Mallinckrodt Pharmaceuticals

October 25, 2021

Vermont Attorney General's Office
109 State Street
Montpelier, VT 05609
AGO.highcostprescriptiondrugs@vermont.gov

As required by 18 V.S.A § 4637 (b), Mallinckrodt Pharmaceuticals is providing the following information with respect to the launch of a new drug product. This information is only to be used per the requirements of 18 V.S.A § 4637 and not for other purposes.

NDC	Product	Strength	Package Size	WAC/Pkg	Launch Date
73612020001	StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat)	1 cm2/cm2	100cm2/sheet	$4,000	10/22/2021

Note on Strength: The entire StrataGraft construct is defined as the active ingredient.

Statutory Requirements:

(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

In accordance with Mallinckrodt's drug pricing pledge, we price our innovative drugs to reflect the value to patients, providers, and the healthcare system as a whole. StrataGraft is a highly specialized product used in the hospital setting for the treatment of deep partial thickness burns. The product will only be directly marketed to healthcare practitioners, including surgeons, operating in approximately 115 burn centers across the US.

(2) the estimated volume of patients who may be prescribed the drug;

According to the American Burn Association Fact Sheet (https://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/) on Burn Incidence, there are approximately 486,000 burn injuries that receive medical treatment on an annual basis. Of those, approximately 40,000 patients are hospitalized for their burns on an annual basis and approximately 25 percent of these patients receive an autograft during their stay and could potentially be eligible to receive StrataGraft. StrataGraft is only indicated for deep partial thickness burn treatment, and only a limited subset of patients would be eligible for treatment with this product.

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

The product received priority review by the FDA.

(4) the date and price of acquisition if the drug was not developed by the manufacturer
n/a