### Guideline Page and Request

<table>
<thead>
<tr>
<th>External request:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission from Bayer HealthCare Pharmaceuticals suggesting the following for consideration:</td>
</tr>
<tr>
<td>1. Principles of Systemic Therapy: Add bullet “Larotrectinib is recommended for tumors harboring an NTRK gene fusion.”</td>
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<tr>
<td>2. First-line Single-agent or Second-line/Subsequent Therapy: Add “larotrectinib if NTRK+”</td>
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<tr>
<td>3. Salivary Gland Tumors, Unresectable Disease or Distant Metastases: Add “larotrectinib if NTRK+”</td>
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</tbody>
</table>

### Panel Discussion/References

Based on a review of data and discussion, the panel consensus supported the inclusion of NTRK therapy (eg, larotrectinib) as an option for recurrent NTRK gene fusion-positive salivary gland tumors with distant metastases, PS 0-3 (on page SALI-4). This is a category 2A recommendation.

See Submission for references.

### Institution Vote

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>ABSTAIN</th>
<th>ABSENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
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### CHEM-A (1 of 6) Internal request:

Panel comment to review the data for cetuximab + concurrent RT as a primary definitive therapy option for oropharyngeal cancer (p16-negative and p16-positive), hypopharyngeal cancer, and laryngeal cancer.

Based on the discussion and noted references, the panel consensus was that cetuximab + concurrent RT has limited clinical use for the primary treatment of:
- Hypopharynx, larynx, p16-negative oropharynx cancers
- p16-positive oropharynx cancers

The category was changed from a category 1 to a 2B recommendation for cancers of the oropharynx (p16-positive and p16-negative), hypopharynx or larynx.

References:
Internal request:

Institutional review comment to consider including the following regimens as options for select ethmoid/maxillary sinus tumors (i.e. small cell, SNEC, high-grade olfactory esthesioneuroblastoma, SNUC with neuroendocrine features):

- Cisplatin/etoposide ± concurrent RT
- Carboplatin/etoposide ± concurrent RT
- Cyclophosphamide/doxorubicin/vincristine (without concurrent RT)

Based on the discussion and noted references, the panel consensus supported the inclusion of the following regimens for select ethmoid/maxillary sinus tumors (i.e. small cell, SNEC, high-grade olfactory esthesioneuroblastoma, SNUC with neuroendocrine features):

- As primary definitive therapy options:
  - Cisplatin/etoposide ± concurrent RT
  - Carboplatin/etoposide ± concurrent RT
  - Cyclophosphamide/doxorubicin/vincristine (without concurrent RT) (category 2B)

- As first-line or subsequent-line therapy options for recurrent, unresectable, or metastatic disease:
  - Cisplatin/etoposide
  - Carboplatin/etoposide
  - Cyclophosphamide/doxorubicin/vincristine (category 2B)

References:


External request:

Submission from Merck & Co., Inc., to:

- Consider the inclusion of pembrolizumab monotherapy as a first-line treatment recommendation in patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) that expresses PD-L1 combined positive score (CPS) > 1.
- Consider the inclusion of pembrolizumab in combination with chemotherapy with a platinum and 5-FU as a first-line treatment recommendation in patients with recurrent or metastatic HNSCC.

Based on a review of data, the panel consensus supported the inclusion of pembrolizumab as a first-line therapy option, useful in certain circumstances for patients with recurrent or metastatic, PD-L1 positive, non-nasopharyngeal head and neck squamous cell carcinoma. This is a category 2B recommendation.

See Submission for references.
| CHEM-A (2 of 6) | External request: Submission from Merck & Co., Inc., requesting the category of evidence and consensus for pembrolizumab be changed from a category 2A to a category 1 recommendation in patients with non-nasopharyngeal, recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy. | Based on a review of data, the panel consensus was that pembrolizumab is supported by high-level evidence and the category was changed from a category 2A to a category 1 subsequent therapy option in patients with non-nasopharyngeal, recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum therapy. See Submission for references. | 21 | 1 | 1 | 4 |