

# Cost of care and budget impact of novel first-line treatments in patients with locally advanced or metastatic urothelial carcinoma in Costa Rica

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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 Costa Rica using a 1-year cost-of-care model and a 5-year budget impact analysis (BIA) from the payer's perspective
- CT → BSC had the lowest total direct medical costs in the first year of treatment (€36,301,754), followed by CT → avelumab + BSC (€70,752,627); higher costs were observed for NIV + CT (€75,339,069) and EV + PEM (€119,286,784)
- Based on acquisition costs, for each patient treated with EV + PEM, approximately 2 patients could be treated with CT → avelumab + BSC, whereas NIV + CT had broadly comparable acquisition costs to CT → avelumab + BSC
- In the 5-year cumulative BIA, EV + PEM resulted in the largest budget increase (+26%) while CT → avelumab + BSC showed the lowest cumulative budget impact (+7.7%)
- This analysis demonstrates the economic impact of 1L treatments for la/mUC with few current therapeutic options available, providing predictable costs to support the decision-making process of including innovative and effective treatments, including avelumab, in the public payer reimbursed list, thus broadening access for eligible patients in Costa Rica

## PLAIN LANGUAGE SUMMARY

- This study estimated the costs of the first year of treatment of patients with advanced urothelial cancer in Costa Rica 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 each patient treated with enfortumab vedotin + pembrolizumab, 2 patients could be treated with platinum-based chemotherapy followed by avelumab maintenance
- Over a 5-year period, increased use of enfortumab vedotin + pembrolizumab would result in the largest budget increase
- 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

## BACKGROUND

- UC is the most common cancer of the bladder<sup>1</sup>
  - In Costa Rica, approximately 147 new cases are reported annually<sup>2</sup>
  - Incidence rates of bladder cancer were 4.4 and 1.2 per 100,000 in male and female patients, respectively<sup>2</sup>
- Systemic treatment is recommended for la/mUC and aims to prolong survival and manage symptoms<sup>3</sup>

- Historically, CT was the first-line (1L) standard of care, but most patients have disease progression within the first year<sup>3</sup>
  - 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<sup>4-6</sup>
  - In Costa Rica, avelumab is registered but not reimbursed by the public payer; access is limited and mainly occurs through judicial mechanisms
  - At the time of analysis, EV + PEM and NIV + CT were not reimbursed by the public healthcare system

## METHODS

### Cost-of-care model

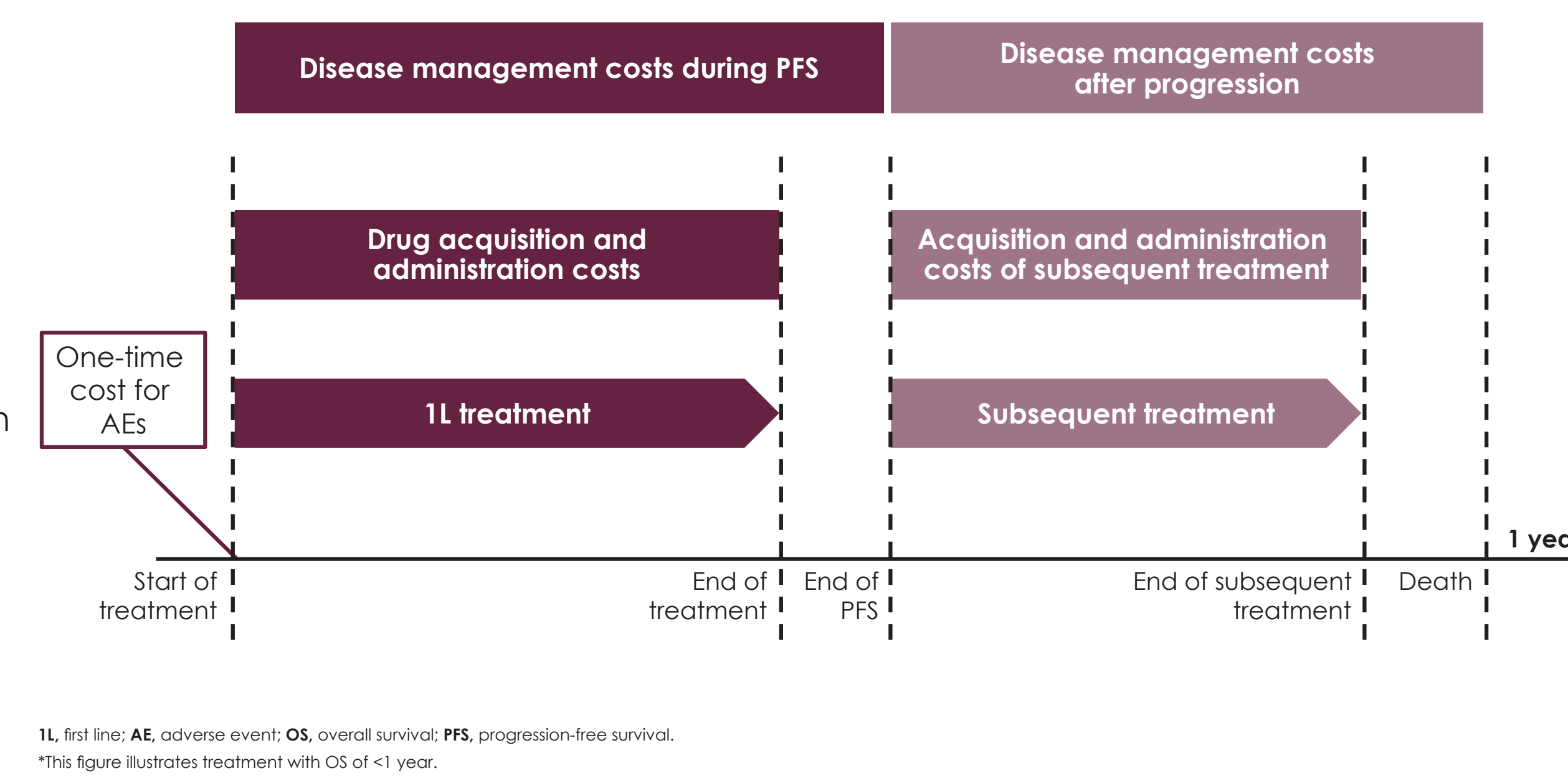
- A cost-of-care model was developed to estimate the direct medical costs associated with the treatment of patients with la/mUC during the first year of therapy; the model captures the full 1L setting, in which the analysis starts at the beginning of the induction treatment phase followed by maintenance treatment phase, and includes other relevant 1L treatments
- The cost-of-care model compared CT → avelumab + BSC, CT → BSC, EV + PEM, and NIV + CT using parameters from JAVELIN Bladder 100,<sup>4</sup> EV-302,<sup>5</sup> and CheckMate 901,<sup>6</sup> including overall survival (OS), progression-free survival (PFS), and duration of treatment (Table 1)
- Costs associated with drug acquisition and administration, management of serious adverse events (AE), disease management, and subsequent treatments were incorporated from the payer's perspective (Figure 1)
  - Follow-up, disease management, and AE costs were estimated using a microcosting exercise with support from local clinical experts
- Unit prices were derived from Sistema Integrado de Compras Públicas (2024) and Costa Rican Social Security Fund reports<sup>7</sup>
- Direct medical costs were estimated on a per-patient basis and reported in Costa Rican colones (₡) using an exchange rate of 1 US \$ = ₡515 (2024)<sup>8</sup>
- 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 <sup>a</sup>                  | CT → ave + BSC <sup>a</sup>                         | EV + PEM <sup>b</sup> | NIV + CT <sup>b</sup> | CT (non-responders) <sup>c</sup> |
|-----------------------------------|----------------------------------------|-----------------------------------------------------|-----------------------|-----------------------|----------------------------------|
| Median treatment duration, months | CT: 3.7<br>BSC: 3.0                    | CT: 3.7<br>Ave + BSC: 5.8                           | EV: 7.0<br>PEM: 8.5   | NIV: 7.4<br>CT: 4.1   | 5.2 <sup>d</sup>                 |
| Median PFS, months                | CT → BSC: 7.4 <sup>e</sup><br>BSC: 2.1 | CT → ave + BSC: 10.8 <sup>f</sup><br>Ave + BSC: 5.5 | 12.5                  | 7.9                   | 7.0 <sup>g</sup>                 |
| Median OS, months                 | 20.5                                   | 29.7                                                | 31.5                  | 21.7                  | 11.0 <sup>h</sup>                |

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.  
<sup>a</sup>Calculated as the median treatment duration of the induction phase (3.7 months) plus the median treatment duration from KEYNOTE045 (1.5 months). <sup>b</sup>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 (5.8 months). <sup>c</sup>Calculated as the median treatment duration of the induction phase (3.7 months) plus median PFS from KEYNOTE045 (3.3 months). <sup>d</sup>Calculated as the median treatment duration of the induction phase (3.7 months) plus median OS from KEYNOTE045 (7.3 months).

Figure 1. Cost-of-care model



## RESULTS

### Cost-of-care model

#### Medication acquisition costs in the first year of treatment

- CT → BSC had the lowest acquisition costs in the first year (€1,653,126), followed by CT → avelumab + BSC (€38,774,032), which was 56% lower than EV + PEM (€88,135,926) and 13% lower than NIV + CT (€44,716,390) (Supplementary Figure 2)
- Based on acquisition costs, for each patient treated with EV + PEM or NIV + CT, 2 patients and 1 patient, respectively, could be treated with CT → avelumab + BSC

#### Total direct healthcare costs for the first year of treatment

- The total direct costs of care for each 1L regimen in the first year of treatment were:
  - CT → avelumab + BSC: €70,752,627
  - CT → BSC: €36,301,754
  - EV + PEM: €119,286,784
  - NIV + CT: €75,339,069
- In the first year of treatment, total direct healthcare costs for CT → BSC were projected to be 49% lower than CT → avelumab + BSC; CT → avelumab + BSC had 41% lower costs than EV + PEM and 6% lower costs than NIV + CT (Table 2)

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

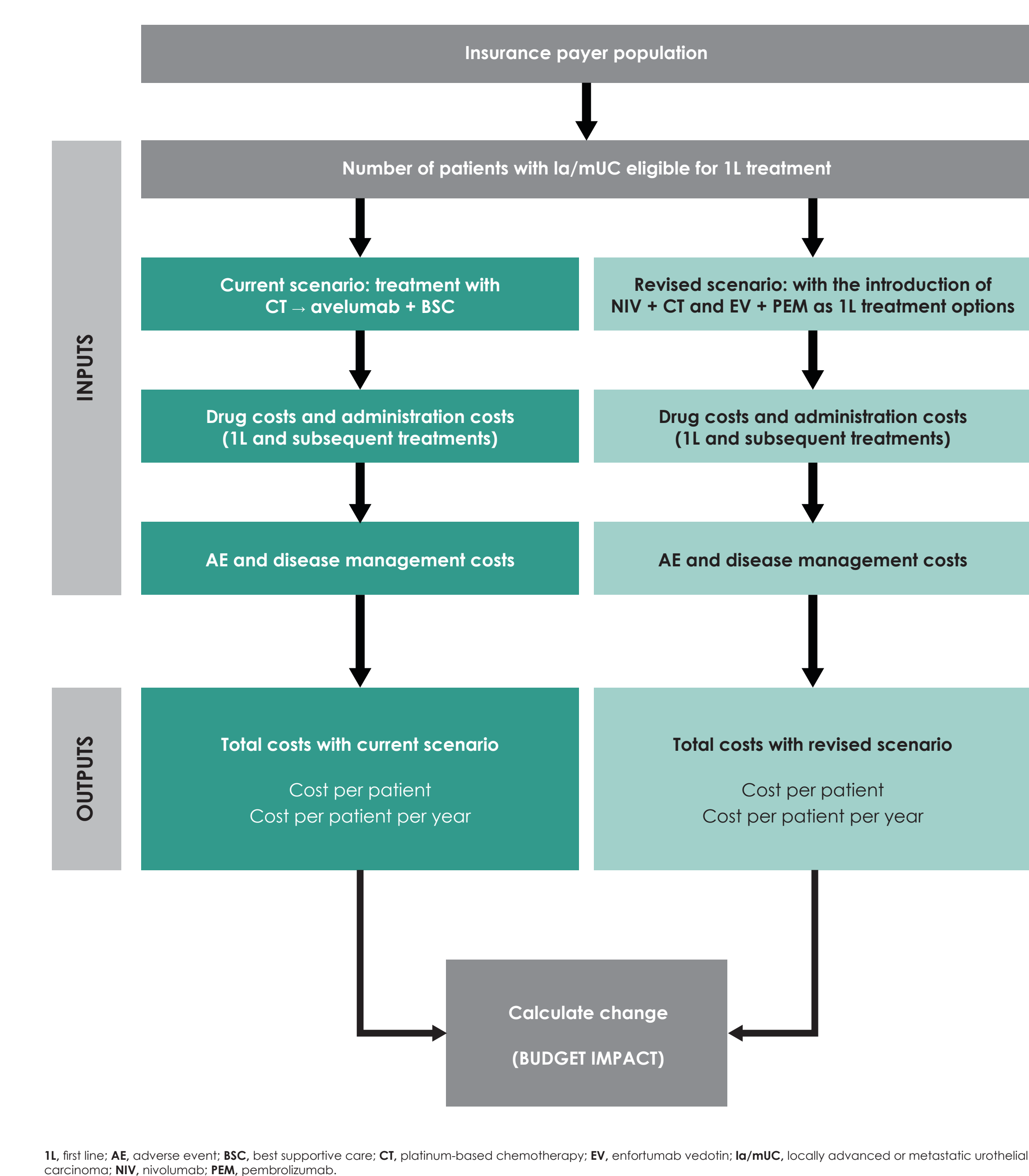
| Costs, ₡                                               | CT → BSC   | CT → avelumab + BSC    | EV + PEM       | NIV + CT   |
|--------------------------------------------------------|------------|------------------------|----------------|------------|
| Drug acquisition                                       | 1,653,126  | 38,774,032             | 88,135,926     | 44,716,390 |
| Drug administration                                    | 12,245,366 | 20,490,496             | 23,284,655     | 18,595,530 |
| AE management*                                         | 1,238,071  | 1,297,285 <sup>f</sup> | 254,521        | 767,214    |
| Disease management                                     | 4,508,169  | 7,952,861              | 7,611,683      | 6,295,550  |
| Acquisition and administration of subsequent treatment | 12,969,269 | 929,803                | 0 <sup>g</sup> | 2,523,307  |
| Disease management for subsequent treatment            | 3,687,753  | 1,308,149              | 0 <sup>g</sup> | 2,441,078  |
| Total cost                                             | 36,301,754 | 70,752,627             | 119,286,784    | 75,339,069 |

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.  
<sup>a</sup>Included grade 3-4 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 presubmission information. All management cost includes the induction CT phase and avelumab maintenance. All management cost was lower for avelumab alone compared with EV + PEM and NIV + CT. In the EV-302 trial, patients treated with EV + PEM were progression free during the first 12 months.<sup>5</sup> Given that the model estimates costs for the first year of treatment, no second-line treatment costs are included within this period.

### 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 Costa Rica, stratified by age and sex, from which UC cases were adjusted for stage distribution and progression to la/mUC<sup>2</sup>
  - The target population, defined in consultation with clinical experts, included adult patients (≥18 years) with la/mUC eligible for 1L systemic therapy
  - Applying eligibility criteria for 1L treatment resulted in an estimated 13 patients in Costa Rica in year 1 (Supplementary Figure 1)
- Three alternative scenarios were evaluated, defined based on relative market share and projected uptake trends over time: EV + PEM, NIV + CT, and CT → avelumab + BSC
- 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.

### 5-year BIA

#### Market scenario

- Hypothetical 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 |
|----------------------------------------|--------|--------|--------|--------|--------|
| <b>Scenario 1: EV + PEM</b>            |        |        |        |        |        |
| EV + PEM                               | 15     | 25     | 30     | 35     | 40     |
| NIV + CT                               | 5      | 6      | 7      | 8      | 9      |
| CT → avelumab + BSC                    | 80     | 69     | 63     | 57     | 51     |
| <b>Scenario 2: NIV + CT</b>            |        |        |        |        |        |
| EV + PEM                               | 5      | 6      | 7      | 8      | 10     |
| NIV + CT                               | 40     | 50     | 60     | 70     | 80     |
| CT → avelumab + BSC                    | 55     | 44     | 33     | 22     | 10     |
| <b>Scenario 3: CT → avelumab + BSC</b> |        |        |        |        |        |
| EV + PEM                               | 10     | 8      | 7      | 7      | 7      |
| NIV + CT                               | 10     | 8      | 7      | 7      | 7      |
| CT → avelumab + BSC                    | 80     | 84     | 86     | 86     | 86     |

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.

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