



Notice Regarding Offer of Refunds to 340B Covered Entities

Takeda Pharmaceuticals America, Inc. (“Takeda”) recalculated 340B Ceiling Prices for the NDC’s referenced below for the period of 3Q2017-2Q2021. As a result of the recalculated 340B Ceiling Prices, Takeda 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 above time period.

The table below identifies the NDCs that are subject to a refund for 3Q2017-2Q2021. The recalculated Ceiling Prices are the result of revised pricing data that was submitted to the Centers for Medicare & Medicaid Services.

Time Period	Product Description	NDC
07/01/2017-09/30/2017	VYVANSE 70MG CAPSULES 100	59417010710
10/01/2017-12/31/2017	VYVANSE 30MG CAPSULES 100	59417010310
10/01/2017-12/31/2017	VYVANSE 40MG CAPSULES 100	59417010410
10/01/2017-12/31/2017	VYVANSE 50MG CAPSULES 100	59417010510
10/01/2017-12/31/2017	VYVANSE 70MG CAPSULES 100	59417010710
10/01/2017-12/31/2017	XIIDRA 5% 12ML Ampule 60	54092060601
01/01/2018-03/31/2018	ADDERALL XR 20MG CAPSULES 100	54092038701
01/01/2018-03/31/2018	ADDERALL XR 30MG CAPSULES 100	54092039101
01/01/2018-03/31/2018	ADVATE BAXJECT III 2ML 1201- 1800 IU	00944305402
01/01/2018-03/31/2018	ADVATE BAXJECT III 2ML 200-400 IU	00944305102
01/01/2018-03/31/2018	ADVATE BAXJECT III 2ML 401-800 IU	00944305202
01/01/2018-03/31/2018	ADVATE BAXJECT III 2ML 801-1200 IU	00944305302
01/01/2018-03/31/2018	ADVATE BAXJECT III 5ML 1801-2400 IU	00944304510
01/01/2018-03/31/2018	ADVATE BAXJECT III 5ML 2401- 3600 IU	00944304610
01/01/2018-03/31/2018	ADVATE BAXJECT III 5ML 3601- 4800 IU	00944304710
01/01/2018-03/31/2018	ADYNOVATE 3000IU BJIII 5MLUS 2501-3500 IU	00944462801
01/01/2018-03/31/2018	ADYNOVATE BJIII HF KIT 2 ML 1000 AQ 800-1250 IU	00944462401

01/01/2018-03/31/2018	ADYNOVATE BJIII HF KIT 2 ML 250 AQ 200-400 IU	00944462201
01/01/2018-03/31/2018	ADYNOVATE BJIII HF KIT 2 ML 500 AQ 401-800 IU	00944462301
01/01/2018-03/31/2018	ADYNOVATE BJIII HF KIT 2ML 2000 AQ 1251-2500 IU	00944462501
01/01/2018-03/31/2018	ADYNOVATE BJIII HF KIT 2ML 750 AQ 600-938 IU	00944462601
01/01/2018-03/31/2018	ADYNOVATE BJIII HF KIT 5 ML 1500 AQ 1251-1800 IU	00944462701
01/01/2018-03/31/2018	CEPROTIN 1000 AQ KIT 10ML 800-1200 IU	00944417910
01/01/2018-03/31/2018	GAMMAGARD LIQUID IV 10% 100ML 10G Vial	00944270005
01/01/2018-03/31/2018	GAMMAGARD LIQUID IV 10% 200ML 20G Vial	00944270006
01/01/2018-03/31/2018	GAMMAGARD LIQUID IV 10% 25ML 2.5 G Vial	00944270003
01/01/2018-03/31/2018	GAMMAGARD LIQUID IV 10% 300ML 30G Vial	00944270007
01/01/2018-03/31/2018	GAMMAGARD LIQUID IV 10% 50ML 5G Vial	00944270004
01/01/2018-03/31/2018	GAMMAGARD LIQUID IV 10% 10ML 1G Vial	00944270002
01/01/2018-03/31/2018	RECOMBINATE BJII 5ML 1241-1800 AU	00944284410
01/01/2018-03/31/2018	RECOMBINATE BJII 5ML 1801-2400 AU	00944284510
01/01/2018-03/31/2018	RECOMBINATE BJII 5ML 220-400 AU	00944284110
01/01/2018-03/31/2018	RECOMBINATE BJII 5ML 401-800 AU	00944284210
01/01/2018-03/31/2018	RECOMBINATE BJII 5ML 801-1240 AU	00944284310
01/01/2018-03/31/2018	RIXUBIS rFIX 1000 IU, 5ML 700-1300 IU	00944303002
01/01/2018-03/31/2018	RIXUBIS rFIX 2000 IU, 5ML 1400-2600 IU	00944303202
04/01/2018-06/30/2018	HYQVIA 10GM 100ML & 5ML Kit	00944251202
04/01/2018-06/30/2018	HYQVIA 2.5GM 25ML & 1.6ML Kit	00944251002
04/01/2018-06/30/2018	HYQVIA 20GM 200ML & 10ML Kit	00944251302
04/01/2018-06/30/2018	HYQVIA 30GM 300ML & 15ML Kit	00944251402
04/01/2018-06/30/2018	HYQVIA 5GM 50ML & 2.5ML Kit	00944251102
07/01/2018-09/30/2018	ADDERALL XR 5MG CAPSULES 100	54092038101
07/01/2018-09/30/2018	CARBATROL 100MG CAPSULES 120	54092017112
07/01/2018-09/30/2018	OBIZUR 400-600 IU	00944500101
07/01/2018-09/30/2018	ULORIC 40mg 30ct	64764091830
07/01/2018-09/30/2018	VONVENDI 1300AQ 10ML 900-1700 IU	00944755302
07/01/2018-09/30/2018	VONVENDI 650AQ 5ML 450-850 IU	00944755102
07/01/2018-09/30/2018	XIIDRA 5% 12ML Ampule 60	54092060601
10/01/2018-12/31/2018	ADVATE BAXJECT III 2ML 1201- 1800 IU	00944305402

10/01/2018-12/31/2018	ADVATE BAXJECT III 2ML 200-400 IU	00944305102
10/01/2018-12/31/2018	ADVATE BAXJECT III 2ML 401-800 IU	00944305202
10/01/2018-12/31/2018	ADVATE BAXJECT III 2ML 801-1200 IU	00944305302
10/01/2018-12/31/2018	ADVATE BAXJECT III 5ML 1801-2400 IU	00944304510
10/01/2018-12/31/2018	ADVATE BAXJECT III 5ML 2401- 3600 IU	00944304610
10/01/2018-12/31/2018	ADVATE BAXJECT III 5ML 3601- 4800 IU	00944304710
10/01/2018-12/31/2018	FLEXBUMIN 25% Solution 100ML	00944049302
10/01/2018-12/31/2018	FLEXBUMIN 5% Solution 250ML	00944049505
10/01/2018-12/31/2018	FLEXBUMIN 25% Solution 50ML	00944049301
10/01/2018-12/31/2018	HYQVIA 10GM 100ML & 5ML Kit	00944251202
10/01/2018-12/31/2018	HYQVIA 2.5GM 25ML & 1.6ML Kit	00944251002
10/01/2018-12/31/2018	HYQVIA 20GM 200ML & 10ML Kit	00944251302
10/01/2018-12/31/2018	HYQVIA 30GM 300ML & 15ML Kit	00944251402
10/01/2018-12/31/2018	HYQVIA 5GM 50ML & 2.5ML Kit	00944251102
10/01/2018-12/31/2018	OBIZUR 400-600 IU	00944500101
10/01/2018-12/31/2018	RECOMBINATE BJII 5ML 1241-1800 AU	00944284410
10/01/2018-12/31/2018	RECOMBINATE BJII 5ML 1801-2400 AU	00944284510
10/01/2018-12/31/2018	RECOMBINATE BJII 5ML 220-400 AU	00944284110
10/01/2018-12/31/2018	RECOMBINATE BJII 5ML 401-800 AU	00944284210
10/01/2018-12/31/2018	RECOMBINATE BJII 5ML 801-1240 AU	00944284310
10/01/2018-12/31/2018	VONVENDI 1300AQ 10ML 900-1700 IU	00944755302
10/01/2018-12/31/2018	VONVENDI 650AQ 5ML 450-850 IU	00944755102
10/01/2018-12/31/2018	VYVANSE 60MG CAPSULES 100	59417010610
10/01/2018-12/31/2018	XIIDRA 5% 12ML Ampule 60	54092060601
01/01/2019-03/31/2019	ADVATE BAXJECT III 2ML 1201- 1800 IU	00944305402
01/01/2019-03/31/2019	ADVATE BAXJECT III 2ML 200-400 IU	00944305102
01/01/2019-03/31/2019	ADVATE BAXJECT III 2ML 401-800 IU	00944305202
01/01/2019-03/31/2019	ADVATE BAXJECT III 2ML 801-1200 IU	00944305302
01/01/2019-03/31/2019	ADVATE BAXJECT III 5ML 1801-2400 IU	00944304510
01/01/2019-03/31/2019	ADVATE BAXJECT III 5ML 2401- 3600 IU	00944304610
01/01/2019-03/31/2019	ADVATE BAXJECT III 5ML 3601- 4800 IU	00944304710
01/01/2019-03/31/2019	FLEXBUMIN 25% Solution 100ML	00944049302

01/01/2019-03/31/2019	FLEXBUMIN 5% Solution 250ML	00944049505
01/01/2019-03/31/2019	FLEXBUMIN 25% Solution 50ML	00944049301
01/01/2019-03/31/2019	OBIZUR 400-600 IU	00944500101
01/01/2019-03/31/2019	RECOMBINATE BJII 5ML 1241-1800 AU	00944284410
01/01/2019-03/31/2019	RECOMBINATE BJII 5ML 1801-2400 AU	00944284510
01/01/2019-03/31/2019	RECOMBINATE BJII 5ML 220-400 AU	00944284110
01/01/2019-03/31/2019	RECOMBINATE BJII 5ML 401-800 AU	00944284210
01/01/2019-03/31/2019	RECOMBINATE BJII 5ML 801-1240 AU	00944284310
04/01/2019-06/30/2019	ADVATE BAXJECT III 2ML 1201- 1800 IU	00944305402
04/01/2019-06/30/2019	ADVATE BAXJECT III 2ML 200-400 IU	00944305102
04/01/2019-06/30/2019	ADVATE BAXJECT III 2ML 401-800 IU	00944305202
04/01/2019-06/30/2019	ADVATE BAXJECT III 2ML 801-1200 IU	00944305302
04/01/2019-06/30/2019	ADVATE BAXJECT III 5ML 1801-2400 IU	00944304510
04/01/2019-06/30/2019	ADVATE BAXJECT III 5ML 2401- 3600 IU	00944304610
04/01/2019-06/30/2019	ADVATE BAXJECT III 5ML 3601- 4800 IU	00944304710
04/01/2019-06/30/2019	FLEXBUMIN 25% Solution 100ML	00944049302
04/01/2019-06/30/2019	FLEXBUMIN 5% Solution 250ML	00944049505
04/01/2019-06/30/2019	FLEXBUMIN 25% Solution 50ML	00944049301
04/01/2019-06/30/2019	GAMMAGARD S/D LOW IGA 10G Vial	00944265804
04/01/2019-06/30/2019	GAMMAGARD S/D LOW IGA 5G Vial	00944265603
04/01/2019-06/30/2019	HEMOFIL M NF AHF 1501-2000 IU in 10mL	00944394602
04/01/2019-06/30/2019	HEMOFIL M NF AHF 1501-2000 IU in 10mL	00944394002
04/01/2019-06/30/2019	HEMOFIL M NF AHF 401-800 IU in 10mL	00944394202
04/01/2019-06/30/2019	HEMOFIL M NF AHF 801-1500 IU in 10mL	00944394402
04/01/2019-06/30/2019	LIALDA 1.2g TABLETS 120	54092047612
04/01/2019-06/30/2019	RECOMBINATE BJII 5ML 1241-1800 AU	00944284410
04/01/2019-06/30/2019	RECOMBINATE BJII 5ML 1801-2400 AU	00944284510
04/01/2019-06/30/2019	RECOMBINATE BJII 5ML 220-400 AU	00944284110
04/01/2019-06/30/2019	RECOMBINATE BJII 5ML 401-800 AU	00944284210
04/01/2019-06/30/2019	RECOMBINATE BJII 5ML 801-1240 AU	00944284310
04/01/2019-06/30/2019	VONVENDI 650AQ 5ML 450-850 IU	00944755102
04/01/2019-06/30/2019	XIIDRA 5% 12ML Ampule 60	54092060601

07/01/2019-09/30/2019	COLCRYSs 0.6mg 100ct	64764011901
07/01/2019-09/30/2019	COLCRYS 0.6mg 30ct	64764011907
07/01/2019-09/30/2019	DUETACT 30mg/4mg 30ct	64764030430
07/01/2019-09/30/2019	NESINA 12.5mg 30ct	64764012530
07/01/2019-09/30/2019	NESINA 25mg 30ct	64764025030
07/01/2019-09/30/2019	OSENI 12.5/45mg 30ct	64764012403
07/01/2019-09/30/2019	OSENI 25/30mg 30ct	64764025303
07/01/2019-09/30/2019	ULORIC 40mg 30ct	64764091830
07/01/2019-09/30/2019	VYVANSE 10MG CAPSULES 100	59417010110
07/01/2019-09/30/2019	VYVANSE 20MG CAPSULES 100	59417010210
07/01/2019-09/30/2019	VYVANSE 30MG CAPSULES 100	59417010310
07/01/2019-09/30/2019	VYVANSE 40MG CAPSULES 100	59417010410
07/01/2019-09/30/2019	VYVANSE 50MG CAPSULES 100	59417010510
07/01/2019-09/30/2019	VYVANSE 60MG CAPSULES 100	59417010610
07/01/2019-09/30/2019	VYVANSE 70MG CAPSULES 100	59417010710
07/01/2019-09/30/2019	VYVANSE CHEWABLE 40 MG 100	59417011801
07/01/2019-09/30/2019	VYVANSE CHEWABLE 50 MG 100	59417011901
07/01/2019-09/30/2019	VYVANSE CHEWABLE 60 MG 100	59417012001
10/01/2019-12/31/2019	AMITIZA 24mcg 60ct	64764024060
10/01/2019-12/31/2019	NESINA 25mg 30ct	64764025030
10/01/2019-12/31/2019	OSENI 25/30mg 30ct	64764025303
10/01/2019-12/31/2019	OSENI 25/45mg 30ct	64764025403
10/01/2019-12/31/2019	ULORIC 40mg 30ct	64764091830
10/01/2019-12/31/2019	ULORIC 80mg 30ct	64764067730
10/01/2019-12/31/2019	VYVANSE 10MG CAPSULES 100	59417010110
10/01/2019-12/31/2019	VYVANSE 20MG CAPSULES 100	59417010210
10/01/2019-12/31/2019	VYVANSE 30MG CAPSULES 100	59417010310
10/01/2019-12/31/2019	VYVANSE 40MG CAPSULES 100	59417010410
10/01/2019-12/31/2019	VYVANSE 50MG CAPSULES 100	59417010510
10/01/2019-12/31/2019	VYVANSE 60MG CAPSULES 100	59417010610
10/01/2019-12/31/2019	VYVANSE 70MG CAPSULES 100	59417010710
10/01/2019-12/31/2019	VYVANSE CHEWABLE 10 MG 100	59417011501

10/01/2019-12/31/2019	VYVANSE CHEWABLE 20 MG 100	59417011601
10/01/2019-12/31/2019	VYVANSE CHEWABLE 30 MG 100	59417011701
10/01/2019-12/31/2019	VYVANSE CHEWABLE 40 MG 100	59417011801
10/01/2019-12/31/2019	VYVANSE CHEWABLE 50 MG 100	59417011901
10/01/2019-12/31/2019	VYVANSE CHEWABLE 60 MG 100	59417012001
01/01/2020-03/31/2020	COLCRYS 0.6mg 100ct	64764011901
01/01/2020-03/31/2020	COLCRYS 0.6mg 30ct	64764011907
01/01/2020-03/31/2020	DUETACT 30mg/4mg 30ct	64764030430
01/01/2020-03/31/2020	KAZANO 12.5/1000mg 60ct	64764033760
01/01/2020-03/31/2020	KAZANO 12.5/500mg 60ct	64764033560
01/01/2020-03/31/2020	MOTTEGRITY 1MG TABLETS 30	54092054601
01/01/2020-03/31/2020	NESINA 12.5mg 30ct	64764012530
01/01/2020-03/31/2020	PENTASA 500MG CAPSULES 120	54092019112
01/01/2020-03/31/2020	TRINTELLIX 5mg 30ct	64764072030
01/01/2020-03/31/2020	VYVANSE 10MG CAPSULES 100	59417010110
01/01/2020-03/31/2020	VYVANSE 20MG CAPSULES 100	59417010210
01/01/2020-03/31/2020	VYVANSE 30MG CAPSULES 100	59417010310
01/01/2020-03/31/2020	VYVANSE 40MG CAPSULES 100	59417010410
01/01/2020-03/31/2020	VYVANSE 50MG CAPSULES 100	59417010510
01/01/2020-03/31/2020	VYVANSE 60MG CAPSULES 100	59417010610
01/01/2020-03/31/2020	VYVANSE 70MG CAPSULES 100	59417010710
04/01/2020-06/30/2020	Colcrys 0.6mg 100ct	64764011901
04/01/2020-06/30/2020	Colcrys 0.6mg 30ct	64764011907
04/01/2020-06/30/2020	Oseni 25/30mg 30ct	64764025303
04/01/2020-06/30/2020	PENTASA 500MG CAPSULES 120	54092019112
04/01/2020-06/30/2020	Trintellix 20mg 30ct	64764075030
04/01/2020-06/30/2020	VYVANSE 20MG CAPSULES 100	59417010210
04/01/2020-06/30/2020	VYVANSE 60MG CAPSULES 100	59417010610
01/01/2021-03/31/2021	AMITIZA 24mcg 60ct	64764024060
01/01/2021-03/31/2021	FIRAZYR Subcutaneous Solution 30 MG/3ML – 1 ct	54092070202
01/01/2021-03/31/2021	FIRAZYR Subcutaneous Solution 30 MG/3ML – 3 ct	54092070203
01/01/2021-03/31/2021	KAZANO 12.5/500mg 60ct	64764033560

01/01/2021-03/31/2021	MYDAYIS Capsule Extended Release 24 Hour 25 MG	54092047101
01/01/2021-03/31/2021	MYDAYIS Capsule Extended Release 24 Hour 37.5 MG	54092047401
01/01/2021-03/31/2021	MYDAYIS Capsule Extended Release 24 Hour 50 MG	54092047701
01/01/2021-03/31/2021	TRINTELLIX 5mg 30ct	64764072030
01/01/2021-03/31/2021	TRINTELLIX 10mg Tablet	64764073030
01/01/2021-03/31/2021	TRINTELLIX 20mg Tablet	64764075030
01/01/2021-03/31/2021	VYVANSE 10MG CAPSULES 100	59417010110
01/01/2021-03/31/2021	VYVANSE 20MG CAPSULES 100	59417010210
01/01/2021-03/31/2021	VYVANSE 30MG CAPSULES 100	59417010310
01/01/2021-03/31/2021	VYVANSE 40MG CAPSULES 100	59417010410
01/01/2021-03/31/2021	VYVANSE 50MG CAPSULES 100	59417010510
01/01/2021-03/31/2021	VYVANSE 60MG CAPSULES 100	59417010610
01/01/2021-03/31/2021	VYVANSE 70MG CAPSULES 100	59417010710
01/01/2021-03/31/2021	VYVANSE CHEWABLE 10 MG 100	59417011501
01/01/2021-03/31/2021	VYVANSE CHEWABLE 20 MG 100	59417011601
01/01/2021-03/31/2021	VYVANSE CHEWABLE 30 MG 100	59417011701
01/01/2021-03/31/2021	VYVANSE CHEWABLE 40 MG 100	59417011801
01/01/2021-03/31/2021	VYVANSE CHEWABLE 50 MG 100	59417011901
01/01/2021-03/31/2021	VYVANSE CHEWABLE 60 MG 100	59417012001
04/01/2021-06/30/2021	FIRAZYR Subcutaneous Solution 30 MG/3ML – 1 ct	54092070202
04/01/2021-06/30/2021	FIRAZYR Subcutaneous Solution 30 MG/3ML – 3 ct	54092070203
04/01/2021-06/30/2021	MYDAYIS Capsule Extended Release 24 Hour 12.5 MG	54092046801
04/01/2021-06/30/2021	MYDAYIS Capsule Extended Release 24 Hour 37.5 MG	54092047401
04/01/2021-06/30/2021	MYDAYIS Capsule Extended Release 24 Hour 50 MG	54092047701
04/01/2021-06/30/2021	TRINTELLIX 5mg 30ct	64764072030
04/01/2021-06/30/2021	TRINTELLIX 10mg Tablet	64764073030
04/01/2021-06/30/2021	TRINTELLIX 20mg Tablet	64764075030
04/01/2021-06/30/2021	VYVANSE 10MG CAPSULES 100	59417010110
04/01/2021-06/30/2021	VYVANSE 20MG CAPSULES 100	59417010210
04/01/2021-06/30/2021	VYVANSE 30MG CAPSULES 100	59417010310
04/01/2021-06/30/2021	VYVANSE 40MG CAPSULES 100	59417010410
04/01/2021-06/30/2021	VYVANSE 50MG CAPSULES 100	59417010510

04/01/2021-06/30/2021	VYVANSE 60MG CAPSULES 100	59417010610
04/01/2021-06/30/2021	VYVANSE 70MG CAPSULES 100	59417010710
04/01/2021-06/30/2021	VYVANSE CHEWABLE 10 MG 100	59417011501
04/01/2021-06/30/2021	VYVANSE CHEWABLE 20 MG 100	59417011601
04/01/2021-06/30/2021	VYVANSE CHEWABLE 30 MG 100	59417011701
04/01/2021-06/30/2021	VYVANSE CHEWABLE 40 MG 100	59417011801
04/01/2021-06/30/2021	VYVANSE CHEWABLE 50 MG 100	59417011901
04/01/2021-06/30/2021	VYVANSE CHEWABLE 60 MG 100	59417012001

Takeda will be working through Apexus, the HRSA 340B Prime Vendor, to issue refunds to Covered Entities who are entitled to a refund in the aggregate (across all NDCs above) of \$100 or more. Apexus will facilitate the payments of refunds to a Covered Entity's Authorized Distributor. The Distributor will then credit the respective Covered Entity's account. If an active wholesaler account cannot be identified, Apexus will work to issue an ACH or check to those entities.

340B Covered Entities who are entitled to a refund of less than \$100 in aggregate for the above NDCs will not be contacted by, or on behalf of, Takeda. Instead, Takeda is offering a refund to those 340B Covered Entities through this Notice. If a 340B Covered Entity does not receive a communication from, or on behalf of, Takeda and believes it is entitled to a refund, it should contact Takeda at the following email address: takedachargebacks@takeda.com, with a subject line of "340B Refund" and its Covered Entity 340B ID. In addition, please include in the body of your email: NDC Number, Quantity, Original Purchase Invoice Number, Invoice Date, and the Wholesaler the product was purchased through for all affected products so that we can research your inquiry further.

Takeda 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 above products during the relevant time periods. Please direct any questions and/or requests for additional information to Takeda at the following email address: takedachargebacks@takeda.com.