

Imfinzi[®] (durvalumab) – New indication

- On March 31, 2025, [AstraZeneca announced](#) the FDA approval of [Imfinzi \(durvalumab\)](#), in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC).
- Imfinzi is also approved for non-small cell lung cancer, small cell lung cancer, biliary tract cancer, hepatocellular carcinoma, and endometrial cancer.
- The approval of Imfinzi for the new indication was based on NIAGARA, a randomized, open-label study in 1,063 patients with MIBC. Patients were randomized to Imfinzi plus neoadjuvant chemotherapy prior to cystectomy followed by Imfinzi, or neoadjuvant chemotherapy alone prior to cystectomy with no further treatment after surgery. The major outcome measure was event-free survival (EFS). Overall survival (OS) was an additional outcome measure.
 - **The median EFS was not reached in the Imfinzi arm vs. 46.1 months in the chemotherapy alone arm** (hazard ratio [HR] 0.68, 95% CI: 0.56, 0.82; $p < 0.0001$).
 - Median OS was not reached in either group (HR 0.75, 95% CI: 0.59, 0.93; $p = 0.0106$).
- The most common adverse reactions ($\geq 20\%$) with Imfinzi use for MIBC are decreased hemoglobin, decreased neutrophils, increased blood creatinine, decreased sodium, nausea, increased alanine transaminase, decreased calcium, decreased platelets, fatigue, increased potassium, decreased lymphocytes, increased aspartate aminotransferase, constipation, decreased magnesium, decreased appetite, increased alkaline phosphate, rash, pyrexia, diarrhea, vomiting and abdominal pain.
- The recommended intravenous dose of Imfinzi for the treatment of MIBC for:
 - Patients with a body weight of ≥ 30 kg:
 - Neoadjuvant: 1,500 mg in combination with gemcitabine and cisplatin every 3 weeks for 4 cycles prior to surgery
 - Adjuvant: 1,500 mg as a single agent every 4 weeks for up to 8 cycles after surgery.
 - Patients with a body weight of < 30 kg:
 - Neoadjuvant: 20 mg/kg in combination with gemcitabine and cisplatin every 3 weeks for 4 cycles prior to surgery
 - Adjuvant: 20 mg/kg as a single agent every 4 weeks for up to 8 cycles after surgery.
- Refer to the Imfinzi drug label for dosing for all its other indications.