Real-world data establishing Health Care Resource Utilization and costs for the treatment of patients with Intermediate- to High-Risk Non-Muscle Invasive Bladder Cancer Utilizing Medicare claims data

Anthony Eccleston¹, Sanjana Chandrasekar²,

Jane Chang², Joseph C. Cappelleri², Allison Thompson², Julia Brinkmann³, Amy Schroeder⁴

1. Pfizer Inc, Surrey, GB; 2. Pfizer Inc, New York, NY, USA; 3. Pfizer Inc, Berlin, Germany; 4. Avalere Health, Washington, DC, USA



 To estimate Health Care Resource Utilization (HCRU) and costs for patients with Intermediate- to High-Risk Non-Muscle Invasive Bladder Cancer (NMIBC) who received adequate vs. inadequate Bacillus Calmette-Guerin (BCG) maintenance therapy (as recommended by major guidelines) among Medicare beneficiaries.



- HCRU and costs associated with NMIBC patient hospital stays, procedures and emergency room (ER) visits place a substantial burden on healthcare systems
- Adequate BCG maintenance therapy may be associated with lower HCRU and improved time to event outcomes
- Between 2010 and 2019, 57% of Medicare patients initiating BCG following diagnosis of NMIBC may not have received adequate BCG therapy

Background

- For patients with high-risk-NMIBC, standard of care includes transurethral resection (TURBT) followed by induction and maintenance intravesical immunotherapy with Bacillus Calmette-Guerin (BCG)
- Intermediate-risk-NMIBC standard of care also includes TURBT and BCG with the option to begin intravesical chemotherapy^{1,2}
- Previous research described characteristics and clinical outcomes of Medicare beneficiaries newly diagnosed with NMIBC who initiated BCG therapy following TURBT³
- There is limited real-world evidence describing BCG treatment and disease-related events, particularly in older adult populations⁴
- This study estimates HCRU and costs for patients with Intermediate- to High-Risk NMIBC who received either adequate or inadequate BCG therapy

Materials and Methods

- This was a retrospective cohort study using the 100% sample of Medicare Fee-for-Service medical and pharmacy claims and enrolment data from 2010-2019
- Patients were divided into two subgroups (Figure 1) based on major guidelines as described by Williams et al⁵:
 - Adequate BCG Therapy (Subgroup 1): Patients received ≥7 instillations of BCG within 274 days of index date
 - Inadequate BCG Therapy (Subgroup 2): Patients with NMIBC that received BCG treatment but did not qualify for subgroup 1
 - This classification scheme does not differentiate high-risk-NMIBC patients from intermediate-risk patients
- NMIBC-related claims included hospitalizations or ER visits with a diagnosis code for bladder cancer in the first or second position on claim
- Specific evaluations included number and length of hospital stays, ER visits, procedures and treatment administrations

Figure 1. Subgroup Classification

Medicare FFS beneficiary with ≥ 1 inpatient or ≥ 2 outpatient claims with a diagnosis code for bladder cancer. The earliest date marked the diagnosis date.

No evidence of radiotherapy, metastatic disease, treatments indicated for MIBC or advanced disease, evidence of partial/complete cystectomy, or metastatic disease within the 6 months following the bladder cancer diagnosis date.

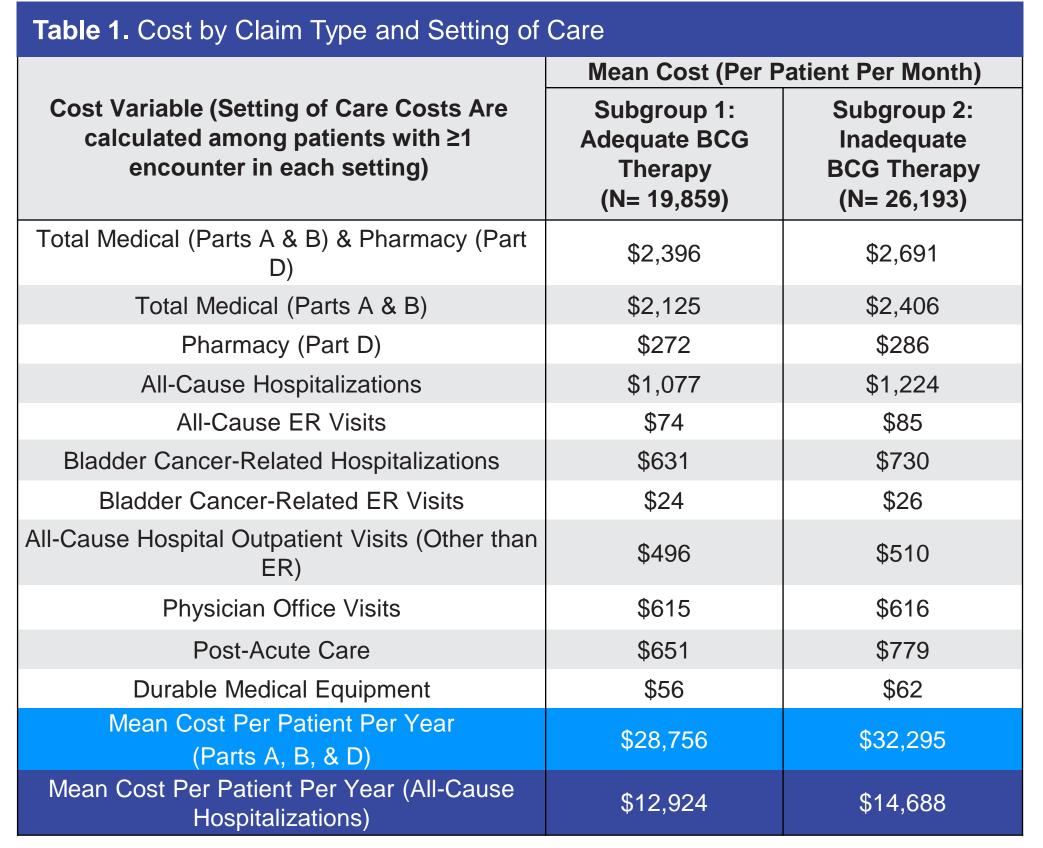
Evidence of TURBT on or after but not in the 12 months prior to the bladder cancer diagnosis date.

Evidence of BCG on or after the first date of TURBT and not in the 12 months prior to bladder cancer diagnosis.

Continuous enrollment in Medicare Parts A, B, and D for 12 months prior to the index date and for ≥12 months following the index date until death, disenrollment, or end of the study period.

Subgroup 1: Received BCG adequate maintenance therapy (≥7 instillations within 274 days of BCG initiation)

Subgroup 2: Received inadequate BCG therapy (<7 instillations within 274 days of BCG initiation or ≥7 instillations over >274 days)



Results

- The mean total medical and pharmacy costs/patient/year were \$28,756 for subgroup 1 vs. \$32,295 for subgroup 2
 - The total medical and pharmacy costs/year were \$571 million for subgroup 1 vs. \$846 million for subgroup 2 (Table 1)
- 12,109 patients of a total 19,850 in subgroup 1 (61%) had ≥1 all-cause hospitalizations vs. 17,209 of a total 26,193 in subgroup 2 (66%)
 - There were 6.69 all-cause hospitalizations/100 patients/year for subgroup 1 vs. 7.70 for subgroup 2 (Table 2)
 - Subgroup 1 saw 52,768 all-cause hospitalization bed days/year compared to 87,749 in subgroup 2
- The mean length of stay among those who were hospitalized was also shorter for those patients in subgroup 1 (3.01 days) vs those in subgroup 2 (3.21 days).
- 14,984 patients (75%) in subgroup 1 had ≥1 all-cause ER visits vs. 20,529 patients (78%) in subgroup 2
 - The mean number of ER visits/100 patients/year was 1.82 for subgroup 1 vs. 2.13 for subgroup 2 (Table 2)
 - The total number of ER visits/year for subgroup 1 was 27,290 vs. 43,790 for subgroup 2

Table 2. Mean HCRU		
	Mean HCRU (Standard Deviation)	
HCRU Outcome (Per 100 Patients Per Month)	Subgroup 1: Adequate BCG Therapy (N= 19,859)	Subgroup 2: Inadequate BCG Therapy (N= 26,193)
All-Cause Hospitalizations	6.69 (6.78)	7.70 (8.04)
All-Cause Hospitalization Length of Stay	36.32 (52.33)	42.49 (62.36)
All Cause Hospitalizations Length of Stay Among Those Who Were Hospitalized, Per Stay (days)	3.01 (2.68)	3.21 (2.85)
All-Cause ER Visits	15.18 (17.13)	17.78 (20.29)
Bladder Cancer-Related Hospitalizations	2.94 (2.44)	3.42 (2.85)
Bladder Cancer-Related Hospitalization Length of Stay	18.06 (25.59)	21.17 (29.14)
Bladder Cancer-Related ER Visits	3.31 (2.93)	3.60 (3.20)
TURBT Procedures	7.09 (6.09)	7.08 (6.22)
BCG Administration	36.17 (21.72)	18.00 (13.08)
Cystoscopy Procedures	20.86 (8.74)	19.21 (9.54)
Intravesical Chemotherapy	17.02 (15.92)	19.21 (18.75)

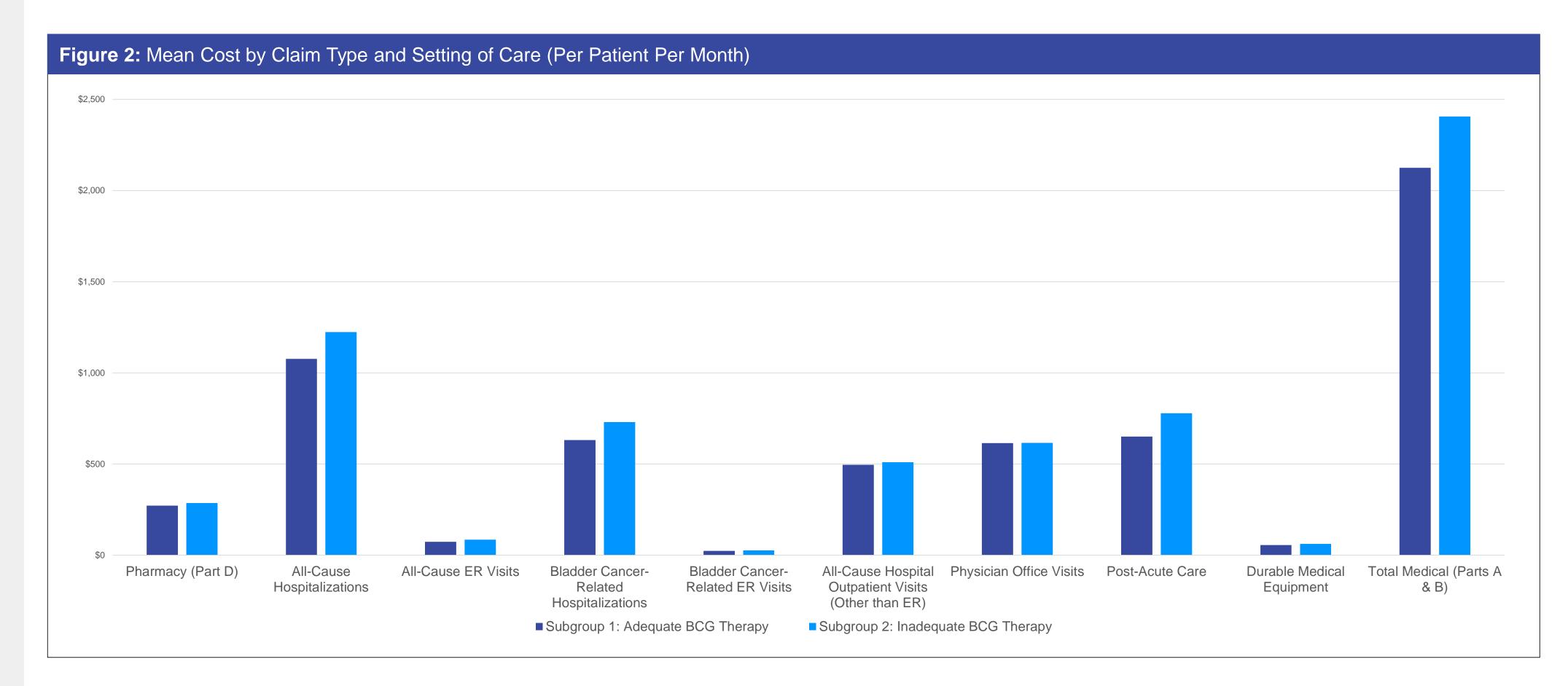


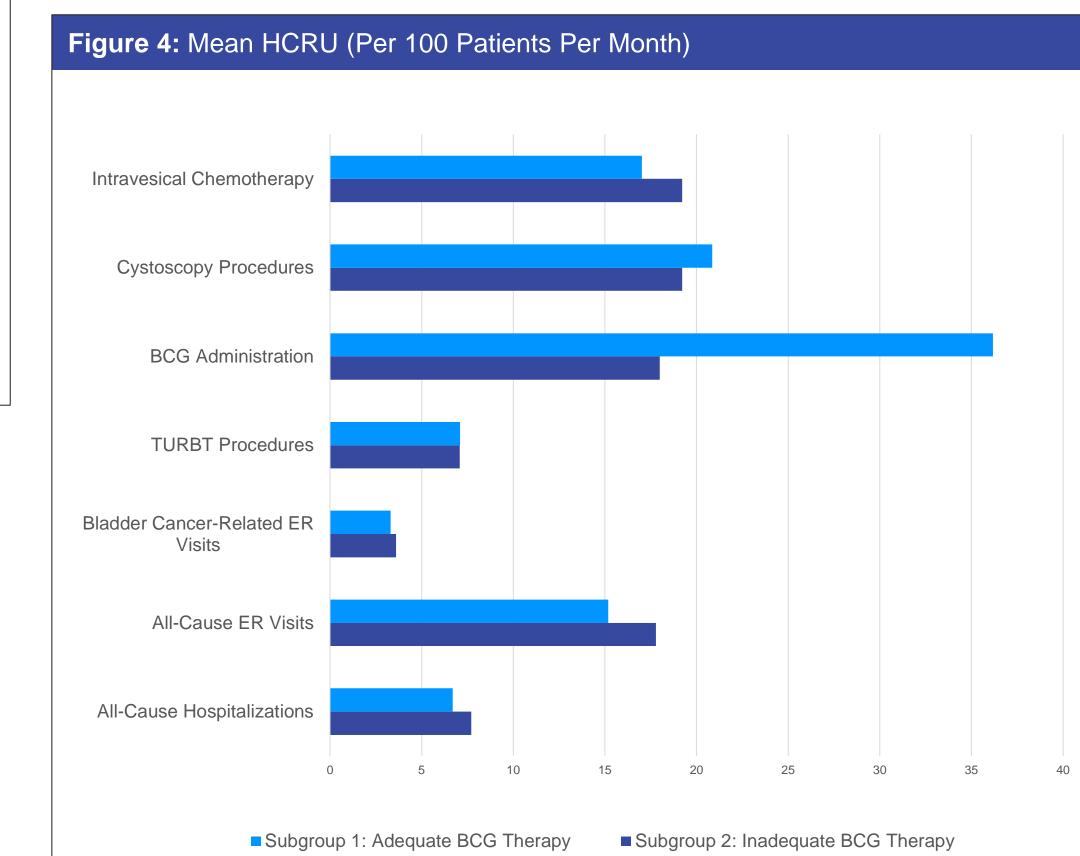
Figure 3: Length of Stay by Type of Hospitalization (Per 100 Patients Per Month) 18.06 Bladder Cancer-Related Hospitalization Length of Stay 21.17 36.32 All-Cause Hospitalization Length of Stay 42.49 Subgroup 1: Adequate BCG Therapy ■ Subgroup 2: Inadequate BCG Therapy

Future Directions for Research

- Additional research is underway to understand the association between intensity of BCG treatment and patient outcomes
- Further research could examine HCRU not captured in Medicare Fee-For-Service data, such as Medicare Advantage or Commercial insurance claims
- HCRU associated with NMIBC recurrence and progression, which require more costly treatments and procedures
- Out-of-Pocket costs paid by patients and/or caregivers associated with NMIBC treatment with BCG

Limitations

- Provider access to BCG (due to supply shortage), BCG tolerability, the ability to distinguish between intermediate- and high-risk patients, and other factors associated with BCG treatment decisions are not captured in claims data
- For drugs administered during hospitalization, administrative claims databases do not capture the specific drug names utilized (unless the treatment is associated with an active Medicare new technology add on payment)
- Definitions of "adequate" and "inadequate" BCG administration vary depending on which treatment guidelines and papers are followed^{1,5}



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