



February 14, 2023

Notice Regarding Offer of Refunds to 340B Covered Entities for Purchases of Zydus Products

Zydus Pharmaceuticals USA Inc. (“Zydus”) has recently recalculated 340B Ceiling Prices for the products listed below for the time periods January 1, 2022 (1Q2022) through October 31, 2022 (3Q2022). As a result of the recalculated 340B Ceiling Prices, Zydus 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 owed to 340B Covered Entities that purchased these products during these time periods. The table below identifies the NDCs that are subject to a refund in each applicable quarter. The recalculated Ceiling Prices are the result of revised pricing data for the period July 1, 2021 through March 31, 2022 that were submitted to the Centers for Medicare & Medicaid Services.

The table below shows the impacted products and PHS invoice period 1Q2022, 2Q2022, and 3Q2022:

NDC_DESC	NDC	2022-1	2022-2	2022-3
Acamprosate Calcium DR Tabs (333 mg 180ct)	68382-0569-28	Y		
ALLOPURINOL TAB 100MG (100 CT)	70710-1209-01	Y		
ALLOPURINOL TAB 100MG (1000 CT)	70710-1209-00	Y		
Amiodarone Tab 200mg (500 Ct)	68382-0227-05		Y	
Amiodarone Tab 200mg (60 Ct)	68382-0227-14		Y	
ARSENIC TRIOXIDE INJ 12MG/6ML (10X6ML)	70710-1610-06	Y	Y	
Atenolol Tab 50mg (100 Ct)	68382-0023-01	Y		
Atenolol Tab 50mg (1000 Ct)	68382-0023-10	Y		
ATENOLOL/CHLORTHAL TAB 100/25MG (100 CT)	70710-1168-01	Y		
ATENOLOL/CHLORTHAL TAB 50/25MG (100 CT)	70710-1167-01	Y		
AZITHROMYCIN OS 100MG/5ML (15ML)	70710-1457-01		Y	
AZITHROMYCIN OS 200MG/5ML (30ML)	70710-1460-02	Y	Y	
BACLOFEN TAB 20MG (100 CT)	70710-1286-01		Y	
Benzonatate Cap 100mg (100 Ct)	68382-0247-01		Y	
Benzonatate Cap 100mg (500 Ct)	68382-0247-05		Y	
BUSPIRONE HYDROCHLORIDE TABS (5 MG 500)	68382-0180-05	Y	Y	
BUSPIRONE HYDROCHLORIDE TABS (5 MG 100)	68382-0180-01	Y	Y	
Carvedilol Tab 12.5mg (100 Ct)	68382-0094-01		Y	
Carvedilol Tab 25mg (100 Ct)	68382-0095-01	Y		
Carvedilol Tab 25mg (500 Ct)	68382-0095-05	Y		
Cholestyramine Light 4gm (231gm Can)	68382-0529-42		Y	
CLOBETASOL PROP SPRAY 0.05% (125ML BOTTLE)	68382-0998-02	Y	Y	
CLOBETASOL PROP SPRAY 0.05% (59ML BOTTLE)	68382-0998-01	Y	Y	

NDC_DESC	NDC	2022-1	2022-2	2022-3
COLESEVELAM TAB 625MG (180 CT)	68382-0619-28		Y	
DEFERASIROX TAB 90MG (30 CT)	70710-1275-03		Y	
DEXTRO AMPHET&SULF AMPHET ASPAR&SULF 10MG (100 CT)	68382-0952-01	Y	Y	Y
DEXTRO AMPHET&SULF AMPHET ASPAR&SULF 15MG (100 CT)	68382-0954-01			Y
DEXTRO AMPHET&SULF AMPHET ASPAR&SULF 20MG (100 CT)	68382-0955-01	Y		
DEXTRO AMPHET&SULF AMPHET ASPAR&SULF 30MG (100 CT)	68382-0956-01		Y	
DEXTRO AMPHET&SULF AMPHET ASPAR&SULF 5MG (100 CT)	68382-0950-01			Y
DILTIAZEM HCL CD CAP 120MG (90 CT)	68382-0595-16		Y	
DILTIAZEM HCL CD CAP 240MG (90 CT)	68382-0597-16		Y	
DILTIAZEM HCL CD CAP 300MG (90 CT)	68382-0598-16	Y	Y	
DILTIAZEM HCL CD CAP 360MG (90 CT)	68382-0599-16	Y		
Doxazosin Tab 4mg (100 Ct)	68382-0785-01	Y		
Doxazosin Tab 8mg (100 Ct)	68382-0786-01	Y	Y	
DOXYCYCLINE TAB 100MG (50 CT)	70710-1123-07	Y		
Entecavir Tab 0.5mg (30 Ct)	68382-0920-06	Y	Y	Y
Famotidine OS 40mg/5mL (50 mL)	68382-0444-05	Y	Y	
Fluconazole Tab 200mg (100 Ct)	70710-1140-01	Y	Y	
Fluconazole Tab 200mg (30 Ct)	70710-1140-03	Y	Y	
FLUOCINONIDE TOP SOL 0.05% (60 ML)	70710-1284-03	Y		
FLUPHENAZINE HCL TAB 1MG (100 CT)	70710-1488-01	Y		
Glipizide & Metformin Tabs (2.5 mg & 500 mg 100ct)	68382-0185-01	Y		
Glipizide & Metformin Tabs (5 mg & 500 mg 100ct)	68382-0186-01	Y	Y	
INDOMETHACIN INJ 1MG (1 SD VIAL)	68382-0470-01	Y		
LANSOPRAZOLE DR OD TAB 15MG (10 X10 BLISTER)	68382-0771-77		Y	
LANSOPRAZOLE DR OD TAB 30MG (10 X10 BLISTER)	68382-0772-77	Y	Y	
Losartan Potassium Tab 25mg (90 Ct)	68382-0135-16		Y	
MEMANTINE ER CAP 28MG (30 CT)	68382-0549-06		Y	
MESALAMINE SUPPOSITORIES 1000MG (30 CT)	70710-1302-07	Y	Y	
Metformin Hydrochloride Tabs (850 mg 100)	68382-0759-01	Y		
Metformin Hydrochloride Tabs (850 mg 500)	68382-0759-05	Y	Y	
Metformin Hydrochloride Tabs (500 mg 100)	68382-0758-01		Y	
Metformin Hydrochloride Tabs (500 mg 1000)	68382-0758-10		Y	
Metformin Hydrochloride Tabs (500 mg 500)	68382-0758-05		Y	
Metformin Hydrochloride Tabs (850 mg 1000)	68382-0759-10	Y	Y	
Oseltamivir OS 6mg/mL (60 mL)	70710-1165-06		Y	
Oxybutynin Cl ER Tab 10mg (100 Ct)	68382-0256-01	Y		
OXYBUTYNIN CL ER TAB 10MG (500 CT)	68382-0256-05	Y		
Oxybutynin Cl ER Tab 5mg (100 Ct)	68382-0255-01	Y	Y	

NDC_DESC	NDC	2022-1	2022-2	2022-3
OXYBUTYNIN CL ER TAB 5MG (500 CT)	68382-0255-05	Y	Y	
PHYTONADIONE TAB 5MG (30 CT)	70710-1014-03	Y		
Potassium Chloride ER Tabs (8 mEq 100)	68382-0776-01	Y	Y	
Potassium Citrate ER Tabs (10 mEq 100 ct)	68382-0537-01		Y	
Promethazine HCl Tab 25mg (100 Ct)	68382-0041-01	Y		
Promethazine HCl Tab 25mg (1000 Ct)	68382-0041-10	Y	Y	
Risperidone Tab 0.25mg (500 Ct)	68382-0112-05	Y		
Risperidone Tab 0.25mg (60 Ct)	68382-0112-14	Y		
Risperidone Tab 0.5mg (500 Ct)	68382-0113-05	Y		
Risperidone Tab 0.5mg (60 Ct)	68382-0113-14	Y		
RIVASTIGMINE PATCH 4.6MG/24HR (30 CT)	70710-1196-07		Y	
TADALAFIL TAB 10MG (30 CT)	68382-0898-06	Y	Y	
TADALAFIL TAB 2.5MG (30 CT)	68382-0896-06	Y	Y	
TADALAFIL TAB 5MG (30 CT)	68382-0897-06	Y	Y	
TELMISARTAN TABS (40 MG 30)	68382-0472-78	Y		
TIADYL ER (DILTIAZEM) CAP 420MG (90 CT)	68382-0750-16	Y	Y	
Topiramate Cap 15mg (60 Ct)	68382-0004-14	Y	Y	
Topiramate Cap 25mg (60 Ct)	68382-0005-14	Y	Y	
TRIAMTERENE/HCTZ TAB 75/50MG (100 CT)	68382-0857-01		Y	
Venlafaxine HCl ER Cap 37.5mg (90 Ct)	68382-0034-16		Y	
Venlafaxine HCl ER Cap 75mg (90 Ct)	68382-0035-16		Y	
Venlafaxine HCl Tab 37.5mg (100 Ct)	68382-0019-01		Y	

Please note that Zydus is offering refunds to affected 340B Covered Entities in two ways:

1. 340B Covered Entities that are entitled to an aggregated refund across applicable NDCs for \$25 or more will be contacted directly by, or on behalf of, Zydus with information on how the refund will be processed.
2. The 340B Covered Entities that are entitled to an aggregated refund across applicable NDCs for less than \$25.00 will not be contacted directly by, or on behalf of, Zydus. Instead, Zydus is offering a refund to these 340B Covered Entities through this Notice. If a 340B Covered Entity does not receive a communication from, or on behalf of, Zydus and that 340B Covered Entity believes it is entitled to a refund on the applicable NDCs, then the 340B Covered Entity should contact Zydus at the following email address: PHSrefund2023@zydususa.com to request the refund and accept Zydus's refund offer. Zydus will then work with the 340B Covered Entity to process any refund that is due to the 340B Covered Entity for the applicable NDCs.



Zydus 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 the products identified above and to offer a refund to any of the 340B Covered Entities that may have purchased the products identified above during the relevant time periods. Please direct any questions and/or requests for additional information to Zydus at the following email address: PHSrefund2023@zydususa.com.