Stephen B. Williams¹, Jinghua He², Aeja Jackson², Andrea Ireland², Hiremagalur Balaji², Wenxi Huang², Qian Shi², Lorie Ellis², Mukul Singhal²

¹The University of Texas Medical Branch, Texas, USA; ²Janssen Scientific Affairs, LLC, NJ, USA

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KEY TAKEAWAY

A large retrospective real-world study among a Medicare population with HR NMIBC found that iGEM use has increased substantially in recent years (2019-2020). Shortage of BCG supply may have played a significant role in increased uptake.

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CONCLUSIONS

- The use of iGEM in management of HR NMIBC has increased dramatically since 2019 in overall intravesical treated patients.
 - Treatment duration of iGEM was observed to be sub-optimal with the majority of patients stopping therapy within 4 months.
 - Given the increased practice and lack of phase 3 trials on iGEM use in the HR NMIBC setting, studies of real-world clinical outcomes will become important in understanding the clinical benefits and risks of iGEM and the optimal duration of treatment.

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BACKGROUND

- Although Bacillus Calmette-Guérin (BCG) remains the standard of care for newly diagnosed high-risk (HR) non-muscle invasive bladder cancer (NMIBC), intravesical gemcitabine (iGEM) use among these patients has shown effectiveness towards preventing or delaying tumor recurrence.^{1,2,3}
- Data characterizing iGEM use and associated treatment patterns in existing literature is limited. Real-world research of treatment patterns in the HR NMIBC population is warranted to better understand iGEM utilization.

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OBJECTIVES

 To report iGEM utilization and treatment patterns during the 12-month period following iGEM initiation in newly diagnosed HR NMIBC patients in the United States, stratified by those who were BCG naïve (BCG-N) or exposed to BCG (BCG-Exp) prior to iGEM initiation.

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METHODS (1 of 4)

This retrospective cohort study used data from the Surveillance, Epidemiology, and End Results (SEER)-Medicare database of patients newly diagnosed with bladder cancer (BC) between January 1, 2007 and December 31, 2019, with Medicare claims up to December 31, 2020 (**Figure 1**).

 The SEER-Medicare database represents a subset of the SEER population, which is created by merging the SEER data of cancer patients eligible for Medicare with their claims for covered health care services under Medicare.⁴

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METHODS (3 of 4)

Study Population

- Inclusion criteria: aged ≥65 years at initial BC diagnosis; diagnosed with HR NMIBC, defined by Tis, Ta, T1, N0, M0; iGEM use between January 1, 2008 and December 31, 2020 (first iGEM claim = index date); continuous enrollment in Medicare Part A & B FFS for ≥12 months before index date (up to 1-month gap was permitted)
- Exclusion criteria: missing TNM stage; low/ intermediate risk group NMIBC; other primary cancer diagnosis; diagnoses that were reported on death certificate

Cohort Definitions

- BCG-N: Patients without a BCG claim prior to the index date
- BCG-Exp: Patients with at least 1 BCG claim prior to the index date

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METHODS (4 of 4)

Outcomes

- Treatment patterns during the baseline period and one-year post-index date
- The percentage of patients treated with iGEM (alone or in combination) among those treated with any intravesical therapy was reported by year, regardless of their BCG exposure.

Statistical Analyses

Means, standard deviations (SD), and medians were reported for continuous variables; counts and percentages were reported for categorical variables. No statistical comparisons between the BCG-N and BCG-Exp cohorts were made.

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RESULTS (1 of 6)

Patient Disposition **FIGURE 2: Patient disposition** Approximately 293,000 unique BC patients

were identified (Figure 2). • 37,762 (12.9%) patients met the criterion for HR NMIBC diagnosis among BC patients during prespecified period.

• The final analysis set of 679 patients included 277 (41%) BCG-N patients and 402 (59%) BCG-Exp patients receiving iGEM.



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BC: bladder cancer; BCG: Bacillus Calmette-Guérin; BCG-Exp: BCG exposed; BCG-N: BCG naïve; FFS: fee-for-service; HR NMIBC: high-risk non-muscle invasive bladder cancer; iGEM: intravesical gemcitabine.

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RESULTS (2 of 6)

Patient Demographics, Clinical and Treatment Characteristics (Table 1)

- On the index date for both cohorts, mean age was >75 years, >80% were male, and >90% were White.
- Higher proportions of patients with tumor stage Ta and lower proportions of patients with T1 and Tis were noted in the BCG-N group at baseline.
- From 2008-2020, use of iGEM increased in both cohorts. Of all patients included in the study, 70% of BCG-N patients and 64% of BCG-Exp patients initiated iGEM in 2019-2020.
- Intravesical therapy use beyond a perioperative instillation during the baseline period was observed in 27.4% of BCG-N and 36.1% of BCG-Exp patients; docetaxel (17.3% BCG-N, 20.4% BCG-Exp) and mitomycin (11.6% BCG-N, 17.2% BCG-Exp) were most common.

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Age (years), mean (SD)

65-69, n (%)

70-74, n (%)

75-79, n (%)

80-84, n (%)

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TABLE 1: Baseline demographics and clinical characteristics

85+, n (%) Sex, Male, n (%) 225 (81.2) 323 (80.3) 264 (95.3) 377 (93.8) Race, White, n (%) Marital status, Married, n (%) 180 (65) 294(73.1) Metro area, n (%) 225 (81.2) 332 (82.6) Urban/Metro Rural 52 (18.8) 70 (17.4) BC initial diagnosis year, n (%) 2008-2012 26 (9.4) 78 (19.4) 2013-2016 54 (19.5) 133 (33.1) 2017-2018 71 (25.6) 130 (32.3) 2019 126 (45.5) 61 (15.2) Index year, n (%) 2008-2012 12 (4.3) 22 (5.5) 28 (10.1) 2013-2016 59 (14.7) 2017-2018 42 (15.2) 62 (15.4) 2019-2020 195 (70.4) 259 (64.4) Days from BC diagnosis to index date, mean (SD) 452 (774) 973 (849) Tumor stage, n (%) 113 (40.8) 178 (44.3) T1 Та 138 (49.8) 162 (40.3) Tis 26 (9.4) 62 (15.4) 0.78 (0.68) 0.80 (0.70) NCI Comorbidity Index*, mean (SD) Comorbid conditions, n (%) 87 (31.4) Diabetes 118 (29.4) 86 (31.0) 124 (30.8) Peripheral vascular disease 84 (30.3) 126 (31.3) Chronic Pulmonary Disease Renal disease 71 (25.6) 153 (38.1) Cerebrovascular disease 53 (19.1) 78 (19.4) **Congestive Heart Failure** 52 (18.8) 82 (20.4) Liver disease 37 (13.4) 37 (9.2) 28 (10.1) 41 (10.2) Myocardial infarction history Intravesical chemotherapy treatments, n % Any[†] 76 (27.4) 145 (36.1) Mitomycin 32 (11.6) 69 (17.2) Docetaxel 48 (17.3) 82 (20.4)

BCG-N (n=277

77.9 (7.35)

35 (12.6)

67 (24.2)

72 (26.0)

49 (17.7)

54 (19.5)

BCG-Exp (n=40

78.6 (6.22)

13 (3.2)

108 (26.9)

116 (28.9)

96 (23.9)

69 (17.2)

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BC: bladder cancer; BCG: Bacillus Calmette-Guérin; BCG-Exp: BCG exposed; BCG-N: BCG naïve; NCI: National Cancer Institute; SD, standard deviation *Reference: https://healthcaredelivery.cancer.gov/seermedicare/considerations/comorbidity.html [†]Includes mitomycin, docetaxel, valrubicin, epirubicin.

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RESULTS (4 of 6)

iGEM initiation

FIGURE 3: Proportion of HR NMIBC patients treated with iGEM among the HR NMIBC population receiving intravesical therapy*, by year

 From 2008-2020, use of iGEM increased over the study period, most notably, since 2019. (Figure 3).

BCG: Bacillus Calmette-Guérin; iGEM: intravesical gemcitabine. *The total represents the number of unique patients over the entire 2008-2020 period. Patients may have received treatment i multiple calendar years. BCG, iGEM, mitomycin, docetaxel, valrubicin, epirubicin.



17.8%



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20%

18%

16%

14%

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Treatment Patterns During Follow-up

- The median number of iGEM doses per patient in the BCG-N cohort was 6 (IQR 1,8) with mean (SD) retreatment interval of 28 (43) days. In BCG-Exp, the median number of iGEM doses was 6 (IQR 2,9) with mean (SD) of 23 (26) days of retreatment interval (**Table 2**).
- The percentages of patients who received 1, 2, 3, and 4 doses of iGEM are show in Table 2.
 Over 40% of the BCG-N cohort and over 30% of the BCG-Exp cohort did not receive a 4th dose.
- Docetaxel was used in combination with iGEM in 18.4% of the BCG-N cohort and in 21.4% of the BCG-Exp cohort (Table 2).

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TABLE 2: Treatment patterns during follow-up

	BCG-N (n=277) 5	BCG-Exp (n=402)
Post-index follow-up duration (months), mean (SD)	20 (19.8)	22 (21.6)
iGEM dosing up to 1-year post-index		
Doses per patient, mean (SD)	5.7 (4.4)	6.0 (4.2)
Doses per patient, median (IQR)	6 (1, 8)	6 (2, 9)
Days between any 2 consecutive doses, mean (SD)	28 (43)	23 (26)
Patients who received only 1 dose of iGEM, n (%)	77 (27.8)	70 (17.4)
Patients with 2 doses of iGEM, n (%)	200 (72.2)	332 (82.6)
Days between 1 st and 2 nd consecutive doses, mean (SD)	21 (46)	16 (27)
Patients with 3 doses of iGEM, n (%)	181 (65.3)	301 (74.9)
Days between 2 nd and 3 rd consecutive doses, mean (SD)	13 (27)	18 (32)
Patients with 4 doses of iGEM, n (%)	165 (59.6)	270 (67.2)
Days between 3 rd and 4 th consecutive doses, mean (SD)	14 (32)	19 (36)
Patients who received iGEM in combination with docetaxel*, n (%)	51 (18.4)	86 (21.4)
Combination doses per patient*, mean (SD)	8.9 (5.4)	7.3 (4.7)

BC: bladder cancer; BCG-Exp: BCG exposed; BCG-N: BCG naïve; iGEM: intravesical gemcitabine; IQR: interquartile range; SD, standard deviation *Combination therapy was defined as iGEM and intravesical docetaxel received on the same day.

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LIMITATIONS

- The study was retrospective in nature with inherent limitations of administrative data, including potential inaccurate coding errors leading to misclassification of treatment and clinical outcomes.
- The study didn't account for induction and maintenance phase of the iGEM treatment cycle so results should be interpreted with this consideration.
- Data used in this study were limited by the information recorded and translated into structured data element, and may not have been generalizable to the entire US population.

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DISCLOSURES:

Stephen Williams is a consultant to Johnson and Johnson, Merck, Photocure, Provepharm, UroToday and Valar Labs. Jinghua He, Andrea Ireland, Qian Shi, Hiremagalur Balaji, Lorie Ellis, Mukul Singhal are employees of Janssen Scientific Affairs, LLC and hold stock in Johnson & Johnson. Wenxi Huang is an employee of Janssen Scientific Affairs, LLC at the time of the study

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