COMPENDIA TRANSPARENCY TRACKING FORM

DATE: March 17, 2025

OFF-LABEL ID #: 2808

DRUG NAME: Atezolizumab

OFF-LABEL USE: Urothelial carcinoma Adjuvant treatment in those at high risk for recurrence

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: C, L, A *to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant **advance** over current therapies
C	**Cancer** or cancer-related condition
E	Quantity and robustness of **evidence** for use support consideration
L	**Limited** alternative therapies exist for condition of interest
P	**Pediatric** condition
R	**Rare** disease
S	**Serious**, life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Bellmunt J, Hussain M, Gschwend JE, et al. Adjuvant atezolizumab versus observation in muscle-invasive urothelial carcinoma (IMvigor010): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol*. 2021;22(4):525-537. doi:10.1016/S1470-2045(21)00004-8. PMID: 33721560.	S
Powles T, Assaf ZJ, Degaonkar V, et al. Updated Overall Survival by Circulating Tumor DNA Status from the Phase 3 IMvigor010 Trial: Adjuvant Atezolizumab Versus Observation in Muscle-invasive Urothelial Carcinoma. Eur Urol. 2024;85(2):114-122. doi:10.1016/j.eururo.2023.06.007. PMID: 37500339.	3
Jackson-Spence F, Toms C, O'Mahony LF, et al. IMvigor011: a study of adjuvant atezolizumab in patients with high-risk MIBC who are ctDNA+ post-surgery. Future Oncol. 2023;19(7):509-515. doi:10.2217/fon-2022-0868. PMID: 37082935.	4
Yanagisawa T, Mori K, Matsukawa A, et al. Adjuvant Immune Checkpoint Inhibitors for Muscle-Invasive Urothelial Carcinoma: An Updated Systematic Review, Meta-analysis, and Network Meta-analysis. Target Oncol. 2025;20(1):57-69. doi:10.1007/s11523-024-01114-4. PMID: 39535690.	2
Holzbeierlein J, Bixler BR, Buckley DI, et al. Treatment of Non-Metastatic Muscle-Invasive Bladder Cancer: AUA/ASCO/SUO Guideline (2017; Amended 2020, 2024). J Urol. 2024;212(1):3-10. doi:10.1097/JU.0000000000003981. PMID: 38661067,	4
Alfred Witjes J, Max Bruins H, Carrión A, et al. European Association of Urology Guidelines on Muscle-invasive and Metastatic Bladder Cancer: Summary of the 2023 Guidelines [published correction appears in Eur Urol. 2024 Jun;85(6):e180. doi: 10.1016/j.eururo.2024.03.002.]. Eur Urol. 2024;85(1):17-31. doi:10.1016/j.eururo.2023.08.016. PMID: 37858453	4
Alfred Witjes J, Bruins HM, Carrión A, et al. Corrigendum to "European Association of Urology Guidelines on Muscle-invasive and Metastatic Bladder Cancer: Summary of the 2023 Guidelines" [Eur. Urol. 85 (2024) 17-31]. Eur Urol. 2024;85(6):e180. doi:10.1016/j.eururo.2024.03.002. PMID: 38492977.	4
Roumiguié M, Seisen T, Masson-Lecomte A, et al. French AFU Cancer Committee Guidelines - Update 2024-2026: Upper urinary tract urothelial cancer (UTUC). Fr J Urol. 2024;34(12):102722. doi:10.1016/j.fjurol.2024.102722. PMID: 39581669.	4

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		John D Roberts	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Ineffective	Class III: Not Recommended		B
Jeffrey Klein	Ineffective	Class III: Not Recommended	The use of atezolizumab to treat advanced urothelial cancer patients did not significantly impact disease free survival when compared to patients who did not receive the treatment. In addition, the degree of serious adverse effects were higher in the atezolizumab group. Some patients had to discontinue the treatment due to those serious adverse effects.	
Todd Gersten	Ineffective	Class III: Not Recommended	Adjuvant atezolizumab failed to significantly reduce recurrence risk of urothelial cancer after surgery.	

Warren Brenner	Ineffective	Class III: Not Recommended	This was a large well conducted phase III clinical trial that randomized patients post surgery to Atezolizumab vs observation. The positives of the study include its large size, conducted in multiple countries and included both academic and community cancer centers. It allowed patients who had received neoadjuvant chemotherapy as well as chemo naive patients so representative of real world patients. Most of the patients were white although 16% were Asian and small percentage black - this is fairly typical of most clinical trials where some ethnic groups are under represented. The study clearly showed no benefit to adjuvant 10 therapy and the forest plots show no clear benefit in any specific subtypes of patients. Given the highest level of evidence with a phase III international placebo controlled randomized clinical trial showing no benefit and given higher toxicity and cost of 10 therapy the treatment is ineffective and would not recommend.	