



October 25, 2021

BY EMAIL DELIVERY

To: AGO.highcostprescriptiondrugs@vermont.gov

Vermont Attorney General's Office 109 State Street
Montpelier, VT 05609

Re: Thirty-Day Post Launch Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Pursuant to 18 V.S.A. § 4637(c) and within thirty calendar days of the initial three-day notice provided on 10/15/2021, Ascendis Pharma, Inc., ("Ascendis") hereby provides the attorney General of Vermont, additional information regarding the introduction to market of a new prescription drug with a wholesale acquisition cost ("WAC") that exceeds the threshold set for a specialty drug under the Medicare Part D program. Ascendis has limited the information herein to that which is publicly available.

Particulars of the prescription drug are set forth below:

Name of Drug	NDC	Description of New Prescription Drug	Strength/pkg	WAC/pkg	Launch Date
SKYTROFA®	73362-0003-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	12 mg	\$2,622.00	10/13/2021
	73362-0004-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	14.4	\$3,146.40	10/13/2021
	73362-0005-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	17.2	\$3,758.20	10/13/2021
	73362-0006-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	20.8	\$4,544.80	10/13/2021

Name of Drug	NDC	Description of New Prescription Drug	Strength/pkg	WAC/pkg	Launch Date
	73362-0007-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	25.2	\$5,506.20	10/13/2021
	73362-0008-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	30.4	\$6,642.40	10/13/2021
	73362-0009-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	36.4	\$7,953.40	10/13/2021
	73362-0010-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	44	\$9,614.00	10/13/2021
	73362-0011-01	Lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, water for Injection	53.2	\$11,624.20	10/13/2021
PLEASE NOTE: WAC per mg is \$218.50					
WAC is an undiscounted price that does not reflect chargebacks, discounts, rebates or other price reductions received by customers.					
The amount the patient pays will largely depend on his/her prescription drug insurance plan or eligibility for support programs.					

Additional Information:

Requested Information	Ascendis Submission
<i>Description of the marketing and pricing plans used in the launch of SKYTROFA (Lonapegsomatropin-tcgd) in the United States and internationally</i>	<p>Ascendis does not publicly share the marketing and pricing strategy for SKYTROFA. Therefore, Ascendis declines to disclose this information in accordance with 18 V.S.A. § 4637(d).</p> <p>As with the launch of any new prescription drug, Ascendis seeks to educate stakeholders including prescribers, patients and payers about the drug’s approved indication(s), safety and efficacy profile.</p> <p>Ascendis determined the price of SKYTROFA by considering a number of factors including the drug’s orphan drug designation status by FDA, the value of the therapy to patients, health systems, and society, financial resources required to continue with the innovation of new therapies especially for patients with rare diseases, and access to therapy by patients who need them.</p>
<i>Whether the SKYTROFA was granted breakthrough therapy designation or priority review by the FDA prior to final approval</i>	SKYTROFA was not granted breakthrough therapy designation or priority review by FDA.
<i>The estimated volume of patients who may be prescribed SKYTROFA</i>	Ascendis does not publicly disclose the estimated volume of patients who may be prescribed SKYTROFA, therefore Ascendis declines to provide this information in accordance with 18 V.S.A. § 4637(d).
<i>The date and price of acquisition if SKYTROFA was not developed by the manufacturer</i>	SKYTROFA was solely developed by Ascendis.

Sincerely,

Twayer Matasi, Senior US Legal Counsel
Ascendis Pharma, Inc.