SeattleGenetics®

January 16, 2020

Vermont Attorney General's Office
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Montpelier, VT 05609
(802) 828-3171
AGO.highcostprescriptiondrugs@vermont.gov

To Whom It May Concern:
Reference is made to the notice given on December 19, 2019 by Seattle Genetics pursuant to Act 193, "Notice Of Introduction Of New High-Cost Prescription Drugs", § 4637, that on December 18, 2019, Seattle Genetics introduced a new drug, PADCEV™ (enfortumab vedotin-ejfx injection for IV infusion 20 mg & 30 mg vials), for distribution in Vermont with a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program.

Pursuant to § 4637, below is additional information regarding PADCEV™:

(1) "a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally"
   a. With regard to marketing plans, efforts to ensure that healthcare providers with appropriate patients are aware of PADCEV™ include customary digital and print media campaigns, oncology account managers sharing information with healthcare providers, and engagement of healthcare providers at congresses.
   b. With regard to pricing plans, Seattle Genetics has a passion for helping patients, and that passion includes ensuring that we reach as many of the patients with cancers that our products treat as we can. Our pricing considerations are informed by that passion, and we incorporate diverse perspectives of stakeholders in the healthcare system. We also consistently seek to balance rewarding innovation while providing appropriate access for patients. Finally, we consider the clinical value our products deliver to patients, the severity of the cancers we treat, availability of alternative treatments, market dynamics, our continued ability to deliver new state-of-the-art innovations in response to other deadly cancers, and the meaningful impact we make on patient's lives.

(2) "the estimated volume of patients who may be prescribed the drug"
   a. As a result of the lack of publicly available information, Seattle Genetics is unable to provide an accurate estimate of the number of patients in the U.S. with a condition for which the drug may be prescribed. Accordingly, Seattle Genetics is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
   b. Seattle Genetics notes this product is indicated for metastatic urothelial carcinoma, a type of bladder cancer, and we are able to provide the following publicly available information on bladder cancer more generally. Specifically, in 2018, more than 82,000 people were diagnosed with bladder cancer in the U.S. However, this data does not include patients who progress to metastatic stage or recur. According to SEER statistics from 2009-2015, 5% of urinary bladder cancers were metastatic (distant), and 7% were locally advanced (regional). Please note that this data is out of date. According to a retrospective analysis of 1,703 metastatic bladder cancer patients from 2004 to 2011, 42% of patients received a first-line treatment, and 35% of that population received a second-line

treatment. This data likely underestimates the percentage of treated patients, as the data was gathered prior to the introduction of checkpoint inhibitors.

(3) "whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval"
   a. PADCEV™ was granted breakthrough therapy designation and priority review by FDA prior to final approval.

(4) "the date and price of acquisition if the drug was not developed by the manufacturer"
   a. Not applicable.

Please note that the information referenced in this letter may be subject to change.

In the event that § 4637 is found invalid, Seattle Genetics reserves all of its legal rights. In issuing this notice in an attempt to comply with § 4637, Seattle Genetics does not waive any legal claims or legal rights related to potential constitutional defects within § 4637.

Sincerely,

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