

## DRUG MANUFACTURER 340B POLICY SUMMARY

**MAY 2024** 

Number	Drug Manufacturer	Impacted 340B CE Types	Grantee Exemption	Manufacturer Using		Allows CP Designation Only (No Data Required)		CP <sup>s</sup> Must be within 40 Miles of	of LDD <sup>5</sup> /	Submission of Claims Data to 340BESP™	Allowed with Claims	340BESP™ Claim Submission	Products Impacted	NDCs Listed On 340B	State Exemption	Policy Start Date	Policy Last Updated
				340BESP™	Pharmacy Exemption	if CE has In-House <sup>4</sup> Pharmacy	nouse Pharmacy	Parent	Specialty Pharmacy	Required	340BESP™	Lookback Period <sup>®</sup>	See 340BESP™,	ESP™			
1	abbvie	Hospitals	Yes	Yes	No	No	Yes, 1 Retail & 1 Specialty	Yes	Yes	Yes Yes, if in-house	No	45 Days	Duopa™ and Imbruvica® are LDD⁵	Yes		2/1/2022	5/1/2024
2	AMGEN	All CE's	No	Yes	No	Yes	Yes, Wholly Owned or CP	Yes	No	must submit data for CP & in- house	No	45 Days	See 340BESP™	Yes	AR	12/31/2021	4/2/2024
3	astellas	Hospitals	Yes	Yes	No	No	Yes	No	Yes, Xtandi <sup>®</sup>	No	No	N/A	Xtandi <sup>®</sup> & Myrbetriq <sup>®</sup> NDCs from Medi-Span	No	AR, LA	9/1/2023	5/1/2024
4	AstraZeneca	All CE's	No	Yes	No	No	Yes	No	No	No	No	45 Days	See 340BESP™	Yes		10/1/2020	8/1/2023
5	BAUSCH Health	All CE's	No	Yes	No	No	Yes	Yes	No	No	No	45 Days	See 340BESP™	Yes	AR	8/1/2022	3/12/2024
6	BAYER ER R	Hospitals	Yes	Yes	No	Νο	Yes, Wholly Owned or CP	Yes	Yes, for drug Adempas®	No	Νο	45 Days	See 340BESP™, Adempas is LDD⁵	Yes	AR	3/1/2023	4/1/2024
7	Biogen	Hospitals	Yes	Yes	Yes	Νο	Yes, but not if Wholly Owned Exemption	Νο	Νο	Νο	Νο	N/A	Avonex <sup>®</sup> and Plegridy <sup>®</sup> , NDCs from Medi-Span	Νο		2/1/2023	12/1/2023
8	Boehringer Ingelheim	All CE's	No	Yes	No	Νο	Yes, Wholly Owned or CP	Yes	Yes, for drug OFEV®	No	No	N/A	See 340BESP™	Yes		8/1/2021	8/1/2023
9	( <sup>III)</sup> Bristol Myers Squibb	All CE's	No	Yes	No	Νο	Yes, 1 for IMiD drugs,1 for non-IMiD drugs and 1 for Camzyos®	No	Yes	Yes, for IMiDs Only (Claim Data to BMS Directly)	No	60 Days for IMiDs	BMS provides non- IMiD NDCs. other NDCs from Medi-Span	No	AR	3/1/2022	3/28/2024
10	Eisai	Hospitals	Yes	Yes	No	No	Yes, Wholly Owned or CP	No	Yes	No	No	N/A	NDCs per manufacturer's latest policy	No		11/1/2023	
11	EMD	Hospitals	Yes	Yes	Yes	No	Yes, if no in-house or wholly owned	No	Yes, for Serostim®	No	No	N/A	NDCs per manufacturer's latest policy	No		3/1/2023	10/1/2023
12	EXELIXIS	Hospitals	Yes	Yes	Yes, with Data Submission	No	Yes	No	N/A - Policy only applies to LDD Products	Yes	Yes	45 Days	Cometriq <sup>®</sup> and Cabometyx <sup>®</sup> , See 340BESP™	Yes		7/6/2022	6/26/2023
13	<b>Genentech</b> A Member of the Roche Group	Hospitals	Yes	Yes	Νο	No	Yes	Νο	Νο	No	Νο	N/A	See 340BESP™	Yes		5/1/2024	
14	🌠 GILEAD	All CE's	No	Yes	Νο	No	Yes, Wholly Owned or CP	No	No	No	Yes	45 Days	See 340BESP™, Hepatitis C products Epclusa <sup>®</sup> , Harvoni <sup>®</sup> , Sovaldi <sup>®</sup> , Vosevi <sup>®</sup>	Yes		5/2/2022	1/30/2024
15	GlaxoSmithKline	All CE's	Νο	Yes	Yes	Νο	Yes	No	Yes	Νο	Νο	N/A	NDCs per manufacturer's latest policy	No		4/1/2022	11/1/2023
16	Incyte	Hospitals	Yes	Yes	No	Νο	Yes, Wholly Owned or CP	Νο	No	No	Νο	N/A	Opzelura®, See 340BESP™	Yes		10/16/23	
17	Jazz Pharmaceuticals.	Hospitals	Yes	Yes	No	Νο	Yes, Wholly Owned or CP	No	Νο	No	Νο	N/A	Epidiolex <sup>®</sup> , NDCs per manufacturer's latest policy	No		10/9/2023	
18	Johnson "Johnson	Hospitals	Yes	Yes	Νο	Yes, Wholly Owned or CP, Data from In-House Required	Yes, Wholly Owned or CP with Data Required	Yes	Yes, PAH LDD Drugs	Yes	Νο	45 Days	See 340BESP™, PAH LDD⁵ Drugs	Yes		5/2/2022	3/7/2023
19	Lilly	All CE's	Νο	Yes	Yes	Νο	Yes	Νο	Νο	Νο	Yes, (Insulin 340B Cost Must be Passed to Patient. No Mark-up for CE or Pharmacy.)	45 Days	See 340BESP™	Yes		9/1/2020	11/16/2023
20	🕅 Liquidia	All CE's	Νο	Yes	No	No	Yes, single Accredo or Caremark/CVS Specialty	Νο	No	Yes	No	45 Days	Yutrepia™ Not Currently FDA Approved	Yes	AR	4/1/2024	
21		Hospitals, CH/CHC	Yes, Except CH/CHC	Yes	No	Νο	Yes, Wholly Owned or CP	Yes	No	No	Νο	45 Days	See 340BESP™	Yes	AR, LA <sup>8</sup>	9/1/2021	4/12/2024
22	J	Hospitals	Yes	Yes	Yes	No	Yes	No	No	No	Νο	N/A	See 340BESP™	Yes		11/16/2020	5/1/2023
23	NOVARTIS	Hospitals	Yes	Yes	Yes, with Data Submission	Yes, 1 Retail & 1 Specialty	Yes, 1 Retail & 1 Specialty	No	Yes	No	Νο	45 Days	See 340BESP™	Yes	AR <sup>8</sup>	1/1/2021	1/19/2024
24	novo nordisk <sup>®</sup>	Hospitals	Yes	Yes	Νο	No	Yes, Wholly Owned or CP with Data Required	No	No	Yes	Νο	45 Days	See 340BESP™	Yes	AR, LA <sup>8</sup>	7/1/2023	12/1/2023
25	<b>Pfizer</b>	Hospitals	Yes	Yes	Yes, Oral Oncology & Vyndamax <sup>®</sup> and Vyndaqel <sup>®</sup>	Νο	Yes	No	Yes	No	Yes, Oral Oncology & Vyndamax <sup>®</sup> and Vyndaqel <sup>®</sup>	45 Days	See 340BESP™	Yes	AR, LA	3/1/2022	11/1/2023
26	SANDOZ	Hospitals	Yes	Yes	Yes	No	Yes, Data Required	Yes	No	Yes	No	Not Defined	See 340BESP™	Yes	AR, LA	12/1/2023	
27	sanofi	CAH, DSH, RRC, SCH & CH/CHC	Yes, Except CH/CHC	Yes	Yes, CH/CHC Only	Yes, CH/CHC Only	Yes, Wholly Owned or CP with Data Required	Νο	Νο	No	Yes, CH/CHC Only	45 Days	See 340BESP™	Yes	AR	10/1/2020	3/18/2024
28	Sumitomo Pharma	All CE's	No	Yes	Yes, for Orgovyx®	No	Yes	Yes	Yes, for Orgovyx®	No	No	45 Days	See 340BESP™	Yes	AR, LA <sup>8</sup>	5/1/2024	
29	Takeda	Hospitals	Yes	Yes	Yes, with Data Submission	No	Yes, Wholly Owned or CP with Data Required	Yes	Yes	Yes	Νο	45 Days	See 340BESP™	Yes		1/22/2024	3/22/2024
30	teva	Hospitals	Yes	Yes	No	No	Yes, Wholly Owned or CP with Data Required	Yes	No	Yes	No	45 Days	See 340BESP™	Yes	AR	7/5/2023	4/8/2024
31		Hospitals	Yes	Yes	No	No	Yes	No	No	No	No	N/A	NDCs per manufacturer's latest	No		12/13/2021	10/2/2023
	🛋 United												policy All drugs except				
32	C O R P O R A T I O N	All CE's	No	Yes	No	Yes	Yes	No	No	Yes	Yes	Not Defined	Adcirca®, See 340BESP™	Yes		11/20/2020	12/1/2021

Key Terms	Definition
<sup>1</sup> Grantee Exemption	Grantee exemption means that the drug manufacturer policy does not apply to federal grantees. Federal grantees. Federal grantees that receive certain Federal grants, Federal contracts, Federal designations, or establish Federal projects.
<sup>2</sup> Wholly Owned/Common Ownership	Pharmacies registered as contract pharmacies which are wholly owned by a 340B covered entity or have common ownership with a 340B covered entity.
<sup>3</sup> CP	CP stands for Contract Pharmacy.
<sup>4</sup> In-house	Pharmacies which are owned by the 340B covered entity but not registered as a contract pharmacy. The pharmacy shipping address should appear on the 340B OPAIS database under shipping addresses.
<sup>5</sup> LDD	LDD stands for limited distribution drug. A limited distribution drug is a specialty drug which the pharmaceutical manufacturer has limited the number of specialty pharmacies that have access to the drug.
<sup>6</sup> Lookback Period	Once 340B pricing is restored for a specific contract pharmacy, the covered entity may then place a replenishment order for those qualified claims with a fill date that occurred within the 45 days prior to the data submission).
State Exemption	Manufacturers' policy specifically defines the policy does not apply in a State(s). AR = Arkansas, LA = Louisiana.
<sup>8</sup> State Exemption Limitation	CE required to submit data via 340B ESP™ or required to submit data via 340B ESP™ for 340B pricing at all contract pharmacies.





