

Matching-adjusted Indirect Comparisons (MAIC) of INLEXZO™ (gemcitabine intravesical system) vs. FDA-approved novel agents in BCG-unresponsive High-risk NMIBC with CIS¹

Background^{1,2}

An MAIC is a methodology that allows for statistical comparison of efficacy between two drugs in the absence of head-to-head comparative data by:



Matching the individual patient data from SunRISe-1 and summary-level data from the USPI and primary journal publications of the comparators



Assigning weights to the outcomes of patients in the trials, based on each patient's **proximity of baseline characteristics to the published trial aggregate baseline characteristics**

An unanchored MAIC is the only methodology available to conduct an ITC in the BCG unresponsive HR NMIBC CIS setting since there is no common comparator between trials

[Additional information](#) →

Baseline characteristics

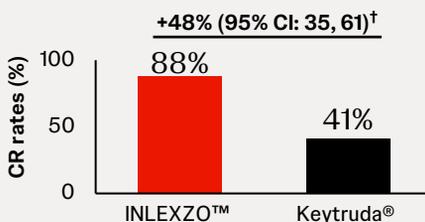
MAIC assumes comparator studies have similar study design and patient characteristics after matching. Adjustment for prognostic factors and treatment effect modifiers is required.*

| Variable | Categories | SunRISe-1 ³ | KEYNOTE-057 ^{4,5} | CS-003 ^{6,7} | QUILT 3.032 ^{8,9} |
|--------------------------|------------------------|------------------------|----------------------------|-----------------------|----------------------------|
| Population | Full | 85 | 96 | 98 | 77 |
| | Adjusted ¹⁰ | -- | 36 | 67 | 65 |
| Age in years | Median (Range) | 71 (40-88) | 73 (44-92) | 70 (44-89) | 73 (50-91) |
| Gender | Male % | 80.0 | 84 | 88 | 86 |
| | Female % | 20.0 | 16 | 12 | 14 |
| Race | White % | 87.1 | 67 | 92 | 90 |
| | Non-white % | 13 | 33 | 8 | 10 |
| ECOG | 0 % | 91.8 | 73 | 90 | 83 |
| | 1+ , % | 8.2 | 27 | 10 | 17 |
| # Prior BCG instillation | Median | 12 | 12 | 12 | 12 |
| | CIS+T1 % | 10.6 | 13 | 5 | 10 |
| Stage | CIS+Ta % | 22.4 | 25 | 19 | 21 |
| | CIS alone % | 67.1 | 63 | 76 | 69 |

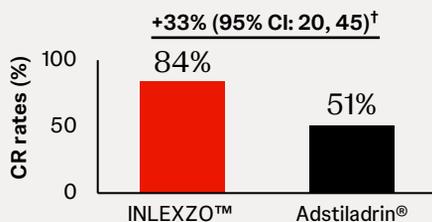
Results

MAICs of INLEXZO™ vs. FDA-approved novel agents: adjusted CR at any time (absolute rate differences) P<0.05 for all comparisons

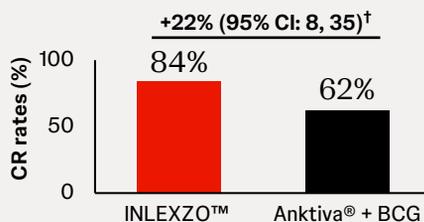
INLEXZO™ vs. Keytruda® (pembrolizumab)



INLEXZO™ vs. Adstiladrin® (NF)



INLEXZO™ vs. Anktiva® (NAI) + BCG



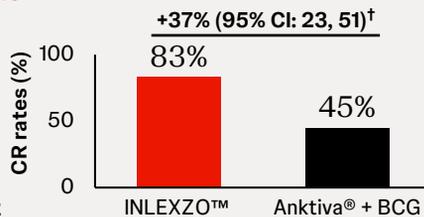
MAIC of INLEXZO™ vs. Anktiva® (NAI) + BCG: Adjusted CR at first disease assessment (absolute rate difference)

To account for CR rate after reinduction with Anktiva® (NAI) + BCG in QUILT 3.032

Anytime CR = $\frac{48 \text{ responders}}{77 \text{ patients}}$ (62%)

24 patients received reinduction: 13 of which achieved CR.⁹

$\frac{48 \text{ total responders} - 13 \text{ responders after reintroduction}}{77 \text{ total patients}} = 45.5\% \text{ of patients achieved CR at first disease assessment}$



Based on these results, INLEXZO™ demonstrated a significantly higher CR rate at any time versus FDA approved novel agents in BCG-unresponsive HR NMIBC with CIS, as well as at first disease assessment compared to Anktiva® NAI + BCG.†

For complete information on INLEXZO™, please refer to the full **Prescribing Information and Instructions for Use**.

*The MAIC methodology can only adjust for observed and reported baseline characteristics. Any confounders not consistently reported or missing across studies may impact internal validity. Some differences in study design and outcomes can introduce biases that the MAIC cannot fully address. †Rate difference has been rounded. ‡ "Significant" based on statistical significance of P<0.05 for all comparisons.

BCG, Bacillus Calmette Guerin; CIS, carcinoma in situ; CR, complete response; ECOG, Eastern Cooperative Oncology Group; HR, high-risk; ITC, indirect treatment comparison; NF, nadofaragene firadenovec-vncg; NAI, nogapendekin alfa inbakicept-pmln; NMIBC, non-muscle invasive bladder cancer; USPI, US prescribing information.

1. Daneshmand et al. Presented at The Professional Society for Health Economics and Outcomes Research (ISPOR); May 16, 2025; Montreal, QC, Canada. 2. Signorovitch J, et al. *Value Health*. 2012;15(6):940-7. 3. Danshmand S, et al. *Urol. Oncol*. 2025;S1078-1439. 4. Keytruda® [Prescribing Information]. Rahway, NJ: Merck & Co., Inc. 5. Balar A, et al. *Lancet Oncol*. 2021;22(7):919-930. 6. Adstiladrin® [Prescribing information]. Kastrop, Denmark: Ferring Pharmaceuticals. 7. Boorjian S, et al. *Lancet Oncol*. 2021;22(1):107-117. 8. Anktiva® [Prescribing information]. Culver City, CA: ImmunityBio Inc. 9. Chamie K, et al. *NEJM Evidence*. 2023;2(1). 10. Data on file. Johnson & Johnson and affiliates.

MAIC methodology



A MAIC (Matching-adjusted Indirect Comparisons) is a **3-step methodology that allows for statistical comparison** of efficacy between two drugs in the absence of head-to-head comparative data.¹

MAICs may be anchored or unanchored²:

- **Anchored** MAICs include a common comparator
- **Unanchored** MAICs lack a common comparator and/or include single-arm studies

Prior to comparing the efficacy, there is a process to **review, analyze, and match the trials**¹:



MAIC, match-adjusted indirect comparison.

1. Signorovitch J, et al. *Value Health*. 2012;15(6):940-7. 2. Phillippo D, et al. *Medical Decision Making*. 2018;38(2):200-211.