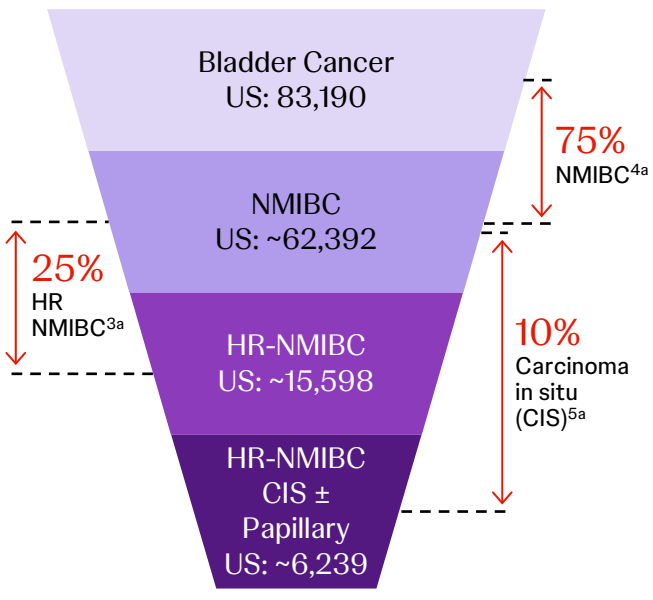
EVIDENCE AND VALUE SUMMARY: INLEXZO™ (gemcitabine intravesical system)

INLEXZO™ (gemcitabine intravesical system | 225 mg) is indicated for the treatment of adult patients with BCG-unresponsive, NMIBC with CIS with or without papillary tumors[1]

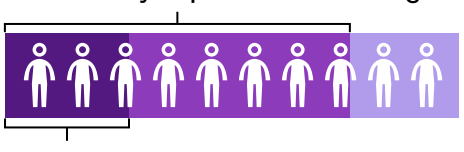
Disease burden

Estimated incidence of bladder cancer[2]



Within 5 years:

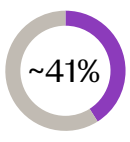
Up to **78%** of patients with high-risk NMIBC may experience recurring disease[6]



This includes up to **30%** of patients who progress to MIBC[7]

5-year survival:

Decreases to <50% when patients **progress to MIBC**[8]



of MIBC patients received radical cystectomy[9b]

In hypothetical 1M member health plans, the prevalence of BCG-unresponsive HR-NMIBC with CIS is estimated to be low (2024)[2c,d]

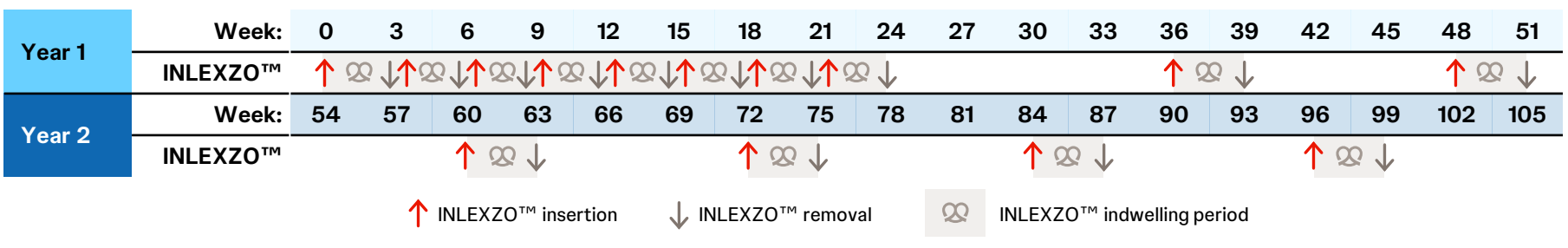
Commercial		Medicare
1M	Total plan population	1M
1,978	Bladder cancer	9,190
1,484	NMIBC	6,893
148	HR-NMIBC CIS	689
61	HR-NMIBC CIS (BCG-treated)	285
25	HR-NMIBC CIS (BCG-unresponsive)	114
19	BCG-UR HR-NMIBC CIS without cystectomy	90

INLEXZO™: Dosing - in-office procedure with prolonged local drug delivery[1e]

INLEXZO™ is placed into the **bladder** using urinary catheter

Insertion schedule: **Q3W** Up to 6 months → **Q12W** Up to 18 months

In-dwelling period of 3 weeks



10 doses administered to patients over **13 visits** during Year 1

4 doses administered to patients over **8 visits** during Year 2

In-office procedure with no anesthesia or bladder holding requirements[1,10f]

Utilization of familiar catheterization procedure[10]

99% (745/755) Insertion success rate[11]

Off-the-shelf room temperature storage and handling[1]

INLEXZO™, its packaging, and used urinary catheter and stylet can be **disposed of per facility procedures** and per applicable federal, state, and local regulations[1]

For additional information on storage, handling, dosing, and administration, please see the INLEXZO™ Prescribing Information and Instructions for Use.

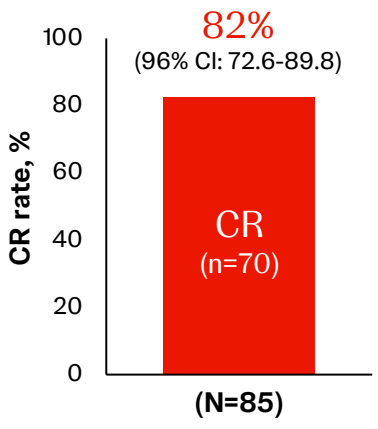
SunRISe-1 Cohort 2 clinical efficacy and safety[11]

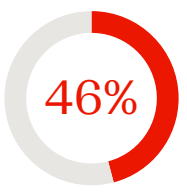
Clinical results shown are based on analysis of the total population included in cohort 2 of the SunRISe-1 study reported in the 2025 Journal of Clinical Oncology publication.[11] The efficacy and safety results below may vary from that in the INLEXZO product labeling due to differences in the efficacy analyses and in evaluation of the individual safety events, contributing to differences in reported n-values and percentages. Please refer to the INLEXZO™ Prescribing Information for additional information.

Overall complete response rate of 82%, with 53% DOR

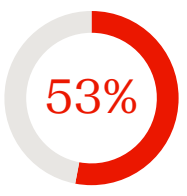
SunRISe-1 cohort 2: A phase 2, randomized, open-label study of INLEXZO™ monotherapy in patients with BCG-unresponsive HR-NMIBC with CIS, with or without papillary tumors

Overall CR rate[g]
primary endpoint
82%
(96% CI: 72.6-89.8)





Observed CR rate at 12 mos[h] (39/85)



Observed 12-mo DOR rate (37/70)

25.8 mos
Median DOR[h,j] (95%CI: 8.3-NE)

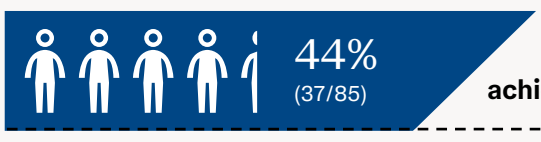
(95% CI: 76.6-92.6)
Cystectomy-free at 12 mos

(n=4)
Had ≥T2 progression[i]

44% of patients achieved and maintained CR for ≥12 months

12-month DOR
CR for ≥12 month/responders

Anytime CR X 12-month DOR



Proportion of all patients who achieved and maintained CR for ≥12 months

Safety data

Patients with events N (%)	INLEXZO™ (N=85)[k] Any grade	Grade ≥ 3
≥ 1 TRAE[l]	71 (83.5)	11 (12.9)
Most frequent TRAEs (≥ 10%)[m,n]		
Pollakiuria	37 (43.5)	0
Dysuria	34 (40.0)	0
Micturition urgency	21 (24.7)	0
Urinary tract infection	18 (21.2)	1 (1.2)
Hematuria	14 (16.5)	0
Urinary tract pain	9 (10.6)	4 (4.7)

Most TRAEs were Grade 1 to 2

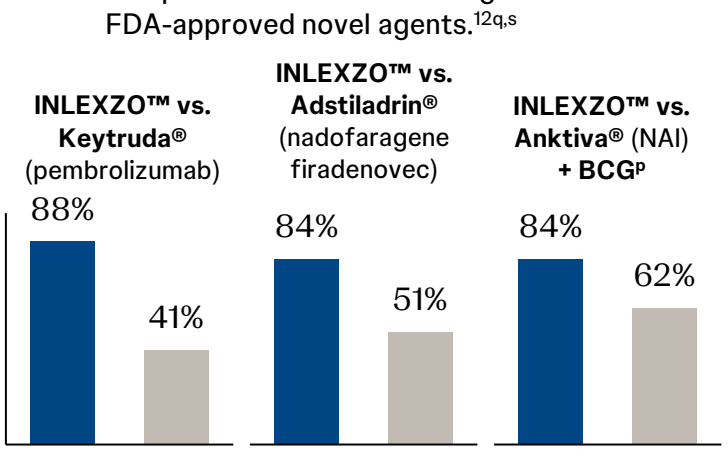
AEs resolved after a median of 3.0 **weeks**

5.9%
(n=5)
had ≥1 serious TRAEs[o]

3.5%
(n=3)
had TRAEs that led to treatment discontinuation[p]

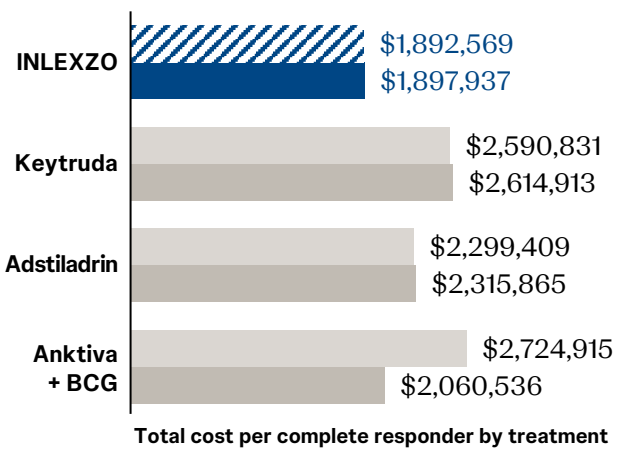
INLEXZO™: Real-world evidence

In a matching-adjusted indirect comparison, **INLEXZO™ demonstrated statistically significant higher CR rates at any time** compared to those of existing FDA-approved novel agents.[12q,s]



INLEXZO™ also demonstrated statistically **significant higher CR rate at first disease assessment** compared to NAI + BCG.[12]

Substantial cost savings per responder were observed with INLEXZO™ versus other FDA-approved novel treatments in a Medicare population with BCG-unresponsive HR-NMIBC with CIS[2r,s]



Cost difference per responder of INLEXZO™ relative to: 3 doses of re-induction for Anktiva	No re-induction with efficacy adjustment
-$716,976	-$698,262
-$417,928	-$406,840
-$162,599	-$832,346

Cost-per-responder model cost inputs include: initial treatment, subsequent treatment, radical cystectomy, and medical costs. Subsequent treatments assumed equal distribution across novel, FDA-approved therapies.

INLEXZO™: Future considerations[t]

Non-muscle invasive ~75% of cases

NMIBC High-risk BCG-naïve → **SunRISe-3[13]** TAR-200 ± CET

NMIBC High-risk, BCG-exp, papillary-only (no CIS) → **SunRISe-5[14]** TAR-200 vs intravesical chemotherapy

Muscle invasive ~25% of cases

MIBC scheduled RC, ineligible/refusing platinum-based neoadjuvant chemotherapy → **SunRISe-4[15]** TAR-200 + CET *Non-registrational study*

The safety and efficacy of the investigational uses of this product have not been determined. There is no guarantee that the investigational uses listed will be filed with and/or approved for marketing by the FDA. For more information on ongoing trials, go to ClinicalTrials.gov.

For additional information, please see INLEXZO™ Prescribing Information.

[a]Assumptions based on literature review. [b]Based on 2013 study using the National Cancer Data base, Of a total of 28,691 patients, 8,232 received radical cystectomy (RC) without neoadjuvant chemotherapy, 530 received RC with neoadjuvant chemotherapy and 3,064 received RC with adjuvant chemotherapy for a total of 41%. [c]Data for coverage of NMIBC by health plan type is sourced from IQVIA claims data. [d]Proportions of Medicare and Commercial health plan enrollees are assumed to be 70% and 120%, respectively, for each of the bladder cancer subgroups. [e]Based on FDA-approved therapies for BCG-UR NMIBC as of October 2025. [f]Insertion/removal by trained personnel takes a few minutes and patients do not need to remain in the clinic after insertion to rotate sides or hold bladder. [g]Complete response is based on centrally reviewed urine cytology, local cystoscopy, and central biopsy (if available). A CR is defined as having a negative cystoscopy and negative (including atypical) centrally read urine cytology, or positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative (including atypical) centrally read cytology at any time point. [h]Kaplan-Meier estimate. [i]Disease persistence, recurrence, or progression event was based on positive central cytology, high-grade central pathology, or positive imaging. All results are based on highest stage from local TURBT results, investigator-assessed clinical stage, and pathologic stage after cystectomy. Patients who discontinued study before disease evaluation are excluded. [j]Median follow-up in responders was 20.2 months (range, 5 to 48). [k]Safety is shown for all patients who received at least 1 dose of INLEXZO™ in Cohort 2 (N=85). [l]An AE was categorized as related if the investigator determined that there was a possible, probable, or causal relationship between the AE and study drug/procedure. Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. [m]Reported in ≥10% of patients. [n]TRAEs of Grade ≥3 reported in ≥2% of patients. All other TRAEs of Grade ≥3 were reported in only 1 patient each and included acute kidney injury, pseudomonal cystitis, and urosepsis. Patients may have had ≥1 Grade ≥3 TRAE. [o]1 event each of acute kidney injury (grade 3), bladder pain (grade 2), cystitis with bladder pain (grade 2), pseudomonal cystitis (grade 3), urinary tract infection (grade 3), urinary tract pain (grade 3), and urosepsis with acute kidney injury (grade 3). [p]TRAEs leading to discontinuation were noninfective cystitis (n=2) and pollakiuria and urinary tract disorder (n=1). [q]Data displayed includes re-induction for Anktiva. [r]Based on patients who achieved and sustained CR ≥12 months at the 15 months time horizon. Clinical data are from clinical trial publications. Keytruda®, Adstiladrin®, and Anktiva®+ BCG: wholesale acquisition costs (WAC) as of April 2025; Medicare CMS average selling price (ASP) pricing file as of April 2025. [s]There are no published direct head-to-head trials for these products. This information is not intended to make efficacy or safety comparisons. Efficacy or safety comparisons cannot be made in the absence of head-to-head clinical trial data. [t]Trial status on Clinicaltrials.gov is active, not recruiting (closed to enrollment).

BCG, Bacillus Calmette-Guérin; CET, cetrelimab; CIS, carcinoma in situ; CR, complete response; DOR, duration of response; FDA, Food and Drug Administration; HR, high-risk; mos, months; IVT, intravenous therapy; MIBC, muscle invasive bladder cancer; NAI, nogapendekin alfa inbakicept-pmln; NE, not estimable; NMIBC, non-muscle invasive bladder cancer; Q3W, once every 3 weeks; Q12W, once every 12 weeks; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; UR, unresponsive.

1. INLEXZO™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. Data on File. Johnson & Johnson and its affiliates. 3. Bedke J, et al. *Urol Oncol*. 2023;41(12):461-475. 4. Grabe-Heyne K, et al. *Front Oncol*. 2023;13:1170124. 5. Douglass L, et al. *Bladder Canc*. 2016;2(3):285-292. 6. Van Rhijn BWG et al. *Eur Urol*. 2009;56:430-442. 7. Boegemann M et al. *Mini Rev Med Chem*. 2020;20(12):1133-1152. 8. Knowles MA, et al. *Nat Rev Cancer*. 2015;15(1):25-41. 9. Gray P, et al. *European Urology* 63.5 (2013): 823-829. 10. Daneshmand S, et al. Urol. Oncol. 2025;S1078–1439. 11. Daneshmand S, et al. *J Clin Oncol*. 2025: 10.1200/JCO-25-01651 (ePub). 12. Daneshmand et al. Presented at The Professional Society for Health Economics and Outcomes Research (ISPOR); May 16, 2025; Montreal, QC, Canada. 13. Clinicaltrials.gov. https://clinicaltrials.gov/study/NCT05714202. 14. Clinicaltrials.gov. https://clinicaltrials.gov/study/NCT06211764. 15. Clinicaltrials.gov. https://clinicaltrials.gov/study/NCT04919512.

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