

Pharmaceutical Manufacturer 340B Price Restriction Policies and Exemptions Summary*

Applicable CE** Types	Manufacturer & Applicable Drugs	Exception Policy
All CE Types	AstraZeneca Bevespi Aerosphere, Breztri Aerosphere, Brilinta, Bydureon, Byetta, Crestor, Daliresp, Farxiga, Kombiglyze XR, Okelma, Nexium, Onglyza, Pulmicort, Qtern, Seroquel, Seroquel XR, Symbicort, Symlin, Xigduo XR	One CP: CEs without an in-house pharmacy may designate one CP
	Bausch Health Applies to all drugs	One CP: CEs without an in-house pharmacy may designate one CP within 40 miles of the parent site Owned/Affiliated: Treated same as other CPs
	Boehringer Ingelheim Applies to all drugs	One CP, Geographical: For BI's "primary care" drugs, CEs without an in-house pharmacy may designate one CP that is not a central fill pharmacy and is within 40 miles of the parent site One Specialty CP for OFEV: For specialty drug OFEV/Nintedanib: (1) CE with an in-house pharmacy capable of dispensing OFEV may use that pharmacy; (2) CE without such an in-house pharmacy may designate one CP from BI's limited network Owned/Affiliated CP: Treated same as other CPs
	Bristol Myers Squibb (BMS) Immunomodulatory drugs (IMiDs): Revlimid, Pomalyst, and Thalomid	One CP: CEs without an in-house pharmacy in BMS' limited network may designate one CP from BMS' limited specialty pharmacy network REMS Program/340B Claims Data: CE may register and track patients with FDA; educate physician and patients before prescribing; dispense only at certain pharmacies; submit 340B claims data (not including payer data) to BMS Owned Pharmacies: CEs that own in-house pharmacies that are already party of BMS' limited specialty pharmacy network will continue to access 340B pricing through those pharmacies
	Eli Lilly Applies to all drugs	One Non-Central Fill CP: CEs without an in-house pharmacy may designate one CP that is not a central fill pharmacy: these CEs are not required to submit 340B claims data. Insulin Exception: 340B pricing on insulin products if (1) CP passes 340B price to patients at point of sale; (2) no markups or dispensing fees charged; (3) no insurer or payer is billed; and (4) CE provides claims data showing satisfaction of requirements Claims Data: CEs may submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs Owned/Affiliated CP: CPs that are wholly owned by CE hospital, or under common ownership with CE's health system, may receive 340B pricing without uploading claims data (CP must be registered for CE with HRSA)

* Subject to the exceptions and limitations explained herein, these manufacturers have restricted 340B pricing on drugs that are shipped to contract pharmacies.
 ** CE means a "covered entity" as described in the 340B statute at 42 U.S.C § 256b(a)(4); CP means "contract pharmacy" as described in HRSA's 2010 Contract Pharmacy Guidance at 75 Fed. Reg. 10,272-79 (Mar. 5, 2010).
 *** CHC means "consolidated health centers."

This document was created by the Powers 340B Team and is a summary only, based on publicly available information, and should not be construed or relied upon as legal advice. Information is current as of July 6, 2023. For an updated version of this chart or general 340B-related support, please email William von Oehsen at William.vonOehsen@PowersLaw.com, Barbara Williams at Barbara.Williams@PowersLaw.com, Peggy Tighe at Peggy.Tighe@PowersLaw.com, Jason Reddish at Jason.Reddish@PowersLaw.com, or Mark Ogunsusi at Mark.Ogunsusi@PowersLaw.com.



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	GSK Applies to all drugs	<u>One CP:</u> CEs without an in-house pharmacy may designate one CP (this one CP may be owned by/affiliated with CE) <u>One Specialty CP:</u> CE may designate one specialty CP that is part of the GSK specialty pharmacy network <u>Owned/Affiliated CP:</u> CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing
	United Therapeutics All drugs except Adcirca/Tadalafil	<u>Claims Data:</u> CEs may submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs
All Hospitals (except children's and cancer) and CHCs	Sanofi Applies to all drugs	<u>One CP:</u> CEs without an in-house pharmacy may designate one CP <u>Claims Data:</u> CHCs (not hospitals) may submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs <u>Owned/Affiliated CP:</u> For hospitals (not CHCs), treated same as other CPs
All Hospitals and CHCs***	Merck Belsomra, Januvia, Janumet, Janumet XR, Steglatro, Steglujan, Segluromet, and Verquvo	<u>One CP:</u> CEs without an in-house pharmacy may designate one CP within 40 miles of the parent site <u>Claims Data:</u> CEs may submit 340B claims data to 340B ESP platform to access 340B pricing at all contract pharmacies <u>Owned/Affiliated:</u> Treated same as other CPs
Hospitals Only	AbbVie Applies to 25 AbbVie drugs, including Humira/adalimumab and Imbruvica	<u>One CP, Claims Data, Geographical:</u> CEs without an in-house pharmacy may submit 340B claims data to 340B ESP platform to designate one CP within 40 miles of parent hospital site <u>One Specialty CP:</u> CEs that do not wholly own an in-house specialty pharmacy may designate one CP that is part of AbbVie's specialty pharmacy network (it is unclear whether claims data is required for designating one specialty CP) <u>Owned/Affiliated CP:</u> Treated same as other CPs



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Hospitals Only	<p>Amgen Repatha, Enbrel, Otezla, and Aimovig, Amijevita, Tezspire</p>	<p>One CP, Geographical: CEs without an in-house pharmacy may designate one CP within 40 miles of parent hospital site One CP (in-house permitted), Claims Data, Geographical: CEs that have an in-house pharmacy may submit 340B claims data to 340B ESP for both the CP and in-house pharmacy to designate one CP within 40 miles of parent hospital site (this one CP may be owned by/affiliated with CE) Owned/Affiliated CP: Treated same as other CPs</p>
	<p>Astellas Xtandi (enzalutamide)</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP Owned/Affiliated: Treated same as other CPs</p>
	<p>Bayer All Bayer drugs except Aliqopa, Jivi, Kerendia, Kogenate, Kovaltry, Kyleena, Lampit, Mirena, Skyla, Nubeqa, Xofigo</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP within 40 miles of the parent site for applicable drugs except Adempas One Specialty CP: CEs may designate one specialty CP that is part of Bayer's limited distribution network to dispense Adempas Owned/Affiliated: Treated same as other CPs</p>
	<p>Biogen Avonex and Plegridy</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP and are not required to submit 340B claims data Owned/Affiliated CP: CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing at these pharmacies only</p>
	<p>Bristol Myers Squibb (BMS) Non-immunomodulatory drugs (non-IMiDs)</p>	<p>One CP: CE hospitals without an in-house pharmacy may designate one CP Owned/Affiliated CP: CPs that are wholly owned by CE hospital, or under common ownership with hospital's health system, may receive 340B pricing</p>
	<p>EMD Serono Rebif and Gonal-f</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP and are not required to submit 340B claims data Owned/Affiliated CP: CPs that are wholly owned by CE hospital, or under common ownership with CE's health system, may receive 340B pricing</p>
	<p>Exelixis Applies to Cometriq and Cabometyx</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP and are not required to submit 340B claims data Claims Data: CEs may submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs Owned/Affiliated: Treated same as other CPs</p>



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	<p>Novartis Applies to all drugs</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP Owned/Affiliated CP: CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing and the CE may not designate another CP</p>
	<p>Novo Nordisk Applies to all drugs</p>	<p>One CP: CEs may designate one retail CP regardless of whether the CE has an in-house pharmacy One Specialty CP: CEs may designate one specialty CP regardless of whether the CE has an in-house specialty pharmacy Owned or Affiliated CPs/Claims Data: CEs may designate multiple owned or affiliated CPs if they submit claims data for those CPs</p>
	<p>Organon Applies to all drugs</p>	<p>One CP/Claims Data: CEs without an in-house pharmacy may designate one CP and may submit claims data for that CP Owned/Affiliated: Treated same as other CPs</p>
	<p>Pfizer Xeljanz (tofacitinib), Xalkori (crizotinib), Inlyta (axitinib), Sutent (sunitinib), Bosulif (bosutinib), and Ibrance (palbociclib)</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP Claims Data: CEs may submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs (except for Xeljanz) One Specialty CP: CE may designate one specialty CP that is part of the Pfizer's Designated Oncology Network to dispense Xeljanz Owned/Affiliated: Treated same as other CPs</p>
	<p>Teva Applies primarily to Teva's brand name drugs</p>	<p>One CP/Claims Data: CEs without an in-house pharmacy may designate one CP and may submit claims data for that CP Owned/Affiliated: Treated same as other CPs</p>
	<p>UCB Applies to all drugs</p>	<p>One CP: CEs without an in-house pharmacy may designate one CP Owned/Affiliated CP: CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing</p>



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