



11/1/2023

Notice Regarding Offer of Refunds to 340B Covered Entities

GlaxoSmithKline plc (“GSK”) has recently recalculated 340B Ceiling Prices for the NDC’s referenced below for the time period of October 1, 2021 through December 31, 2021 (4Q2021). As a result of the recalculated 340B Ceiling Prices, GSK has determined that, pursuant to 42 U.S.C. § 256b(d)(1)(B)(ii) and 42 C.F.R. § 10.11(b)(4), a refund is or may be owed to 340B Covered Entities that purchased any of the below NDCs during the time period of October 1, 2021 through December 31, 2021 (4Q2021).

The table below identifies the NDCs that are subject to a refund for October 1, 2021 through December 31, 2021. The recalculated Ceiling Prices are the result of revised pricing data that were submitted to the Centers for Medicare & Medicaid Services.

Time Period	Product	NDC-11
10/01/2021 – 12/31/2021	ANORO ELLIPTA 62.5/25 MCG INH PWDR 1X30 DS	00173-0869-10
10/01/2021 – 12/31/2021	ANORO ELLIPTA 62.5/25 MCG INH PWDR 1X7 DS INST	00173-0869-06
10/01/2021 – 12/31/2021	ARNUITY (FF) ELLIPTA INH PWDR 50MCG 1X30 DOSE TRD	00173-0888-10
10/01/2021 – 12/31/2021	ARNUITY ELLIPTA 100MCG DRY PWD INH 1X 14D INST	00173-0874-14
10/01/2021 – 12/31/2021	ARNUITY ELLIPTA 100MCG DRY PWD INH 1X 30D TRD	00173-0874-10
10/01/2021 – 12/31/2021	ARNUITY ELLIPTA 200MCG DRY PWD INH 1X 14D INST	00173-0876-14
10/01/2021 – 12/31/2021	ARNUITY ELLIPTA 200MCG DRY PWD INH 1X 30D TRD	00173-0876-10
10/01/2021 – 12/31/2021	BREO ELLIPTA 100/25 MCG INH PWDR 14 DOSE NDPI INST PAC X 1	00173-0859-14
10/01/2021 – 12/31/2021	BREO ELLIPTA 100/25 MCG INH PWDR 30 DS NDPI TRD PACK X 1	00173-0859-10
10/01/2021 – 12/31/2021	BREO ELLIPTA 200/25 MCG INH PWDR 1X 14D INST	00173-0882-14
10/01/2021 – 12/31/2021	BREO ELLIPTA 200/25 MCG INH PWDR 1X 30D	00173-0882-10
10/01/2021 – 12/31/2021	IMITREX INJ STATDOSE REFILL 6MG/0.5ML 2S	00173-0478-00
10/01/2021 – 12/31/2021	INCRUSE ELLIPTA INH PWDR 62.5MCG 1X30 DOSE TRD	00173-0873-10
10/01/2021 – 12/31/2021	INCRUSE ELLIPTA INH PWDR 62.5MCG 1X7 DOSE INST	00173-0873-06
10/01/2021 – 12/31/2021	NUCALA SOLUTION INJECT AI 100MG/ML 1X1ML	00173-0892-01
10/01/2021 – 12/31/2021	NUCALA SOLUTION INJECT SS 100MG/ML 1X1ML	00173-0892-42
10/01/2021 – 12/31/2021	TRELEGY ELLIPTA 1X30D TRD 100/62.5/25MCG PK/CA	00173-0887-10
10/01/2021 – 12/31/2021	TRELEGY ELLIPTA 200/62.5/25MCG 1X14D INST PACK	00173-0893-14
10/01/2021 – 12/31/2021	TRELEGY ELLIPTA 200/62.5/25MCG 1X30D TRADE PACK	00173-0893-10
10/01/2021 – 12/31/2021	TRELEGY ELLIPTA INH PWDR 100/62.5/25MCG 1X14 DOSE INST	00173-0887-14
10/01/2021 – 12/31/2021	VENTOLIN HFA 90MCG INH AER 60 ACTN	00173-0682-24
10/01/2021 – 12/31/2021	VENTOLIN HFA DC INH.AER. 18G 200INHL 1S	00173-0682-20

Based on the recalculation for the product(s) noted above, GSK intends to refund any amount equal to or in excess of \$100 (aggregate for all applicable NDCs) for the periods listed directly to the 340B Covered Entity of record. Separate correspondence including a check and details of the payment will be sent to the 340B Covered Entity.

For 340B Covered Entities who may be owed less than \$100 in aggregate or who have questions about the above-referenced recalculation for this period, GSK invites interested parties to contact it via email at GSK.340BRefunds@gsk.com, with a reference to the NDC and time period.

GSK has asked the Health Resources and Services Administration (HRSA) to post this Notice on the HRSA's public website to ensure transparency to all 340B Covered Entities regarding the Ceiling Price recalculations for all NDC's identified above and to offer a refund to any of the 340B Covered Entities that may have purchased the above NDCs during the relevant time periods. Please direct any questions and/or requests for additional information to GSK at the following email address: GSK.340BRefunds@gsk.com.