

Evaluating the economic burden of metastatic urothelial carcinoma (mUC): a real-world analysis using Hungarian claims data

E. Tischler,¹ B. Nagy,² T. Macher,² J. Jeskó,² A. Maráz,³ CS. Csongvai,¹ M. Kearney⁴

¹Merck Kft., Budapest, Hungary, an affiliate of Merck KGaA; ²Healthware Consulting Ltd, Budapest, Hungary; ³Department of Oncotherapy, University of Szeged, Szeged, Hungary;

⁴Merck Healthcare KGaA, Darmstadt, Germany

SCOPE

- This study explored patient characteristics, treatment patterns, healthcare resource use (HCRU), and direct medical costs using claims data for mUC in Hungary

CONCLUSIONS

- This retrospective real-world study is the first to use the Hungarian National Health Insurance Fund Administration (NHIFA) database claims to assess the clinical management and economic burden of mUC in Hungary
- This study quantifies the economic burden of patients irrespective of whether or not they received first-line (1L) systemic anticancer treatment; the latter represents more than half of the patients presenting with mUC¹
- The annual health insurance treatment cost of mUC in 2020 was €2.66 million in Hungary
- 76.4% of cumulative direct medical costs were incurred in the first year following mUC diagnosis, with drugs (70.3%) being the key cost driver
- These findings provide relevant information for healthcare providers, payers, and other stakeholders about the clinical and economic burden of mUC in a mainly older male comorbid population
- This study can serve as a benchmark for future real-world analyses to assess the clinical and economic impact of immuno-oncology (IO) therapies, if and when they become routinely reimbursed in Hungary

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Correspondence: Dr Nagy Bence, nagy.b@healthware.hu



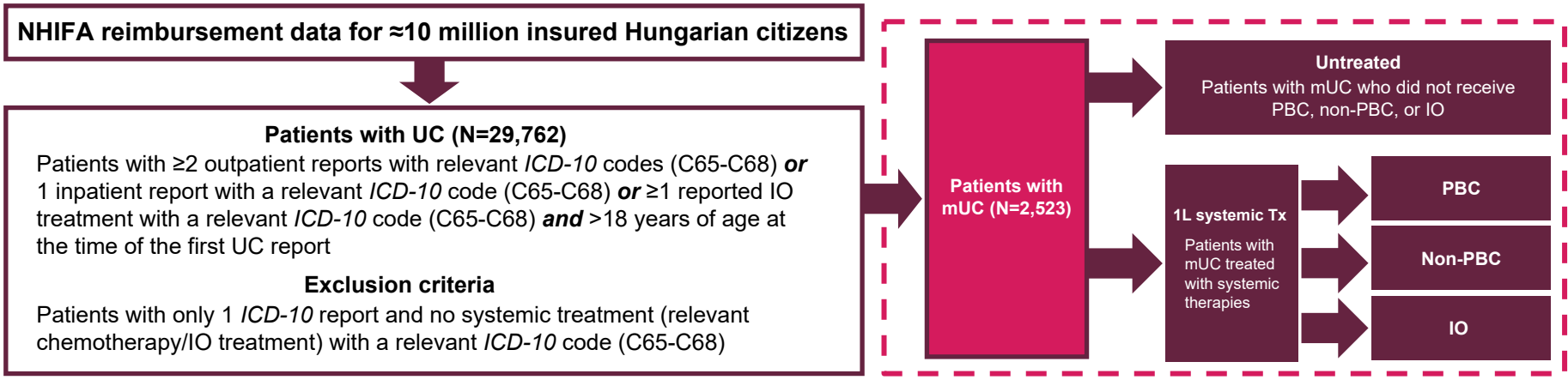
BACKGROUND

- Urothelial carcinoma (UC) is the most common malignancy involving the urinary system and is the fourth most common tumor in developed countries²
- UC is ~4 times more common in men than women, with an incidence of 9.6 per 100,000 in men and 2.4 per 100,000 in women worldwide³
- The age-standardized incidence and mortality rates for all ages and sexes were estimated at 16.9 per 100,000 and 3.6 per 100,000, respectively, in Hungary in 2018^{3,4}
- As outlined in current international guidelines, platinum-based chemotherapy (PBC) is the 1L standard-of-care treatment for patients with mUC,^{5,6} with patients receiving cisplatin or carboplatin + gemcitabine depending on eligibility,⁷ followed by 1L maintenance IO with avelumab in patients who are progression free⁸
- 1L IO agents were approved by the European Commission in 2017 and accepted into the Named Patient-Based Reimbursement (NPBR) program in 2018 in Hungary
- Few real-world studies have explored HCRU and healthcare costs in patients with mUC. To our knowledge, none have been performed to explore the clinical and economic burden of mUC in Eastern Europe

METHODS

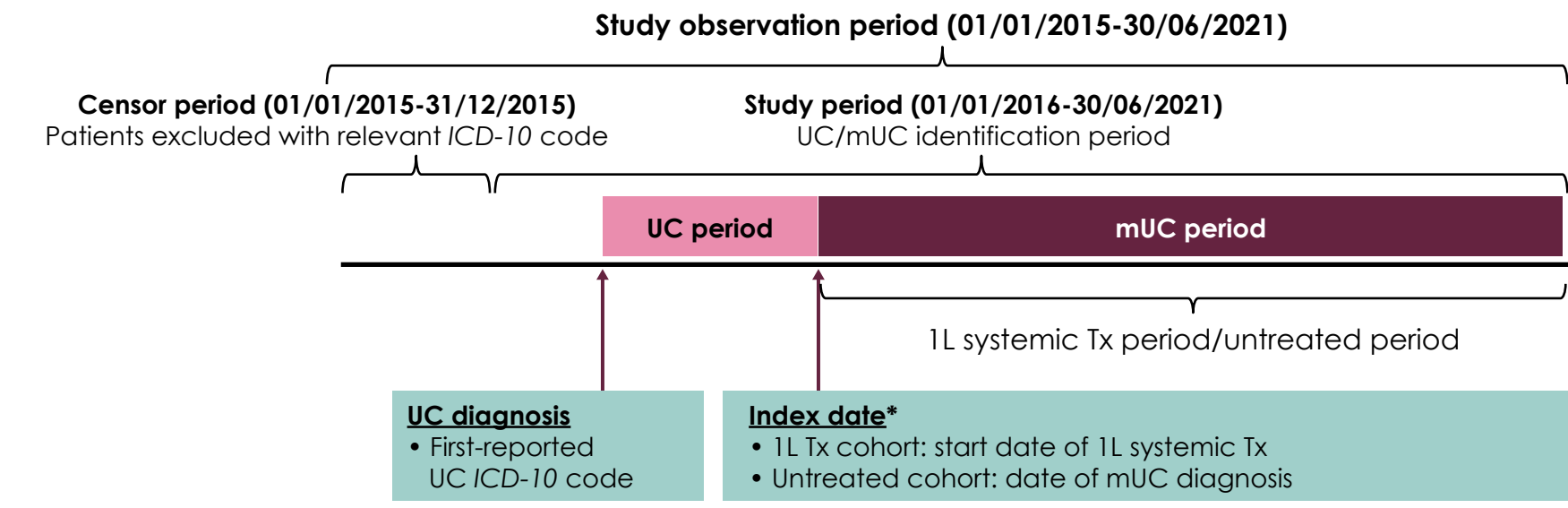
- Anonymized claims from the NHIFA database, a single payer covering the population of 10 million inhabitants, were analyzed⁸
- The study period was from 1 January 2016 through 30 June 2021, with a 1-year baseline period
- Adults with an incident mUC diagnosis at the index date (ICD-10 codes C65-C68, malignant neoplasms of urinary tract) with evidence of metastatic disease (ICD-10 codes C77-C79) and ≥2 outpatient or ≥1 inpatient claim were included (Figures 1 and 2)
- Patients were categorized into 2 cohorts: untreated and treated. The treated cohort was subdivided by the type of 1L treatment received: PBC, non-PBC, or IO monotherapy per label (Figure 1)
- Results were summarized using descriptive statistics
- Patient characteristics were described at the index date; treatments, HCRU, and costs were described during follow-up
- HCRU and direct healthcare costs were evaluated from a payer perspective overall and on a per patient per year (PPPY) basis and adjusted to the average euros exchange rate from January to May 2022 (€=370.37 Hungarian forint)
- The following cost categories were included: drugs, inpatient care, outpatient care, medical imaging, and laboratory diagnostics
- The inpatient cost calculations are based on the Hungarian Diagnosis-Related Group financing system. The outpatient care services, including imaging and laboratory, are based on the OENO system, which is an adaptation of the World Health Organization's International Classification of Health Interventions system. Drug costs are derived from published reimbursed prices
- Ethics approval, as required by Ministerial decree No. 23/2002 (V.9) for noninterventional studies, was provided by the Hungarian Medical Research Council (No. IV/7775-4/2021/EKU [EKU 2022])⁹

Figure 1. Patient attrition



1L, first line; ICD-10, International Classification of Diseases, Tenth Revision; IO, immuno-oncology; mUC, metastatic urothelial carcinoma; NHIFA, National Health Insurance Fund Administration; PBC, platinum-based chemotherapy; Tx, treatment; UC, urothelial carcinoma.

Figure 2. Study design



1L, first line; ICD-10, International Classification of Diseases, Tenth Revision; mUC, metastatic urothelial carcinoma; Tx, treatment; UC, urothelial carcinoma. *The length of the mUC period started from the index date. The follow-up period was from the index date until the last relevant reported ICD-10 code within the study period.

RESULTS

Patient characteristics

- A total of 2,523 eligible patients with mUC were identified
 - Mean age was 67.3 years (SD, 8.39 years; median, 67 years), and 72.22% were male (Table 1)
 - Mean Deyo-Charlson Comorbidity Index score was 1.89 (SD, 1.68; median, 2)
 - Median (interquartile range [IQR]) follow-up was 7.1 (2.2-17.0) months for the total population. Median follow-up was shorter in the untreated and IO-treated cohorts (5.3 [IQR, 1-16.5] and 2.1 [IQR, 1-8] months, respectively) than in the PBC- and non-PBC-treated cohorts (8.9 [IQR, 4.4-18.3] and 6.4 [IQR, 2.8-13.5] months, respectively)

Treatment patterns

- Most patients (n=1,256) underwent ≥1 surgical procedure (61.47%) and nearly half received systemic anticancer therapy (49.78%); radiation therapy was less frequent (2.26%)
- Of the patients who had an identified 1L systemic treatment, the majority (n=1,082 [86.1%]) received guideline-recommended 1L PBC, followed by non-PBC (n=97 [7.7%]) and IO (n=77 [6.1%]). IO use was limited as it only became available by NPRP later in the study period (since 2018)⁹

HCRU

- Patients with mUC had a median (IQR) PPPY of 5 (2-9) outpatient visits, 1 (1-2) hospitalization, 2 (1-3) imaging, and 3 (1-5) laboratory encounters (Table 2)
- In patients receiving 1L treatment (n=1,256), HCRU was broadly similar across the 3 cohorts (Table 2)

Costs

- The median all-cause medical PPPY costs were €1,199.7 (IQR, €433.2-€2,794.8) during the follow-up period (Table 3)
- Drug costs (70.3%) were the key cost driver, followed by inpatient (18.5%), imaging (8.3%), outpatient (2.4%), and laboratory (0.5%) use (Figure 3)
- The majority (76.4%) of cumulative direct medical costs occurred in the first year following mUC diagnosis (index date) (Figure 4)
- The rise in direct medical costs during the study period outstripped the increase in the patient population (Figure 5)

Annual health insurance treatment cost of mUC in Hungary

- The total direct medical costs of the prevalent mUC population in 2020 were €2.66 million, more than double the 2016 costs (Figure 5)

Table 1. Demographic characteristics measured at index date* and stratified by treatment type

Baseline characteristics	Total patients (N=2,523)	Untreated (n=1,267)	1L systemic treatment (n=1,256)	PBC (n=1,082)	Non-PBC (n=97)	IO (n=77)
Sex, n (%)						
Male	1,822 (72.2)	912 (72.0)	910 (72.5)	797 (73.7)	65 (67.0)	48 (62.3)
Female	701 (27.8)	355 (28)	346 (27.5)	285 (26.3)	32 (33)	29 (37.7)
Mean age, years (SD)	67.3 (8)	67.8 (9)	66.8 (8)	66.6 (8)	67.1 (8)	70.2 (7)

1L, first line; IO, immuno-oncology; mUC, metastatic urothelial carcinoma; PBC, platinum-based chemotherapy; SD, standard deviation; Tx, treatment.

*Index date for 1L Tx cohort was start date of 1L systemic Tx; index date for untreated cohort was date of mUC diagnosis.

Table 2. All-cause healthcare utilization (PPPY) by treatment status, stratified by care setting

Descriptive values by level of healthcare	Total patients (N=2,523)	Untreated (n=1,267)	1L systemic treatment (n=1,256)	PBC (n=1,082)	Non-PBC (n=97)	IO (n=77)
Inpatient						
All inpatient reported events	4,091	1,920	2,171	1,961	131	79
Median (IQR), PPPY	1 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)
Outpatient						
All outpatient reported events	27,916	10,913	17,003	15,082	1,355	566
Median (IQR), PPPY	5 (2-9)	4 (2-8)	5 (3-10)	5 (3-10)	6 (3-11)	5 (2-9)
Imaging						
All imaging-related events	8,194	4,153	4,041	3,601	280	160
Median (IQR), PPPY	2 (1-3)	2 (1-3)	2 (1-3)	2 (1-3)	2 (1-3)	2 (1-3)
Laboratory						
All laboratory-related events	11,057	4,010	7,047	6,404	476	167
Median (IQR), PPPY	3 (1-5)	2 (1-4)	3 (1-6)	3 (1-6)	3 (2-6)	2 (1-4)

HCRU and costs were collected for all-cause encounters across the treatment cohorts during the follow-up period.

1L, first line; HCRU, healthcare resource use; IO, immuno-oncology; IQR, interquartile range; PBC, platinum-based chemotherapy; PPPY, per patient per year.

Study limitations

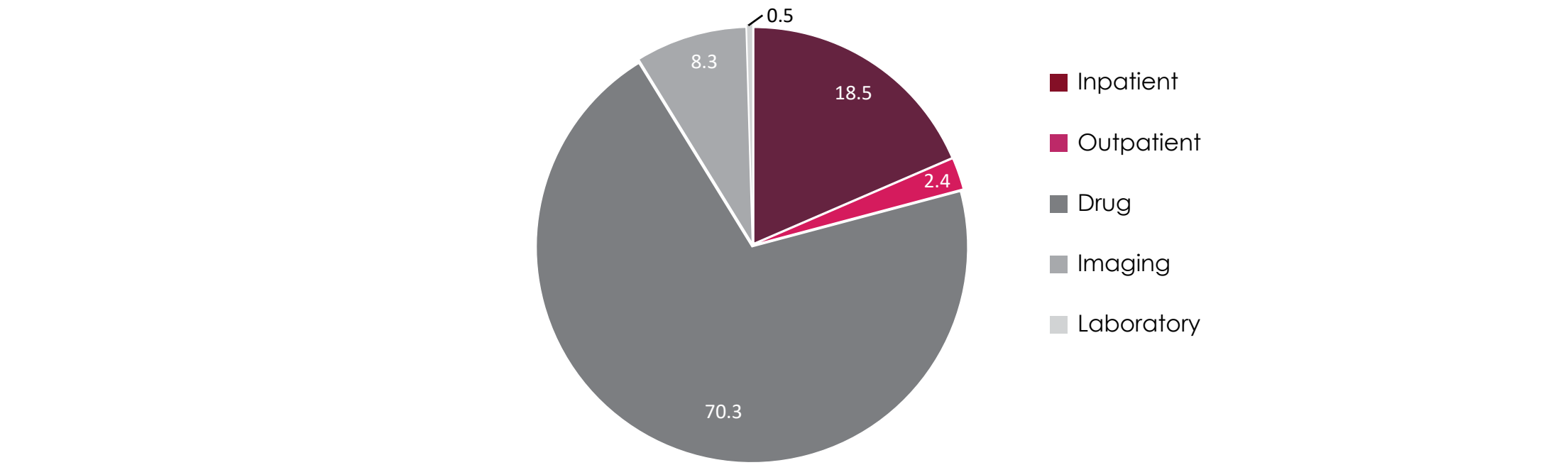
- Factors inherently associated with claims-based studies, including coding errors and insufficient/missing information
- Inclusion of direct measurable healthcare costs only may underestimate the true societal burden of mUC on patients and families
- 1L IO agent use being limited as IOs were accepted in the NPBR program in 2018 (ie, late in the study period)
- Lack of disease-staging information in the claims database; mUC diagnosis was established by ICD-10 codes or receipt of 1L systemic anticancer treatment
- Exclusion of subgroups with <10 patients from this analysis, in line with current data protection regulations of NHIFA

Table 3. All-cause direct healthcare costs, by treatment status, stratified by care setting

Site of care	Total patients (N=2,523)	Untreated (n=1,267)	1L systemic treatment (n=1,256)	PBC (n=1,082)	Non-PBC (n=97)	IO (n=77)
Inpatient						
All reported costs, €	2,050,900.7	979,210.4	1,071,690.3	981,081.1	64,319.0	26,290.2
Median (IQR), € PPPY	614.2 (399.6-1,188.5)	574.7 (399.6-1,034.4)	640.4 (399.6-1,207.4)	689.3 (423.6-1,288.8)	584.2 (308.3-1,000.5)	485.3 (308.3-835.8)
Outpatient						
All reported costs, €	260,913.1	103,023.5	157,889.6	142,084.3	10,910.7	4,894.6
Median (IQR), € PPPY	30.1 (11.6-69.9)	27.4 (11.4-62.2)	32.3 (12.0-75.8)	32.2 (12.2-76.4)	33.3 (13.2-74.3)	31.2 (9.3-66.5)
Drug						
All reported costs, €	7,794,510.2	3,146,428.7	4,648,081.4	3,110,412.1	242,269.6	1,295,399.7
Median (IQR), € PPPY	1,024.7 (318.9-2,427.0)	716.2 (144.2-2,102.3)	1,297.9 (430.3-2,597.9)	1,237.0 (399.5-2,408.2)	919.4 (390.2-1,955.7)	7,789.9 (3,302.3-16,058.1)
Imaging						
All reported costs, €	923,355.0	459,628.3	463,726.7	418,475.1	30,884.7	14,366.9
Median (IQR), € PPPY	1,024.7 (318.9-2,427.0)	716.2 (144.2-2,102.3)	1,297.9 (430.3-2,597.9)	1,237.0 (399.5-2,408.2)	919.4 (390.2-1,955.7)	7,789.9 (3,302.3-16,058.1)
Laboratory						
All reported costs, €	50,825.5	22,737.5	28,088.0	25,638.5	1,954.2	495.3
Median (IQR), € PPPY	4.1 (0.8-19.0)	3.8 (0.8-15.9)	4.4 (0.9-20.0)	4.5 (0.8-20.6)	4.2 (1.0-14.0)	2.7 (0.8-12.5)

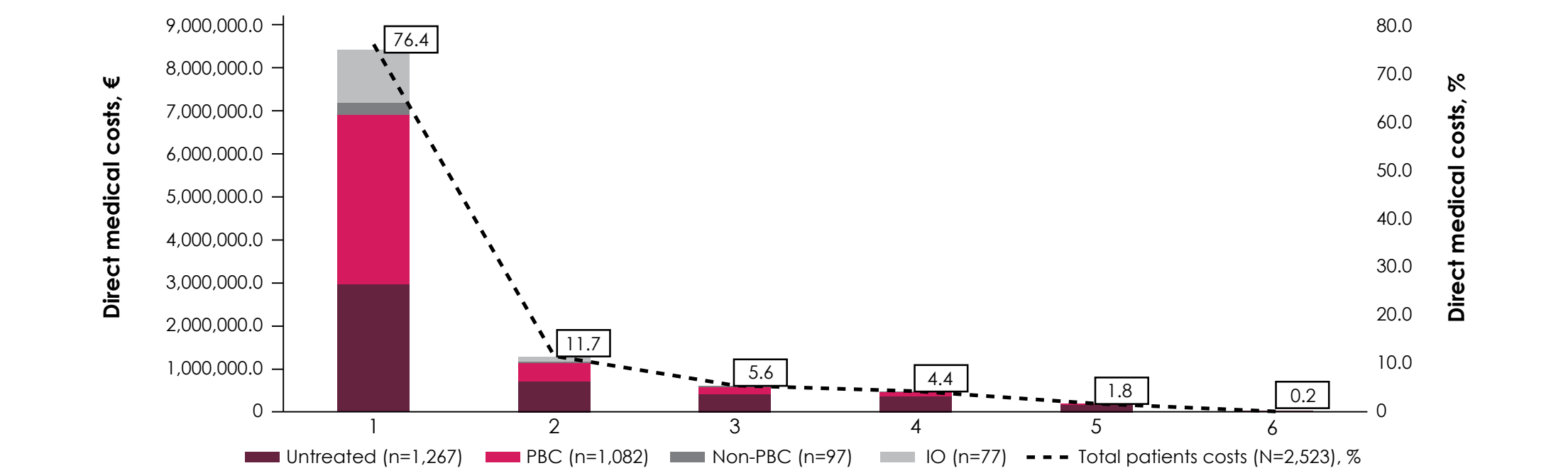
1L, first line; IO, immuno-oncology; IQR, interquartile range; PBC, platinum-based chemotherapy; PPPY, per patient per year.

Figure 3. Distribution of all-cause direct medical costs (%) of all patients with mUC (N=2,523) by cost category during the study period



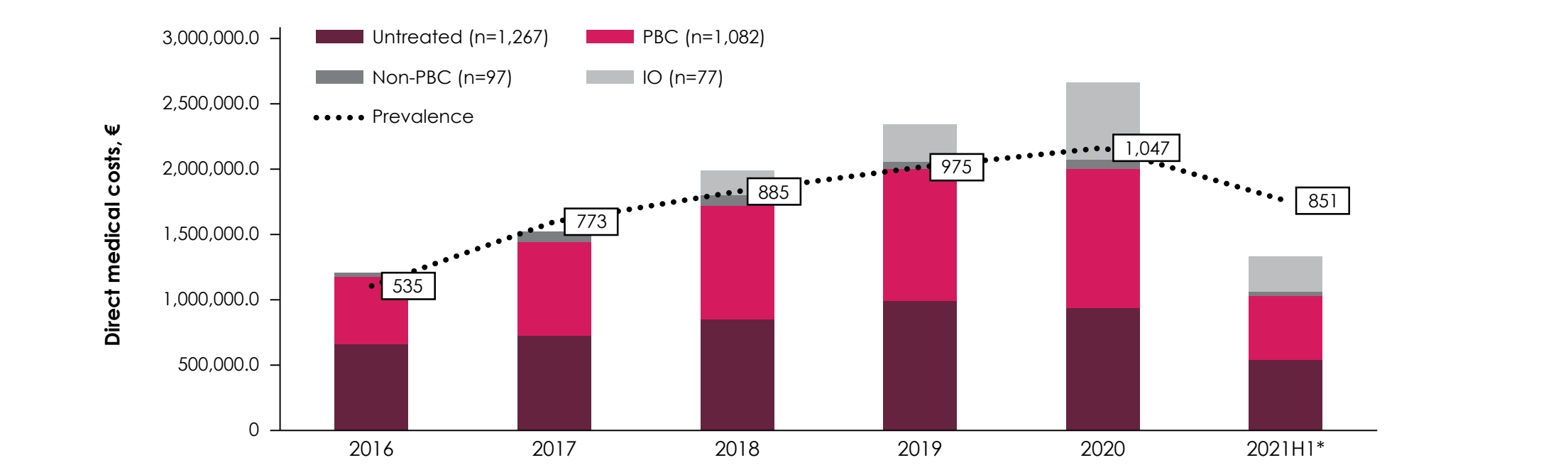
mUC, metastatic urothelial carcinoma.

Figure 4. Cumulative direct medical costs by year during follow-up since mUC diagnosis (index date) by treatment status



IO, immuno-oncology; mUC, metastatic urothelial carcinoma; PBC, platinum-based chemotherapy.

Figure 5. Cumulative direct medical costs by calendar year (2016-2021) and treatment status



1L, first line of year; IO, immuno-oncology; PBC, platinum-based chemotherapy.

*In 2021, data for only the first half of the year are available.