

# A Cost-Consequence Analysis Of Nogapendekin Alfa Inbakicept-pmln (NAI) in Combination with Bacillus Calmette-Guérin (BCG) versus TAR-200 for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma In Situ with or without Papillary Disease

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## Background

- Bladder cancer ranks as the 6th most common cancer in the United States (US), with approximately 75% of cases being non-muscle invasive bladder cancer (NMIBC)<sup>1</sup>
- Bladder cancer is among the most expensive cancers for surviving patients, and costs in the US are expected to increase, both in medical services and prescription drug costs<sup>2</sup>
- Although intravesical BCG remains the standard of care, many patients experience relapse or develop BCG-unresponsive disease<sup>3</sup>
- With more innovative treatment options becoming available for patients living with high-risk NMIBC, evaluating their costs and effectiveness is important for the health care system.
- A cost-consequence analysis was developed comparing NAI plus BCG vs. TAR-200 across various consequences and time horizons using data from respective clinical trials, QUILT-3.032 and SunRISe-1

## Methods

- The target population in the model was US adults diagnosed with NMIBC carcinoma in situ (CIS) who were unresponsive to BCG treatment [5+2]
- A multi-state Markov model with a 3-week cycle length was used, with clinical inputs informed by an indirect treatment comparison based on the single-arm clinical trials evaluating the two FDA-approved treatments
- Efficacy outcomes, including complete response (CR), were informed by a matched-adjusted indirect comparison (MAIC) using six matched baseline characteristics: age, sex, ECOG, prior BCG instillations, race, and tumor stage
- The analysis was conducted from a US Medicare perspective, considering acquisition of therapies and administration, healthcare resource utilization, radical cystectomy, and mortality costs
- The main assumptions used are summarized in **Table 1**

**Table 1.** Main Assumptions

<b>Model structure</b>	A Markov model was used, and comprised of key health states in the NMIBC life-cycle: initiation of BCG-unresponsive NMIBC treatment, disease-free state, NMIBC recurrence state, MIBC state, post-cystectomy state, metastatic disease state, and death
<b>Patient population</b>	BCG-unresponsive, high-risk NMIBC with CIS
<b>Intervention</b>	NAI plus BCG
<b>Comparator</b>	TAR-200
<b>Perspective</b>	US Medicare/Medicaid
<b>Time horizon</b>	1, 2, and 3-years
<b>Cycle length</b>	3 weeks (21 days)
<b>Half-cycle correction</b>	Applied in the base case analysis
<b>Inflation</b>	Based on U.S. Bureau of Labor Statistics from 2012 to 2025 (for prices published prior to 2012, an average rate was applied)
<b>Discounting</b>	3% for costs and benefits
<b>Patient age</b>	73 years old at the start of the model

### ACKNOWLEDGMENTS

Funding for this study and editorial support (Colleen Dumont, Cytel, Inc.; JD Cox, Mayville Medical Communications) was provided by ImmunityBio, Inc.

### REFERENCES

- National Cancer Institute. Treatment of Bladder Cancer by Stage 2025 [Available from: <https://www.cancer.gov/types/bladder/treatment/by-stage>]. 2. Mariotto A. Medical Care Costs Associated with Cancer Survivorship in the United States. 2020. 3. Holzbeierlein JM, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment. J Urol. 2024;211:533-8.

## Results

### Incremental Cost per Cystectomy Avoided

- When comparing the total costs for every cystectomy avoided, NAI plus BCG is \$109,622 less costly than TAR-200 at 1 year (12 months). This cost-to-outcome advantage for NAI plus BCG persists cumulatively at 2 and 3 years (**Table 2**)

**Table 2.** Incremental Cost per Cystectomy Avoided

Data Source	Regimen	Incremental Cost per Cystectomy Avoided (\$)		
		1-Year	2-Year	3-Year
TAR-200 ITC	NAI plus BCG	479,770	656,381	833,316
	TAR-200	589,392	807,819	893,710
	<b>Cost-savings</b>	<b>109,622</b>	<b>151,438</b>	<b>60,393</b>

### Cost per Cystectomy-Free Month

- NAI plus BCG costs \$9,370 less than TAR-200 for each cystectomy-free month achieved at 1 year, and NAI plus BCG continues to show lower costs than TAR-200 at years 2 and 3 as well (**Table 3**)

**Table 3.** Cost per Cystectomy-Free Month

Data Source	Regimen	Cost per Cystectomy-Free Month (\$)		
		1-Year	2-Year	3-Year
TAR-200 ITC	NAI plus BCG	52,724	33,679	26,766
	TAR-200	62,094	39,823	28,286
	<b>Cost-savings</b>	<b>9,370</b>	<b>6,144</b>	<b>1,520</b>

### Cost per Complete Responder

- NAI plus BCG costs less per complete response achieved compared to TAR-200 at 15, 27, and 39 months (1, 2, and 3 years since CR was assessed in the model). While TAR-200 patient reported a numerically higher CR rate, its higher administration and follow-up costs make it less cost-effective overall (**Table 4**)

**Table 4.** Cost per Complete Responder

Data Source	Regimen	Cost per Complete Responder (\$)		
		1-Year	2-Year	3-Year
TAR-200 ITC	NAI plus BCG	1,346,740	1,938,176	2,593,645
	TAR-200	1,660,515	2,220,189	2,604,873
	<b>Cost-savings</b>	<b>313,775</b>	<b>282,013</b>	<b>11,228</b>

### Cost per Month in Complete Response

- NAI plus BCG had lower costs per month in complete response achieved compared to TAR-200 at 15, 27, and 39 months (1, 2, and 3 years since CR was assessed in the model) (**Table 5**)

**Table 5.** Cost per Month in Complete Response

Data Source	Regimen	Cost per Month in Complete Response (\$)		
		1-Year	2-Year	3-Year
TAR-200 ITC	NAI plus BCG	67,994	51,154	44,790
	TAR-200	74,087	56,225	44,983
	<b>Cost-savings</b>	<b>6,092</b>	<b>5,072</b>	<b>193</b>

### Caregiver Burden Costs

- Patients who remain in earlier, less advanced health states with their bladder cancer generally require fewer caregiver resources. Since NAI plus BCG and TAR-200 produce relatively equivalent complete response rates over time, they are both associated with low caregiver-related costs. TAR-200 had slightly lower caregiver burden costs, driven mostly by the higher initial response rate (**Table 6**)

**Table 6.** Caregiver Burden Costs

Data Source	Regimen	Total Caregiver Burden Costs (\$)		
		1-Year	2-Year	3-Year
TAR-200 ITC	NAI plus BCG	17,112	31,676	45,965
	TAR-200	16,274	31,261	45,704
	<b>Cost-savings</b>	<b>-837</b>	<b>-415</b>	<b>-261</b>

### Limitations

- Structural assumptions:** While the model reflects the typical NMIBC clinical pathway, rare direct progressions (e.g., NMIBC → metastatic disease) are not explicitly represented, introducing some structural uncertainty
- Clinical evidence & extrapolation:** Transition rates beyond observed follow-up were projected using accepted methodological approaches. Dynamic transition rates were applied to reflect differing response patterns in the first year versus later years
- Comparative effectiveness evidence:** No head-to-head trials exist comparing NAI plus BCG with TAR-200. Unanchored indirect treatment comparisons were required, which introduce additional uncertainty due to reliance on study-level assumptions rather than randomized comparisons
- Model input assumptions:** Base-case starting age (73 years) reflects QUILT-3.032 but may overestimate the true age of BCG-unresponsive NMIBC patients. This assumption is conservative, as a younger cohort would likely improve cost-effectiveness outcomes.

## Conclusions

- Across the five economic outcomes assessed over 3 years, NAI plus BCG demonstrated favorable cost-to-outcome results:**
  - NAI plus BCG produced yearly cost-savings compared with TAR-200 on efficacy outcomes such as complete response, cystectomy avoidance, and cystectomy-free months
  - Caregiver burden costs were slightly more favorable for TAR-200-treated patients compared with NAI plus BCG-treated patients
- From a US Medicare perspective, NAI plus BCG offers direct cost-savings across measurable clinical outcomes for BCG-unresponsive NMIBC CIS patients compared to TAR-200, which persisted over 3 years**