

NCCN Guidelines for Bladder Cancer V.3.2019 –Follow-Up on 04/16/19

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	ABSTAIN	ABSENT
<p>BL-7 Internal request:</p> <p>In response to the FDA approval of FGFR RGQ RT-PCR for use as a companion diagnostic for erdafitinib, the panel voted on the addition of the FGFR RGQ RT-PCR for patients with Stage IIIB and Stage IV bladder cancer.</p> <p>External request:</p> <p>Submission from Janssen Biotech, Inc. (4/15/19) to consider the addition of molecular testing for <i>FGFR</i> genetic alterations as part of the additional work-up for Stage IVA and Stage IVB bladder cancer.</p>	<p>Based upon review of the data in the submission from Janssen Biotech, Inc. and the recent FDA approval, the panel consensus was to include FGFR RGQ RT-PCR testing for <i>FGFR3</i> or <i>FGFR2</i> genetic alterations within the recommendations for molecular/genomic testing for Stage IIIB (BL-7), Stage IVA (BL-8), and Stage IVB (BL-9) bladder cancer. This is a category 2A recommendation.</p> <p>Based on a review of data, the panel consensus supported the inclusion of molecular testing for <i>FGFR</i> genetic alterations as part of the additional workup for Stage IIIB and Stage IV bladder cancer. This is a category 2A recommendation.</p> <p>See Submission for references.</p>	16	0	4	6
<p>BL-G Internal request:</p> <p>In response to the FDA approval of erdafitinib for the treatment of patients with locally advanced or metastatic urothelial carcinoma, with susceptible <i>FGFR3</i> or <i>FGFR2</i> genetic alterations, that has progressed during or following platinum-containing chemotherapy, the panel voted on the addition of erdafitinib for this indication.</p> <p>External request:</p> <p>Submission from Janssen Biotech, Inc. (4/15/19) to consider the addition of erdafitinib as an option for subsequent systemic therapy for locally advanced or metastatic</p>	<p>Based upon review of the data in the submission from Janssen Biotech, Inc. and the recent FDA approval, the panel consensus was to include erdafitinib as an option for patients with locally advanced or metastatic urothelial carcinoma, with susceptible <i>FGFR3</i> or <i>FGFR2</i> genetic alterations that has progressed during or following platinum-containing chemotherapy. This is a category 2A recommendation.</p> <p>Based on a review of data and discussion, the panel consensus supported the inclusion of erdafitinib as an option for subsequent systemic therapy for locally advanced or metastatic disease (Stage IV) (post-platinum) in patients with susceptible <i>FGFR</i> genetic alterations. This is a category 2A recommendation.</p>	16	0	4	6

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disease (Stage IV) (post-platinum) in patients with fibroblast growth factor receptor (FGFR) genetic alterations.	See Submission for references.				
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