Dear NCCN Guidelines Panel,

On behalf of Genentech, Inc., I respectfully request the Colon and Rectal Cancer Guideline Panel to review the enclosed data for:

- **Tecentriq® (atezolizumab)**


**Specific Changes:**
There are no specific changes being requested. We are providing data on Tecentriq® with or without Cotellic® in patients with chemotherapy-refractory metastatic colorectal cancer.

**FDA Clearance:**

- Tecentriq is not FDA-approved for treatment of patients with chemotherapy-refractory metastatic colorectal cancer.
- Cotellic is not FDA-approved for treatment of patients with chemotherapy-refractory metastatic colorectal cancer.

Please refer to the product prescribing information for full FDA-approved indications and safety information.


**Rationale:**
IMblaze370 is a Phase 3, multicenter, open-label, three-arm, randomized study conducted to evaluate the efficacy and safety of Tecentriq with or without Cotellic vs. regorafenib in patients with locally advanced or metastatic colorectal cancer who have received at least two prior regimens of chemotherapy for metastatic disease. The primary endpoint of overall survival (OS) was not met.
### Median OS of Tecentriq with or without Cotellic vs. regorafenib

<table>
<thead>
<tr>
<th></th>
<th>Tecentriq + Cotellic (n = 183)</th>
<th>Tecentriq (n = 90)</th>
<th>Regorafenib (n = 90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS, mo (95% CI)</td>
<td>8.9&lt;sup&gt;b&lt;/sup&gt; (7.00, 10.61)</td>
<td>7.1&lt;sup&gt;b&lt;/sup&gt; (6.05, 10.05)</td>
<td>8.5 (6.41, 10.71)</td>
</tr>
<tr>
<td>HR vs regorafenib (95% CI)</td>
<td>1.00&lt;sup&gt;b&lt;/sup&gt; (0.73, 1.38)</td>
<td>1.19&lt;sup&gt;b&lt;/sup&gt; (0.83, 1.71)</td>
<td>N/A</td>
</tr>
<tr>
<td>P value</td>
<td>0.99&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.34&lt;sup&gt;b,c&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Notes: *Data cutoff date: March 9, 2018. *Two-sided type I error rate of 0.05 was controlled by hierarchical testing (testing Tecentriq vs regorafenib only if Tecentriq + Cotellic vs regorafenib was positive). *This is in comparison with regorafenib. *For descriptive purposes only.

HRs are from stratified log-rank tests. Abbreviations: CI = confidence interval; HR = hazard ratio; mo = months; N/A = not applicable; OS = overall survival.

Safety in the Tecentriq + Cotellic arm was consistent with the known safety profiles of the individual agents. Grade 3-4 treatment-related adverse events (AEs) occurred in 45%, 10%, and 49% of patients receiving Tecentriq with Cotellic, Tecentriq monotherapy, and regorafenib, respectively. Treatment-related serious AEs occurred in 26%, 8%, and 11% of patients receiving Tecentriq with Cotellic, Tecentriq monotherapy, and regorafenib, respectively.

IMblaze370 is the first study to present results for Tecentriq with or without Cotellic for patients with chemotherapy-refractory metastatic colorectal cancer.

Additional studies have been done to evaluate Tecentriq with Cotellic in metastatic colorectal cancer.  

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If you have any questions, please contact us at the phone number and email provided above.

Respectfully submitted,
Patrice Esser, PharmD, MPH

**Reference:**

1. Desai J, Hong YS, Kim J, et al. Efficacy and safety of cobimetinib and atezolizumab in an expanded Phase 1b study of microsatellite-stable (MSS) metastatic colorectal cancer (mCRC). Presented at the European Society for Medical Oncology in Copenhagen, Denmark; October 7–11, 2016. ESMO Poster #470P.