

Errata to FDA Briefing Document - Gastric and Gastroesophageal Junction Adenocarcinoma  
(Morning Session)

Meeting of the Oncologic Drugs Advisory Committee (ODAC)

September 26, 2024

This document contains corrections to FDA’s briefing information for the September 26, 2024, ODAC meeting discussing the use of immune checkpoint inhibitors in patients with metastatic or unresectable HER2-negative gastric adenocarcinoma.

Page	Line	Action
11	7-8	<p><b>Removed:</b> sequentially evaluated OS in patients with CPS <math>\geq</math> 10, CPS <math>\geq</math> 1, and ITT</p> <p><b>Added:</b> evaluated OS in patients with CPS <math>\geq</math>10 and ITT in parallel, then in CPS <math>\geq</math>1 and ITT sequentially.</p>
16	Table 2	<p><b>NCCN 2024 v4 Guidelines:</b></p> <p><b>Added:</b></p> <p><u>Useful in Certain Circumstances</u></p> <ul style="list-style-type: none"> <li>Fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin and nivolumab (PD-L1 CPS &lt; 5) (category 2B)</li> </ul>
16	Table 2	<p><b>ESMO Guidelines:</b></p> <p><b>Removed:</b></p> <ul style="list-style-type: none"> <li>HER2-negative PD-L1 positive (CPS <math>\geq</math> 5): nivolumab-chemotherapy (IA)</li> </ul> <p><b>Added:</b></p> <ul style="list-style-type: none"> <li>HER2-negative PD-L1 positive CPS <math>\geq</math> 1 <ul style="list-style-type: none"> <li>CPS <math>\geq</math> 5 add PD-1 ICI (IA)</li> <li>CPS 1-4 consider adding PD-1 ICI (IB)</li> </ul> </li> </ul> <p><b>Added:</b> B: Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended</p> <p><b>Footnote:</b> <b>Added</b> Reference: ESMO 2024</p>
34	20	<p><b>References</b></p> <p><b>Added:</b> ESMO 2024: ESMO Gastric Cancer Living Guideline, v1.4 September 2024. Accessed 09/17/2024. <a href="https://www.esmo.org/living-guidelines/esmo-gastric-cancer-living-guideline">https://www.esmo.org/living-guidelines/esmo-gastric-cancer-living-guideline</a></p>