AMGEN

US Value & Access

Amgen Inc.
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August 16, 2019

**To**: The Office of the Attorney General of Vermont

**Via**: Electronic Mail (AGO.DrugCosts@vermont.gov; AGO.highcostprescriptiondrugs@vermont.gov)

**Re**: Notice of New Drug Introduction Pursuant to 18 V.S.A. § 4637 (c)

On July 19, 2019, and pursuant to 18 V.S.A. § 4637 (b), Amgen Inc, USA (Amgen) submitted a new drug introduction for the following:

| Name of New Prescription Drug | NDC Number | Date of Commercial Availability | WAC |
|---|---|---|---|
| **KANJINTI** (420 mg multi dose vial) | 55513-0132-01 | July 19, 2019 | $3,697.26 |

Amgen now provides the following additional information pursuant 18 V.S.A § 4637 (c):

1. United States and international marketing and pricing plans used at launch
   - United States: There will be no direct-to-consumer marketing for KANJINTI such as TV ads, magazine or journal ads. The only platform directed to patients is a section of the KANJINTI.com website entitled "For Patients – Getting to Know KANJINTI". This section of the website is designed to educate patients about HER2+ breast or gastric cancer and potential treatment with KANJINTI, including important safety information.

     Promotional activities to physicians will include professional detailing by Amgen sales representatives. Amgen is utilizing its existing oncology sales force to educate health care professionals about KANJINTI, including the requirements for establishing biosimilarity to the reference product, Herceptin, and important safety information. Professional detailing entails resources such as a core visual aid, clinical reprints, and promotional leave-behind literature. There is no free drug or sample program. Amgen also contracts with payors and providers such a hospitals and clinics to offer KANJINTI at a competitive price and ensure access to the product for appropriate patients.

     International: marketing plan information is not in the public domain. 18 V.S.A. §4637(d)

   - The U.S. Wholesale Acquisition Cost (WAC or "list price") of KANJINTI will be 15% lower than their reference products. KANJINTI is being made available at a WAC of $3,697.26 per 420 mg multi-dose vial, 15% below the WAC of Herceptin. At launch, KANJINTI is priced 13% below the current Herceptin Average Selling Price (ASP).

     International: pricing plan information is not in the public domain. 18 V.S.A. §4637(d)

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2. Estimate Volume of Patients in the United States:
   - Our estimate of appropriate patients potentially treatable with the class of drug to which KANJINTI belongs is ~42K a year and we intend to compete with other drugs in this class for a share of that patient population.

3. Whether the FDA granted breakthrough therapy designation or priority review:
   - FDA did not grant breakthrough designation or priority review for KANJINTI.

4. Date and price of acquisition:
   - Not Applicable, Amgen did not acquire this product.

Amgen provides this report consistent with its understanding and interpretation of 18 V.S.A § 4637 and its provisions. In providing this report, Amgen does not waive any rights it may have at law or in equity with respect to 18 V.S.A. § 4637, its interpretation, and/or its application to Amgen or any of its affiliates, now or in the future. Amgen, on behalf of itself and its affiliates, expressly reserves all such rights.

Regards,

Kave Niksefat

VP, US Value and Access

Amgen Inc, USA