

Additional Inclusion Criteria for UC Subjects

30. Pathologically or cytologically documented unresectable or metastatic UC of the bladder, renal pelvis, ureter, or urethra. Subjects with histological variants are allowed if urothelial histology is predominant. Small cell/neuroendocrine tumors are not allowed even if mixed histology.
31. Relapse or progression after at least 1 prior line of ICI-containing systemic therapy and 1 prior line of systemic chemotherapy, given in combination with other anticancer therapy or separately, with a maximum of 3 prior therapy lines.
 - a. At least 1 line of therapy should include enfortumab vedotin in countries where enfortumab vedotin is approved and available.
 - b. Perioperative systemic therapies will be counted as 1 line of therapy.
 - c. To meet inclusion criteria requirement of prior ICI-containing therapy, use in the perioperative or metastatic setting will suffice.
 - d. Subjects with actionable target tumor mutation should have been previously treated with targeted therapy.
 - e. The same regimen administered twice in different disease settings will be counted as 1 line of prior therapy.