Notice of Price Adjustment to 340B Covered Entities That Purchased GILENYA® .5 mg capsules from December 9, 2020 through June 30, 2021

July 16, 2021

Novartis Pharmaceuticals Corporation (“Novartis”) is offering refunds to certain 340B covered entities with respect to purchases of GILENYA® (fingolimod) .5 mg capsules, for oral use (“GILENYA”) during the period December 9, 2020 through June 30, 2021 (the “Refund-Eligible Period”).

GILENYA ceased to be on the Orphan Drug Designation List beginning December 9, 2020. Accordingly, a 340B covered entity that meets the following criteria may be eligible for a refund:

1. Was active in the Office of Pharmacy Affairs Information System (“OPAIS”) during the Refund-Eligible Period as one of the following covered entity types: (A) rural referral center (eligible under 42 U.S.C. § 256b(4)(O)), (B) sole community hospital (eligible under 42 U.S.C. § 256b(4)(O)), (C) critical access hospital (eligible under 42 U.S.C. § 256b(4)(N)), or (D) free-standing cancer hospital (eligible under 42 U.S.C. § 256b(4)(M)); and
2. Purchased the NDC 0078-0607-15 (Bottle of 30 .5 mg GILENYA capsules) at a price greater than the 340B ceiling price while the entity was so-active on a date during the Refund-Eligible Period.

Refund Request Process:

Novartis requests that any such entity that made purchases that otherwise would have been eligible for 340B pricing at the time of purchase submit a refund request to the wholesaler from which it purchased GILENYA. Refunds will be issued in the form of a credit in an amount equal to the difference between the original purchase price, net of any applicable discounts, and the 340B ceiling price.

If you have any questions or require assistance with respect to the refund request, please contact hcachargeback.phuseh@novartis.com with “Attention: GILENYA 340b Refund” during regular business hours.

Novartis has asked the Office of Pharmacy Affairs (OPA) to post this Notice on OPA’s public website to give affected covered entities the opportunity to request refunds.

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5 “Eligible” is determined subject to Novartis’ contract pharmacy policy, effective 11/16/20.