OBJECTIVES: This study models the costs of mRCC treatment for selected targeted agents (AIs and mTORs) in 18 US community oncology clinics using medical resource utilization data collected from patient medical charts. METHODS: Data were abstracted for 297 non-trial mRCC patients 21 years or more, treated with sunitinib (n = 131), sorafenib (n = 119), bevacizumab (n = 193), or temsirolimus (n = 28) as first-line targeted agent. Per-patient-per-month (PPPM) costs (2009 USD) were estimated for targeted agents, intravenous administration, other drugs, procedures, hospitalizations, and treatment of adverse events (AEs; including drugs, procedures, hospitalizations, and office visits for AE treatment). Drug costs were estimated using Average Wholesales Price, procedure costs were based on US private insurance reimbursement, hospitalization costs were based on HCUP National Inpatient Sample discharge diagnosis charges and published average cost-to-charge ratios. RESULTS: Median treatment duration was 5.9 (sunitinib), 5.5 (sorafenib), 6.7 (bevacizumab), and 2.8 (temsirolimus) months. Total PPPM costs (mean ± SE) were $9,417.35 ± 670.78 (sunitinib), $7,992.48 ± 682.29 (sorafenib), $14,770.48 ± 1,393.25 (bevacizumab), and $11,439.39 ± 1,265.63 (temsirolimus). All drug costs comprised 64% (sunitinib), 79% (sorafenib), 75% (bevacizumab), and 55% (temsirolimus) of total PPPM cost. AE treatment costs PPPM were $1,972.62 ± 660.86 (sunitinib, 21% of total PPPM costs), $1,302.58 ± 539.54 (sorafenib, 16%), $425.23 ± 265.69 (bevacizumab, 3%), and $1,810.85 ± 627.63 (temsirolimus, 16%). Given the median treatment durations, total costs for treatment of first-line AE were estimated to be $55,362 (sunitinib), $98,862 (bevacizumab), and $32,181 (temsirolimus), including intravenous administration costs of $2,497 (bevacizumab) and $2,111 (temsirolimus). CONCLUSIONS: Targeted agent drug cost was a major contributor to the total health care PPPM costs in patients with mRCC, followed by AE treatment costs. While AEs may be largely related to tolerability for sunitinib and sorafenib, AE treatment cost was as high as 21% and 16% of total cost. This study is limited by small sample sizes for bevacizumab and temsirolimus.

OBJECTIVES: A prior retrospective chart review study described treatment patterns and drug-related adverse events (AEs) for mRCC pts treated with sunitinib or sorafenib in a tertiary center in Italy (ECCO-EMSO, 2009). This study modeled the costs of the inpatient treatments and AEs. METHODS: Medical records were reviewed for non-trial pts with mRCC, 218 years old, treated with sunitinib (n = 85) or sorafenib (n = 60) after January 1, 2005. Data collected included patients’ health care resource utilization cost data for the Italian health care system were obtained from various sources including published literature and publicly available information from the Italian government. The components of the total per-patient-per-month (PPPM) costs (in 2008 Euro) included costs of MKI drugs, diagnostic and therapeutic procedures, hospitalizations, management of MKI-treatment-related adverse events (AEs), and prescription drugs for conditions other than mRCC. RESULTS: Median treatment duration was 6.6 months (sunitinib) and 5.8 months (sorafenib). Total costs PPPM were (mean ± SE) €388.97 ± 710.49 (sunitinib) and €348.01 ± 1,178.76 (sorafenib). MKI drug costs, equal to the largest contributor to total PPPM costs, followed by AE treatment costs of €1107.89 ± 685.42 (sunitinib) and €222.16 ± 991.18 (sorafenib), and procedure costs of €75.48 ± 72.15 (sunitinib) and €79.94 (sorafenib). Given the median treatment durations, the total cost over the course of first-line MKI treatment is estimated to be €25,535 for sunitinib and €19,998 for sorafenib, with the cost of AE treatment amounting to €712 for sunitinib and €1,289 for sorafenib. CONCLUSIONS: This study used health care resource utilization data from a real clinic setting and costs from published literature to estimate costs associated with MKI treatment in patients with mRCC in Italy. MKI drug cost was the major contributor to total PPPM cost, followed by the cost associated with treatment of AEs. This retrospective study is limited by small sample sizes from a single center.

OBJECTIVES: An earlier analysis in first-line treatment of RCC patients with similar baseline characteristics demonstrated significantly greater costs with sunitinib than sorafenib. Evidence from case series supports the use of sorafenib or sunitinib sequen- tial therapy for RCC disease control. Direct medical costs associated with each sequence were quantified. METHODS: Patients in MarketScan®, a U.S. health care claims database covering all U.S. census regions and >18 million lives annually from 2002 to 2009, were retrospectively analyzed. Inclusion: 22 RCC claims (ICD-10 C62.80 or C62.88), continuous health care coverage, ≥1 switch (sorafenib to sunitinib to sunitinib), >180 days’ coverage before switch date. Observation period: first-line therapy ≤12 months before switch, ending ≤12 months after switch. Second-line therapy (switch) ended with next dispensing of sunitinib, sorafenib, bevacizumab, or temsirolimus; disenrollment; death; or study end (March 31, 2009). A person-time approach was used. Limitations include physician coding and lack of disease staging. RESULTS: At time of switch, no significant differences in baseline characteristics were noted. P < 0.001) and higher prevalence of anemia in patients who received sunitinib first (32.9% vs 32.8%, P < 0.001). Univariate incremental total per member per month (PMMP) costs in those who received sunitinib first were $1619 (P = 0.0003) more than those treated with sorafenib first, largely due to significantly higher outpatient costs PMMP in those who received sunitinib first ($1252; P < 0.0001). Overall, this represents an annual cost savings of $19,668 in RCC patients initially treated with sorafenib. CONCLUSIONS: In this retrospective US claims database analysis, we observed statistically significantly lower costs in RCC patients initially treated with sorafenib, the difference mainly attributable to outpatient costs. Future cost analyses should be incorporated into prospective trials of RCC sequencing.

OBJECTIVES: To compare the safety profile of nilotinib, observed in a large study of CML patients in a clinical practice setting to the product information of nilotinib and dasatinib. METHODS: Adult patients with imatinib resistant or intolerant Ph+ CML in chronic phase (CP), accelerated phase (AP), or blast crisis (BC) were recruited in the phase IIIB, open label, multicenter, nonrandomized study. Patients received nilotinib 1,000 mg BID and were not permitted to dose escalate. Follow-up treatment in managing the hematological and non-hematological adverse event (AE), were recorded. Health care resource utilization was estimated by constructing six-month marginal cost increase in patients who received follow-up care for the management of AE. Cost data were obtained from MedStat MarketScan database that contained over 5000 CML patients. RESULTS: A total of 207 patients (172 CP pts, 15 AP pts, and 20 BC pts) were enrolled in the study between June 2006–October 2008. The percentage of patients with grade 3/4 hematological AEs suspected of being study drug-related in CP and AP were thrombocytopenia (12%, 20%), neutropenia (9%, 27%), and anemia (1.2%, 13%). The most frequent non-hematological AEs (all grades) included rash, headache, nausea, and fatigue. The percentage of patients requiring additional therapy for the reported hematological AEs was less than 50% in most cases. Total medical costs associated with managing the AEs, estimated from MedStat cost data, for both hematological and non-hematological AEs were $6314 over a 6-month period. Medical costs associated with managing hematological AEs made up the majority of these costs. The percentage significantly lower costs were attributed to the burden of the AEs in the product information for nilotinib or dasatinib ($9,730 and $12,372, respectively). CONCLUSIONS: Nilotinib related AE costs observed in this large clinical practice setting study compare favorably to the estimated costs from product information from nilotinib and dasatinib.