

Pharmaceutical Manufacturer 340B Price Restriction Policies and Exemptions Summary*

Applicable CE** Types	Manufacturer & Applicable Drugs	Exception Policy
All CE Types	AstraZeneca Applies to all drugs	One CP: CEs that do not have an onsite dispensing pharmacy may designate one CP
	Bausch Health Applies to all drugs	One CP: CEs that do not have an in-house pharmacy may designate one CP and are not required to submit 340B claims data Claims Data: CEs must submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs (including payer data) Owned/Affiliated CP: CPs that are wholly owned by the CE may receive 340B pricing, even without uploading claims data
	Bristol Myers Squibb (BMS) Immunomodulatory drugs (IMiDs): Revlimid, Pomalyst, and Thalomid	One CP: CEs that do not have an in-house pharmacy in BMS' limited network may designate one CP from BMS' limited specialty pharmacy network REMS Program/340B Claims Data: CE must 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 that do not have 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 must submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs (including payer 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, even without uploading claims data (CP must be registered for CE with HRSA)
	Gilead Brand Hepatitis C products: Eplclusa (sofosbuvir / velpatasvir), Harvoni (ledipasvir / sofosbuvir), Sovaldi (sofosbuvir) and Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	One CP: CEs that do not have an in-house pharmacy may designate one CP and are not required to submit 340B claims data Claims Data: CEs must submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs (including payer data) Owned/Affiliated CP: CPs that are wholly owned by CE hospital may receive 340B pricing, even without uploading claims data (CP must be registered for CE with HRSA)
	GSK Applies to all drugs	One CP: CEs without an in-house pharmacy may access 340B pricing at one CP (this one CP may be owned by/affiliated with CE) One Specialty CP: CE may designate one specialty CP that is part of the GSK specialty pharmacy network Owned/Affiliated CP: CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing

* 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;" CAH means "critical access hospitals;" DSH means "disproportionate share hospitals;" RRC means "rural referral centers;" SCH means "sole community hospitals."

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 May 1, 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, or Mark Ogunsusi at Mark.Ogunsusi@PowersLaw.com.



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All CE Types	United Therapeutics All drugs except Adcirca/Tadalafil	Claims Data: CEs must submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs
All Hospitals (except cancer) and CHCs	Sanofi Applies to all drugs	One CP: CE hospital without an in-house pharmacy may designate one CP and is not required to submit 340B claims data Claims Data: CEs must submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs
All Hospitals and CHCs***	Boehringer Ingelheim All drugs except specialty drugs Gilotrif and Praxbind	One CP: CEs without an in-house pharmacy may designate one CP One Specialty CP for OFEV: For specialty drug OFEV/Nintedanib: (1) CE with in-house pharmacy capable of dispensing OFEV must use that pharmacy; (2) CE without in-house specialty pharmacy, may designate one contract pharmacy from BI's limited network; and (3) CE with wholly-owned/affiliated contract pharmacy may use that pharmacy Owned/Affiliated CP: CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing, without uploading claims data
	Merck Applies to all drugs	One CP: CEs without an on-site pharmacy may designate one CP and are not required to submit 340B claims data Claims Data: CEs must submit 340B claims data to 340B ESP platform to access 340B pricing at all
Hospitals Only	AbbVie Applies to 25 AbbVie drugs, including Humira/adalimumab and Imbruvica	One CP, Claims Data, Geographical: CEs without an in-house pharmacy must submit 340B claims data to 340B ESP platform to access 340B pricing at one CP within 40 miles of parent hospital site One Specialty CP: 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) Owned/Affiliated CP: Treated same as other CPs
	Amgen Repatha, Enbrel, Otezla, and Aimovig, Amijevita, Tezspire	One CP, Geographical: CEs without an in-house pharmacy may access 340B pricing at one CP within 40 miles of parent hospital site One CP (in-house permitted), Claims Data, Geographical: CEs that have an in-house pharmacy must submit 340B claims data to 340B ESP for both the CP and in-house pharmacy to access 340B pricing at 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



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Hospitals Only	<p>Bayer All Bayer drugs except Adempas, Aliqopa, Jivi, Kerendia, Kogenate, Kovaltry, Kyleena, Lampit, Mirena, Skyla, Nubeqa, Xofigo</p>	<p>One CP: CEs that do not have an on-site pharmacy may designate one CP and are not required to submit 340B claims data Claims Data: CEs must 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, 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)</p>
	<p>Biogen Avonex and Plegridy</p>	<p>One CP: CEs that do not have an on-site 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 on-site 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 in-house pharmacy may designate one CP and are not required to submit 340B claims data Claims Data: CEs must 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, or under common ownership with CE's health system, may receive 340B pricing, without uploading claims data</p>
	<p>Johnson & Johnson <u>Pulmonary arterial hypertension drugs (PAHs):</u> Opsumit, Tracleer, Upravi, Veletri <u>Non-PAH drugs:</u> Stelara, Tremfya, Simponi Aria, Simponi, Remicade, Xarelto, Invokamet, Invokamet XR, Invokana, Darzalex, Darzalex Faspro, Erleada, Invega HafyeraTM, Invega Sustenna, Invega Trinza, Invega, Symtuza, Prezcobix, Prezista, Zytiga, Procrit, Edurant, Elmiron, Topamax, Yondelis, Rybrevant</p>	<p>One CP, Claims Data, Geographical: CEs <i>without an in-house pharmacy</i> must submit CP 340B claims data to 340B ESP platform to access 340B pricing at one CP within 40 miles of parent hospital site One CP (in-house permitted), Claims Data, Geographical: CEs <i>that have an in-house pharmacy</i> must submit 340B claims data to 340B ESP for both the CP and in-house pharmacy to access 340B pricing at one CP within 40 miles of parent hospital site One Specialty CP, Claims Data: CE may designate one specialty CP that is part of the J&J specialty pharmacy network and submit claims data to 340B ESP for CP "End Customer" Distribution Restriction: End customer (the CE or one CP) is prohibited from further distributing 340B drugs to any non-CE location Owned/Affiliated CP: Treated same as other CPs</p>



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Hospitals Only	<p>Novartis Applies to all drugs</p>	<p>One CP: CEs without an in-house pharmacy may access 340B pricing at 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 that do not wholly own a CP may designate one non-specialty CP (without submitting claims data) Claims Data: CEs must submit 340B claims data to 340B ESP platform to access 340B pricing at all CPs One Specialty CP: CEs that do not wholly own an in-house specialty pharmacy may designate one CP (in addition to one non-specialty CP and without submitting 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, without uploading claims data</p>
	<p>Pfizer Xeljanz (tofacitinib), Xalkori (crizotinib), Inlyta (axitinib), Sutent (sunitinib), Bosulif (bosutinib), and Ibrance (palbociclib)</p>	<p>One CP: CEs that do not have an in-house pharmacy may designate one CP Claims Data: CEs must 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 CP: CPs that are wholly owned by CE, or under common ownership with CE's health system, may receive 340B pricing, even without uploading claims data; for Xeljanz, these pharmacies are treated like 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, even without uploading claims data (CP must be registered for CE with HRSA)</p>



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