 MXN over 5 years
- Scenario 1: EV + PEM resulted in a total budget increase of $4,499,245,123 MXN (+141%)
  - In this scenario, the cost per patient would increase from $1,162,746 MXN to $2,806,525 MXN
- Scenario 2: NIV + CT resulted in a total budget increase of $934,005,618 MXN (+29.3%)
  - In this scenario, the cost per patient would increase from $1,162,746 MXN to $1,503,981 MXN
- Scenario 3: CT → avelumab + BSC resulted in a total budget increase of $361,901,661 MXN (+11.4%)
  - In this scenario, the cost per patient would increase from $1,162,746 to $1,294,966 MXN

LIMITATIONS

- Clinical inputs, including treatment duration, PFS, OS, and AE rates, were based on median estimates from clinical trials, which may not fully represent variability in real-world clinical practice
- Variations in PFS assessment methods across studies (investigator assessment, RECIST criteria, and blinded independent review) may affect the comparability of outcomes between treatments
- As the analysis relies on evidence from separate clinical trials rather than direct comparisons, differences in patient characteristics and study design may introduce uncertainty
- The models focused on direct healthcare costs and do not explicitly account for clinical outcomes such as quality of life or treatment response; indirect costs were not accounted for
- The 1-year time horizon for the cost-of-care model may not capture longer-term economic consequences, including those related to disease progression and subsequent lines of therapy

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