

NOVARTIS - VT New Drug Submission - Mayzent - April 26, 2019

NDC	DRUG_PROD_DESC	INTRODUCED_TO_MARKET_DATE	WAC_AT_INTRODUCTION	MARKETING_PRICING_PLAN	ESTIMATED_PATIENTS	BREAKTHROUGH_THERAPY_INDICATOR	PRIORITY_REVIEW_INDICATOR	ACQUISITION_DATE	ACQUISITION_PRICE	GENERAL_COMMENTS
0078-0986-15	MAYZENT™ is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease (SPMS), in adults. MAYZENT™ is available as 2 mg tablet (equivalent to 2.224mg siponimod fumaric acid): pale yellow, unscored, round biconvex film-coated tablet with beveled edges, debossed with "N" on one side and "II" on other side. Package size for this NDC is 30 tablets.	3/27/2019	\$7,273.97	Novartis considered many factors in determining the price of Mayzent. As the first oral drug to delay disability progression in RRMS, CIS, and active SPMS, Mayzent is poised to substantially reduce the burden of the condition on patients, caregivers, employers, insurers, the US healthcare system and society as a whole. We are focused on access to Mayzent for this patient population.	320,000	N/A	yes, Novartis used a priority review voucher	N/A	N/A	We believe that all information submitted by Novartis to the Department of Vermont Health Access or to the Attorney General under Vt. Stat. tit. 18 §§ 4635 or 4637, including all information contained in this submission, is confidential and proprietary commercial or financial information not subject to disclosure, including under the Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) and applicable laws pertaining to trade secrets. We request that the confidentiality of this submission and of all Novartis' related information herein be maintained to the maximum extent permitted by law. To the extent that any of this designated information is requested, whether under Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) or otherwise, we request that Novartis be notified of the request and afford us the opportunity to submit objections to disclosure.
0078-0979-50	MAYZENT™ is available as 0.25 mg tablet (equivalent to 0.278mg siponimod fumaric acid): Pale red, unscored, round biconvex film-coated tablet with beveled edges, debossed with "N" on one side and "T" on other side. Package size for NDC is 28 tablets.	3/27/2019	\$1,697.26	Novartis considered many factors in determining the price of Mayzent. As the first oral drug to delay disability progression in RRMS, CIS, and active SPMS, Mayzent is poised to substantially reduce the burden of the condition on patients, caregivers, employers, insurers, the US healthcare system and society as a whole. We are focused on access to Mayzent for this patient population.	320,000	N/A	yes, Novartis used a priority review voucher	N/A	N/A	We believe that all information submitted by Novartis to the Department of Vermont Health Access or to the Attorney General under Vt. Stat. tit. 18 §§ 4635 or 4637, including all information contained in this submission, is confidential and proprietary commercial or financial information not subject to disclosure, including under the Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) and applicable laws pertaining to trade secrets. We request that the confidentiality of this submission and of all Novartis' related information herein be maintained to the maximum extent permitted by law. To the extent that any of this designated information is requested, whether under Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) or otherwise, we request that Novartis be notified of the request and afford us the opportunity to submit objections to disclosure.
0078-0979-12	MAYZENT™ is available as 0.25 mg tablet (equivalent to 0.278mg siponimod fumaric acid): Pale red, unscored, round biconvex film-coated tablet with beveled edges, debossed with "N" on one side and "T" on other side. Package size for NDC is Starter Pack – blister card of twelve 0.25 mg tablets in a calendarized blister wallet. Only available through the MAYZENT hub program, the hub for Novartis. NOT FOR SALE.	3/27/2019	N/A							We believe that all information submitted by Novartis to the Department of Vermont Health Access or to the Attorney General under Vt. Stat. tit. 18 §§ 4635 or 4637, including all information contained in this submission, is confidential and proprietary commercial or financial information not subject to disclosure, including under the Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) and applicable laws pertaining to trade secrets. We request that the confidentiality of this submission and of all Novartis' related information herein be maintained to the maximum extent permitted by law. To the extent that any of this designated information is requested, whether under Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) or otherwise, we request that Novartis be notified of the request and afford us the opportunity to submit objections to disclosure.