

## Notice of Changes to 340B Prices

November 12, 2021

Pursuant to 42 C.F.R. § 447.510(b), Eli Lilly and Company (Lilly) has submitted routine updated 3Q2018 Average Manufacturer Prices and Best Prices for certain of its covered outpatient drugs to the Centers for Medicare & Medicare Services (CMS) to account for lagged transactional data. These restated Medicaid prices result in both upward and downward adjustments to 1Q2019 340B Ceiling Prices.

*Table 1: Products Subject to Upward Adjustments to the Previously Reported Ceiling Price*

NDC	Product Description
00002771559	BASAGLAR 100UCD 15.000000 MML
00002771227	HUMALOG KWIKPEN 200UCD 6.000000 MML
00002831501	HUMULIN N 100UCD 10.000000 MML
00002831517	HUMULIN N 100UCD 3 MILLILITER
00002880559	HUMULIN N PEN 100UCD 15 MILLILITER
00002325130	STRATTERA 100MG 30.000000 CAP
00002322730	STRATTERA 10MG 30.000000 CAP
00002323830	STRATTERA 18MG 30.000000 ST
00002322830	STRATTERA 25MG 30.000000 ST
00002322930	STRATTERA 40MG 30.000000 CAP
00002325030	STRATTERA 80MG 30.000000 CAP
00002143380	TRULICITY 0.75 MG 2.000000 MILLILITER
00002143480	TRULICITY 1.5MG 2.000000 MML

Lilly has elected not to seek recoupment of these underpayments from Covered Entities.

*Table 2: Products Subject to Downward Adjustments to the Previously Reported Ceiling Price*

NDC	Product Description <sup>1</sup>
00002197590	AXIRON 30MG 90.000000 MML
00002446534	CIALIS 2.5MG 30.000000 TA
00002446234	CIALIS 5 MG 30.000000 TABLET
00002446230	CIALIS 5MG 30.000000 TA
00002814701	HUMATROPE 6 MG 1.000000 MILLILITER
00002323930	STRATTERA 60MG 30.000000 ST

**Lilly uses wholesaler chargeback records to calculate and automatically issue refund payments to impacted eligible Covered Entities at the address listed in the HRSA database.**

Lilly does not directly contact or automatically issue checks to Covered Entities who may be eligible for amounts less than \$1.00 resulting from this restatement. For these de minimis changes, Lilly is offering to refund such Covered Entities through this Notice.

<sup>1</sup> All of these products were available in generic formulations during the quarter at issue.

Covered Entities who believe they may be entitled to a refund amount less than \$1.00 for purchases of the above listed products in 1Q2019 or have questions about refunds Lilly already issued may contact Lilly at [basesupport\\_cma@lilly.com](mailto:basesupport_cma@lilly.com) with “Attn: 340B Recalculation” in the subject line to confirm any applicable amounts at issue and to initiate the payment process.

In addition, the Orphan Drug designation for Strattera has been withdrawn. Accordingly, Covered Entities registered under the 340B Program as Free-Standing Cancer Hospitals, Critical Access Hospitals, Rural Referral Centers, or Sole Community Hospitals (together, “ACA Covered Entities”) may be eligible for a refund for purchases of Strattera at prices above the 340B Ceiling Price in Q1 2021 and Q2 2021.

Lilly does not have wholesaler chargeback data showing purchases of Strattera (atomoxetine) by ACA Covered Entities and thus cannot utilize the process described above to issue such refunds. However, between 8 and 12 generic versions of Strattera (depending on package size) were available during these periods, so we expect Covered Entity orders for Strattera to have been very low. If you were registered as an ACA Covered Entity and you purchased any Strattera (NDCs 00002325130, 00002322730, 00002323830, 00002322830, 00002322930, 00002323930, 00002325030) in Q1 2021 or Q2 2021, please contact Lilly at [basesupport\\_cma@lilly.com](mailto:basesupport_cma@lilly.com) with “Attn: 340B Orphan Drug” in the subject line to confirm any applicable amounts at issue and to initiate the payment process.

Lilly has requested that the Health Resource and Services Administration (HRSA) post this Notice on the HRSA public website to ensure transparency to Covered Entities regarding Lilly’s recalculation and refund process.

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