In response to the FDA approval of pralsetinib for adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

External request from BluePrint Medicines Corp. (12/1/20) to include pralsetinib as a treatment option for:
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Based on the review of the data in the noted references and the FDA approval, the panel consensus was to include pralsetinib as an option for patients with RET-fusion positive papillary carcinoma, follicular carcinoma, or Hürthle Cell Carcinoma who have structurally persistent/recurrent locoregional or metastatic disease not amenable to radioactive iodine therapy. The Panel consensus supported a category 2A systemic therapy option.

See Submission for References.

Based on the review of the data in the noted references and the FDA approval, the panel consensus was to include pralsetinib as an option for patients with RET-fusion positive medullary carcinoma who have recurrent or persistent locoregional or distantly metastatic disease. The Panel consensus supported a category 2A, preferred systemic therapy option.

See Submission for References.

Based on the review of the data in the noted references and the FDA approval, the panel consensus was to include pralsetinib as an option for patients with metastatic RET-fusion positive anaplastic carcinoma. The Panel consensus supported a category 2A, preferred systemic therapy option.
are radioactive iodine-refractory (if radioactive iodine is appropriate).

External request from BluePrint Medicines Corp. (12/1/20) to include pralsetinib as a treatment option for:
• Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

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<th>The Panel also supported the inclusion of pralsetinib to footnote “g” with the reference: Subbiah et al. Clinical activity of the RET inhibitor pralsetinib (BLU-667) in patients with RET fusion positive solid tumors. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting; May 29-31, 2020).</th>
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See Submission for References.