Date: March 21, 2024

Re: New Prescription Drug Notice from Novo Nordisk Inc. – RIVFLOZA™

Submitted via email: AGO.highcostprescriptiondrugs@vermont.gov

Dear Office of the Vermont Attorney General,

On February 22, 2024, Novo Nordisk Inc. ("NNI") submitted notice of a new prescription drug to market from NNI for Rivfloza™. Pursuant to 18 V.S.A. § 4637 (b), NNI is providing the required additional information:

NDC	00169-5308-01	00169-5307-08	00169-5306-10
Drug Product Description	Rivfloza™ 80 mg/0.5 mL (160 mg/mL) vial; 0.5 mL in 1 single-dose vial	Rivfloza™ 128 mg/0.8 mL (160 mg/mL) syringe; 0.8 mL in 1 single-dose pre-filled syringe	Rivfloza™ 160 mg/mL syringe; 1 mL in 1 single-dose pre-filled syringe
Introduced to Market Date	2/19/2024	2/19/2024	2/19/2024
WAC at Introduction	$31,440.00	$50,304.00	$62,880.00
Marketing & Pricing Plan	Marketing and Pricing Plans are not publicly available information.		

Novo Nordisk Inc.
Ethics & Compliance

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Estimated Volume of Patients	1,000 patients. According to Komodo's longitudinal claims data in 2024 there are approximately 80 cumulatively unique primary hyperoxaluria type 1 (PH1) patients utilizing RNAi therapy since 2021. For the estimated patients requirement, Novo Nordisk utilizes product indication, targeted product profile, services, payer prior authorization requirements as well as the time factor to find the specialists managing undiagnosed patients and get them educated to estimate the number of patients who may be prescribed Rivfloza™. Novo Nordisk has estimated 1 patient per month or a total of 12 patients per year as the average number of patients who may be prescribed Rivfloza™ each month in the United States. However, we note that the estimated prevalence for primary hyperoxaluria is roughly 3 in 1,000,000 or 1,000 people. Rivfloza™ is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 9 years of age and older and adults with PH1 and relatively preserved kidney function, e.g., eGFR greater than or equal to (≥) 30 mL/min/1.73 m2. Type 1 (PH1), which Rivfloza™ is indicated for, is the most common form of primary hyperoxaluria, accounting for 80% of cases or 800 people. Given the ultra-rare condition and the symptoms that may resemble other diseases, >80% of the patients remain undiagnosed. Therefore, the estimated number of patients is much less than the prevalence. The full prescribing Information for Rivfloza™ is available at https://www.novo-pi.com/rivfloza.pdf.		
Breakthrough Therapy?	Yes	Yes	Yes
Priority Review?	No	No	No
Acquisition Date	12/28/2021		
Acquisition Price	On December 28, 2021, Novo Nordisk acquired Dicerna Pharmaceuticals, Inc. ("Dicerna"), a biopharmaceutical company focused on the development of investigational ribonucleic acid interference (RNAi) therapies using its proprietary GalXC™ and GalXC-Plus™ RNAi technologies. Novo Nordisk acquired Dicerna for $3,300,000,000. In the course of this transaction we acquired multiple assets, one of which led the approved product Riflovza™.		

Sincerely,

Anthony (AJ) Brunovsky
Senior Manager, Government Accountability
Ethics & Compliance
Novo Nordisk Inc.