

**Notice Regarding Recalculated 340B Ceiling Prices for Chiesi USA, Inc. Products Impacted for the Time Period 3Q2016 – 1Q2020**

Chiesi USA, Inc. has recalculated Average Manufacturer Price (“AMP”) and Best Price (“BP”) values previously submitted to the Centers for Medicare & Medicaid Services (“CMS”) for certain products for the Q1 2016-Q3 2019 time period. Chiesi USA, Inc. has also recalculated the 340B ceiling prices for the products on the attached list and associated quarters of Q3 2016-Q1 2020 based on the corrected AMP and BP values.

Chiesi USA, Inc. has asked the Office of Pharmacy Affairs (“OPA”) to post this notice on OPA’s public website to ensure transparency by providing access to information regarding Chiesi USA, Inc.’s recalculation and potential overpayment by certain 340B Covered Entities for impacted Chiesi USA, Inc. products related thereto. Chiesi USA, Inc. will be communicating with and issuing refunds via Apexus to 340B Covered Entities where the Chiesi USA, Inc. data demonstrates that a 340B Covered Entity has overpaid by \$250.00 or more in the aggregate for the impacted products set forth above for the Q3 2016 through Q4 2018 time period. In the event the Chiesi USA, Inc. data demonstrates that a 340B Covered Entity has overpaid by \$250.00 or less in the aggregate for the impacted products set forth above for the Q3 2016 through Q4 2018 time period, Chiesi USA, Inc. will not be issuing refunds on its own accord. However, if any 340B Covered Entity believes it has overpaid by \$250.00 or less in the aggregate for the impacted products set forth above for the Q3 2016 through Q4 2018 time period and would like a refund, the Covered Entity should contact Chiesi USA, Inc. via email at [us.govprograms@chiesi.com](mailto:us.govprograms@chiesi.com) no later than October 30, 2020. Upon validation, an aggregate overpayment less than \$250.00 by a 340B Covered Entity for the impacted products set forth above for the Q3 2016 through Q4 2018 time period will be refunded by Chiesi USA, Inc. upon the 340B Covered Entity’s request so long as such request is received on or before October 30, 2020.

Chiesi USA, Inc. will be refunding all aggregated overpayments on purchases of the impacted products by 340B Covered Entities in Q1 2019 through Q1 2020 regardless of the total aggregated overpayment.

Any questions about this notice should be directed to Chiesi USA, Inc. via email at [us.govprograms@chiesi.com](mailto:us.govprograms@chiesi.com) no later than October 30, 2020.

## Impacted Products

NDC	Product Name
10122-0313-10	CARDENE® I.V. 20MG/200ML NACL
10122-0314-10	CARDENE® I.V. 20MG/200ML DEX
10122-0325-10	CARDENE® I.V. 40MG/200ML NACL
10122-0326-10	CARDENE® I.V. 40MG/200ML DEX
10122-0510-01	Curosurf® 1.5ml
10122-0510-03	Curosurf® 3.0ml
10122-0610-10	Cleviprex injectable emulsion 25mg/50mL
10122-0611-10	Cleviprex injectable emulsion 50mg/100mL
10122-0620-10	Kengreal for injection 50mg/10ML
10122-0820-28	Bethkis® (Tobramycin Inhalation Solution) 28ct
10122-0820-56	Bethkis® (Tobramycin Inhalation Solution) 56ct