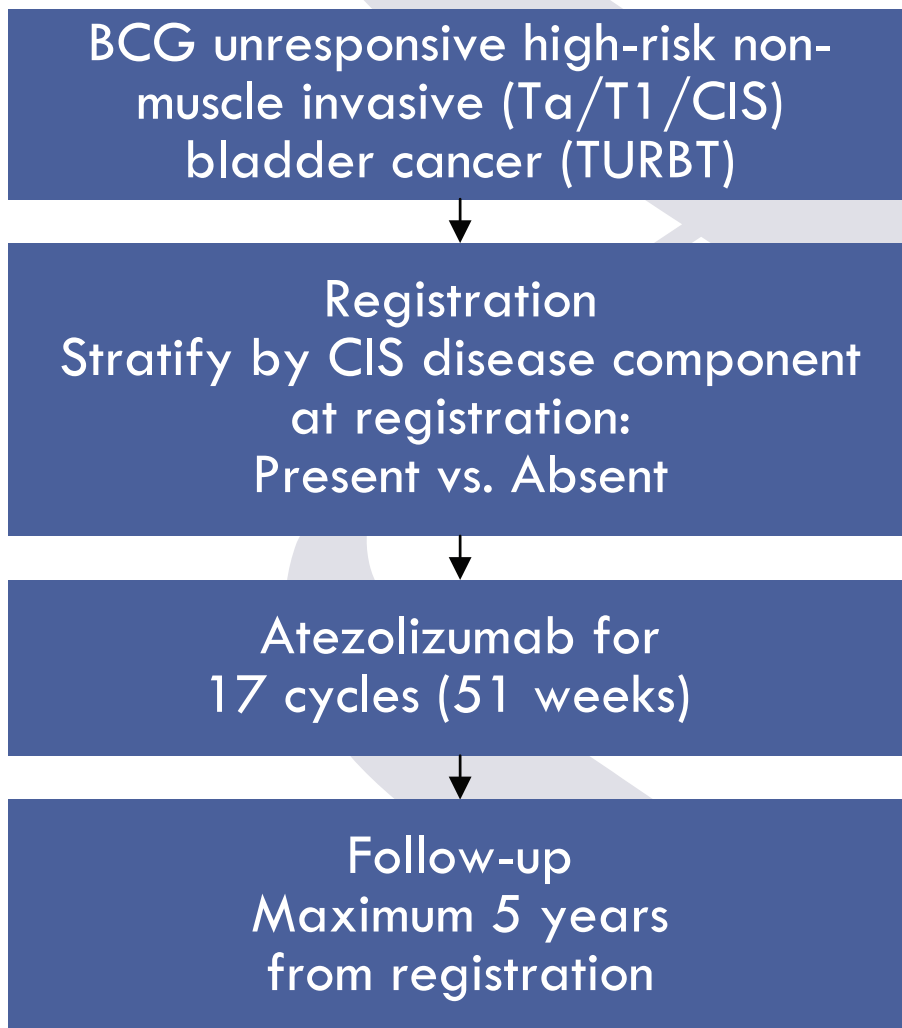


## Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer



\* Cystoscopy and cytology performed as specified in the study calendar (see [Section 9.0](#)). Mandatory biopsy at Week 25 for patients with any CIS component.

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### Eligibility and Data Submission Questions:

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**ELIGIBILITY • Patient must:**

- be  $\geq$  18 years of age
- be deemed unfit for radical cystectomy by the treating physician, or must have refused radical cystectomy
- be BCG-unresponsive
- Zubrod Performance Status  $\leq$  2

**Within 60 days of registration, patients must have:**

- histologically proven, recurrent non-muscle invasive urothelial carcinoma
- Stage T1 high-grade, stage CIS, or stage Ta high-grade
- had all visible tumor resected completely
- tumor tissue from the diagnosis of recurrence available for central path review submission
- undergone re-TURBT if they have stage T1 bladder cancer

**Patients must not:**

- have active tuberculosis
- have active hepatitis B (chronic or acute) or active hepatitis C
- have had systemic chemotherapy or immunotherapy
- be planning to receive concomitant other biologic therapy, radiation therapy, intravesical chemotherapy, surgery, or other therapy
- have received any prior radiation to the bladder for bladder cancer

**Definition of BCG-unresponsive:**

- persistent/recurrent high grade Ta/CIS after induction + maintenance BCG
- persistent/recurrent high grade T1 after induction BCG
- relapse of high grade Ta/T1/CIS within 6 months of last BCG in patients with prior complete response

**See other eligibility criteria in the SWOG SI605 protocol at <https://swog.org/>.**