Dear Ms. McClure,

On behalf of Pfizer Oncology, I am submitting the following to the NCCN Central Nervous System Cancers Guidelines Panel requesting the Panel’s consideration for inclusion in the NCCN Compendia listing.

- **Request for NCCN Guidelines Panel to review data for a specific indication**
  - SUTENT (sunitinib) for the treatment of patients with recurrent and progressive meningiomas that had failed prior surgery and radiation

- **Specific changes recommended within the NCCN Guidelines (one sentence)**
  - For select patients with recurrent/progressive atypical or anaplastic meningiomas

- **Statement of whether the submitted use is or is not FDA approved for that indication**
  - The submitted use is not approved by the FDA for this indication.

- **Rationale for recommended change (one sentence)**
  - Sunitinib was shown to have clinical activity in a phase 2, single-arm trial (6-month PFS achieved by 42% of patients)

- **Citation of literature support and complete articles supporting recommended change:**

A prospective, multicenter, single-arm, phase 2 trial evaluating the efficacy and safety of sunitinib in patients with surgery and radiation-refractory recurrent WHO grades II-III meningioma. Thirty-six patients with high-grade meningioma (30 atypical and 6 anaplastic) were enrolled. The primary endpoint of rate of 6-month progression-free survival (PFS) was achieved by 42% of patients. Median PFS was 5.2 months and median overall survival was 24.6 months. Overall toxicity included one grade 5 intratumoral hemorrhage, two grade 3 and one grade 4 CNS/intratumoral hemorrhage events, one grade 3 and one grade 4 thrombotic microangiopathy event, and one grade 3 gastrointestinal perforation event.

Results from this phase 2 trial were recently published by Kaley et al in *Neuro-Oncology.*
We appreciate the Panel’s thorough consideration of the data for use of sunitinib (SUTENT) in patients with recurrent/progressive atypical or anaplastic meningiomas.

Sincere regards,

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