



900 Ridgebury Rd./P.O. Box 368
Ridgefield, CT 06877-0368
Telephone (203) 798-9988

June 22, 2023

**Notice to 340B Covered Entities:
Update to Boehringer Ingelheim Contract Pharmacy Policy
Effective August 1, 2023**

Dear 340B Covered Entity:

I am writing to inform you that Boehringer Ingelheim Pharmaceuticals, Inc. (BI) is updating its 340B Program contract pharmacy policies that went into effect on August 1, 2021 (Primary Care), December 1, 2021 (OFEV), and September 1, 2022 (CH/CHC covered entity type), respectively. **Please review this information carefully, as you will be required to take action even if you have previously designated a single contract pharmacy and do not believe that your existing contract pharmacy designation is changing.**

Effective August 1, 2023, BI will implement the changes described below to its 340B Program contract pharmacy policy for all covered entity types. This update to our contract pharmacy policy includes BI's entire primary care portfolio and its specialty product OFEV. OFEV is subject to a limited distribution network that includes several specialty pharmacies approved by BI to purchase and dispense OFEV, and a number of in-house pharmacies that are capable of dispensing specialty care products.

First, covered entities that are non-CH/CHC covered entity type Federal grantees are no longer exempt from BI's 340B Program contract pharmacy policy. As a result, except as provided below, BI will no longer provide drugs at the 340B price on shipments of BI products to contract pharmacies, regardless of covered entity type.

Second, BI is revising the exceptions to its contract pharmacy policy to eliminate the exception for shipments to pharmacies that are wholly owned by a covered entity, and to require that any contract pharmacy permissible under BI's policy (except for those dispensing OFEV, as noted below) meet geographic proximity standards relative to the covered entity. To ensure that all 340B covered entity types and their patients continue to have access to life-enhancing products purchased at the 340B price, BI will voluntarily apply the following general exceptions to its approach:

- Any covered entity that does not have an in-house pharmacy capable of dispensing primary care 340B purchased products to its patients may designate a single contract pharmacy location to receive and dispense products purchased at the 340B price. The designated contract pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy, located within a forty (40) mile radius of the covered entity parent site, and cannot be a central fill pharmacy. Contract pharmacies that are wholly owned by a 340B covered entity or are under common ownership with a 340B health system will no longer be separately eligible to receive "Bill To / Ship To" replenishment orders of 340B priced products. A wholly owned pharmacy may instead be designated as the single contract pharmacy location to dispense primary care brands provided it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy, is located within forty (40) miles of the covered entity parent site and is not a central fill pharmacy.

- Any covered entity that does not have an in-house pharmacy capable of dispensing specialty products may also designate one (1) specialty pharmacy from within BI's limited distribution network for the sole purpose of dispensing OFEV at the 340B price to its patients. Contract pharmacies that are wholly owned by a 340B covered entity or are under common ownership with a 340B health system will no longer be separately eligible to receive "Bill To / Ship To" replenishment orders of 340B priced products. A wholly owned pharmacy may instead be designated as a single contract pharmacy location to dispense OFEV provided it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy and is not a central fill pharmacy. If you have any questions regarding designation of a wholly owned contract pharmacy, please reach out to support@340besp.com.

BI is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. 340B covered entities that do not have an in-house pharmacy and have not already registered an account with 340B ESP™ can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a single contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding the change in our 340B distribution model, please contact us at support@340besp.com.

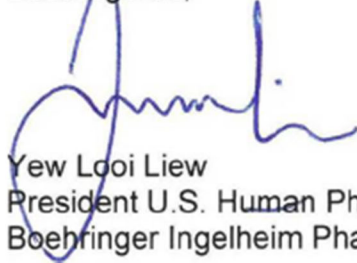
BI is not requiring the submission of limited 340B claims data for claims originating from contract pharmacies. Covered entities may voluntarily provide claims data for their designated contract pharmacy through 340B ESP™.

Covered entities must take action by July 14, 2023, in order for the single contract pharmacy location designation to take effect on the effective date of this policy. Covered entities that have already designated a single contract pharmacy on 340B ESP™, based on BI's previous 340B Program contract pharmacy policy, are required to re-designate a single contract pharmacy on the platform.

In support of a smooth transition to BI's updated 340B Program contract pharmacy policy, 340B covered entities should work with their contract pharmacy administrators and wholesalers/distributors to process any outstanding "Bill To / Ship To" replenishment orders in advance of the August 1, 2023, policy effective date. Subject to the general exceptions described above, PHS contracts administered by BI's wholesalers/distributors will no longer support distribution of 340B priced drugs to 340B contract pharmacies after July 31, 2023.

If you have any questions regarding BI's updated 340B Program contract pharmacy policy, please reach out to support@340besp.com.

Best regards,



Yew Looi Liew
President U.S. Human Pharma
Boehringer Ingelheim Pharmaceuticals, Inc.



Christine Marsh
Senior Vice President, Market Access
Boehringer Ingelheim Pharmaceuticals, Inc.

Frequently Asked Questions

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to BI's policy?

A: Yes, contract pharmacies that are wholly owned by the covered entity are subject to BI's policy. A wholly owned pharmacy may be designated as the single contract pharmacy location provided it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy, is located within a forty (40) mile radius of the covered entity parent site and is not a central fill pharmacy.

Q: Are non-Consolidated Health Center Federal Grantees still exempt from BI's policy?

A: No, under BI's policy, non-Consolidated Health Center Federal Grantees are no longer exempt from BI's 340B contract pharmacy policy.

Q: Will BI allow covered entities to submit claims data for an unlimited number of contract pharmacies?

A: No, under BI's policy, claims data is no longer an exception to permit use of an unlimited number of contract pharmacy locations. However, BI requests that covered entities voluntarily submit claims data.

Q: Does the pharmacy's location that I would like to designate as my single contract pharmacy designation need to be within a forty (40) mile radius of my covered entity's parent location?

A: Yes, under BI's policy, with the exception of OFEV, the single contract pharmacy designation that a covered entity has chosen to distribute BI product must be within a forty (40) mile radius of the covered entity's parent location.

Q: My covered entity utilizes a central-fill pharmacy. Will the central-fill pharmacy be deemed an eligible contract pharmacy when it is utilized to acquire or distribute covered outpatient drugs to a 340B eligible contract pharmacy?

A: No, under BI's policy, centralized pharmacy replenishment facilities or "central-fill pharmacies" are not eligible as designated retail or specialty pharmacy locations. BI will only facilitate shipment or replenishment to the contract pharmacy for product dispensed directly by that contract pharmacy at their own physical location.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing BI products, but we do not use it to dispense BI products. Can my covered entity designate one contract pharmacy instead?

A: No, under BI's policy, if a covered entity has an in-house pharmacy capable of purchasing at the 340B price and dispensing, the entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q: My covered entity has an in-house pharmacy that is capable of dispensing BI's primary care products but does not have the capability to dispense specialty products. Can my entity designate a contract pharmacy that is approved to purchase and dispense OFEV?

A: Yes, under BI's policy, a covered entity is eligible to designate a specialty pharmacy within BI's limited distribution network for OFEV or a wholly owned contract pharmacy capable of dispensing OFEV, if its in-house pharmacy does not have the capability to dispense specialty products.

Q: My covered entity has an in-house pharmacy that is capable of dispensing BI's primary care and specialty products but does not use it to dispense BI products. Can my entity designate its preferred contract pharmacy to dispense BI's primary care and specialty products instead of using its in-house pharmacy?

A: No, under BI's policy, if a covered entity has an in-house pharmacy capable of dispensing both primary care and specialty products, the entity must use that pharmacy and cannot designate a contract pharmacy. BI's limited distribution network gives all covered entity-owned pharmacies the ability to purchase its specialty products at the 340B price. So as long as the covered entity owned pharmacy can dispense OFEV, the entity is not eligible to make any contract pharmacy designations.

Q: My covered entity has an in-house pharmacy that can dispense both primary care and specialty products but does not have the capability to dispense OFEV. Can my entity designate a contract pharmacy that is approved to dispense OFEV?

A: Yes. Covered entities are eligible to make a contract pharmacy designation from within BI's limited distribution network for OFEV only if their covered entity owned pharmacy is not approved to dispense OFEV or such covered entity owned pharmacy does not have the capability to dispense OFEV.

Q: My covered entity does not have an in-house pharmacy and is eligible to designate a contract pharmacy to continue accessing BI products. My entity designated a contract pharmacy that can dispense both primary care and specialty products but cannot dispense OFEV. Can my entity designate another contract pharmacy that is approved to dispense OFEV?

A: Yes. Covered entities are eligible to make a second contract pharmacy designation from within BI's limited distribution network for OFEV only if their designated contract pharmacy is not approved to dispense OFEV or such designated contract pharmacy does not have the capability to dispense specialty products. Such a designation is solely for the purpose of purchasing and dispensing OFEV at the 340B price.

Q: How do I change my contract pharmacy designation?

A: 340B covered entities can elect a single contract pharmacy every twelve (12) months. Changes to the single contract pharmacy designation can only be made by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q: How often can I change my contract pharmacy designation?

A: Covered entities may change its contract pharmacy designation once every twelve (12) months (*from the date of designation*) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q: My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy. Can I designate all locations of the same pharmacy?

A: No. Similar to guidance provided by HRSA in 1996, BI's policy allows 340B covered entities to designate only a single contract pharmacy location within 40 miles of the covered entity. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q: Is BI requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A: Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for BI to manage its process with its wholesalers.

Q: If the contract pharmacy I want to designate does not have a HIN, how do I get one?

A: BI will not register a HIN on your behalf, however, if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q: How long does it take for my contract pharmacy designation to take effect if I make the designation after BI's updated policy goes into effect on August 1, 2023?

A: A covered entity can make contract pharmacy designations after BI's updated policy goes into effect. That designation will take up to ten (10) business days to take effect in the wholesalers' system.

Q: Does my covered entity need to recertify that they do not have in-house pharmacy?

A: Yes, covered entities that have designated a single contract pharmacy must recertify through 340B ESP™ that they do not have an in-house pharmacy. This process is completed on a yearly basis at the anniversary date of the single contract pharmacy designation.

Q: My covered entity does not operate an in-house pharmacy and has previously designated a contract pharmacy that meets the requirements of the new policy. Do I need to re-register my existing contract pharmacy?

A: Yes, covered entities must re-register their contract pharmacies and recertify their eligibility.

Q: Which products are subject to BI's policy?

A: BI's policy applies to all NDCs attached in Exhibit A hereto.

Exhibit A

Boehringer Ingelheim 340B Contract Pharmacy Applicable NDCs

Boehringer Ingelheim's 340B contract pharmacy policy applies to the NDCs listed below

DESCRIPTION	NDC #	UNIT PACKAGING
APTIVUS[®] (tipranavir)		
250mg Capsules	597000302	Bottle of 120
ATROVENT[®] (ipratropium bromide)		
HFA Inhalation Aerosol Complete 12.9grams	597008717	Box of 1
CATAPRES-TTS[®] (clonidine)*		
0.1mg Patch	597003134	1 Package of 4 Patches
0.2mg Patch	597003234	1 Package of 4 Patches
0.3mg Patch	597003334	1 Package of 4 Patches
COMBIVENT[®]RESPIMAT[®] (ipratropium bromide and albuterol)		
Inhalation Spray 20mcg/100mcg	597002402	Box of 1
GLUCAGEN[®] (glucagon(rDNA origin) for injection)*		
1mg Vial w/Diluent (Diagnostic Kit)	597026010	1 Vial in 1 Diagnostic Kit
1mg Vial	597005345	10 Vials in 1 Carton
GLYXAMBI[®] (empagliflozin/linagliptin)		
10mg/5mg Tablets	597018230	Bottle of 30
10mg/5mg Tablets	597018239	30's (3 x 10 Blister Pack)
10mg/5mg Tablets	597018290	Bottle of 90
25mg/5mg Tablets	597016430	Bottle of 30
25mg/5mg Tablets	597016439	30's (3 x 10 Blister Pack)
25mg/5mg Tablets	597016490	Bottle of 90
JARDIANCE[®] (empagliflozin)		
10mg Tablets	597015230	Bottle of 30
10mg Tablets	597015237	3 blister cards x 10 tablets
10mg Tablets	597015290	Bottle of 90
25mg Tablets	597015330	Bottle of 30
25mg Tablets	597015337	3 blister cards x 10 tablets
25mg Tablets	597015390	Bottle of 90
JENTADUETO[®]		
(linagliptin and metformin HCL)		
2.5mg/500mg Tablets	597014618	Bottle of 180
2.5mg/500mg Tablets	597014660	Bottle of 60
2.5mg/850mg Tablets	597014718	Bottle of 180
2.5mg/850mg Tablets	597014760	Bottle of 60
2.5mg/1000mg Tablets	597014818	Bottle of 180
2.5mg/1000mg Tablets	597014860	Bottle of 60
JENTADUETO XR[®]		
(linagliptin and metformin hydrochloride extended-release)		
2.5mg/1000mg	597027073	Bottle of 60
2.5mg/1000mg	597027094	Bottle of 180
5mg/1000mg	597027533	Bottle of 30
5mg/1000mg	597027581	Bottle of 90

DESCRIPTION	NDC #	UNIT PACKAGING
MICARDIS[®] (telmisartan)		
20mg Tablets	597003937	30's (3 x 10 Blister Pack)
40mg Tablets	597004037	30's (3 x 10 Blister Pack)
80mg Tablets	597004137	30's (3 x 10 Blister Pack)
MICARDIS HCT[®] (telmisartan/hydrochlorothiazide)		
40mg/12.5mg Tablets	597004337	30's (3 x 10 Blister Pack)
80mg/12.5mg Tablets	597004437	30's (3 x 10 Blister Pack)
80mg/25mg Tablets	597004237	30's (3 x 10 Blister Pack)
MIRAPEX ER[®] (pramipexole dihydrochloride extended-release)		
0.375mg Tablets	597010930	Bottle of 30
0.75mg Tablets	597028530	Bottle of 30
1.5mg Tablets	597011330	Bottle of 30
2.25mg Tablets	597028630	Bottle of 30
3.0mg Tablets	597011530	Bottle of 30
3.75mg Tablets	597028730	Bottle of 30
4.5mg Tablets	597011630	Bottle of 30
MOBIC[®] (meloxicam)*		
7.5mg Tablets	597002901	Bottle of 100
OFEV[®] (nintedanib)		
100mg	597014360	Bottle of 60
150mg	597014560	Bottle of 60
PRADAXA[®] (dabigatran etexilate)		
75mg Capsules	597035509	Bottle of 60
75mg Capsules	597035556	10 blister cards (6 caps/card)
110mg Capsules	597010854	Bottle of 60
110mg Capsules	597010860	10 blister cards (6 caps/card)
150mg Capsules	597036055	Bottle of 60
150mg Capsules	597036082	10 blister cards (6 caps/card)
SPIRIVA[®] HandiHaler[®] (tiotropium bromide inhalation powder)		
18mcg (tiotropium) per Capsule	597007575	1 Blister Card x 5 Capsules/Carton with HandiHaler
18mcg (tiotropium) per Capsule	597007541	3 Blister Card x 10 Capsules/Carton with HandiHaler
18mcg (tiotropium) per Capsule	597007547	9 Blister Card x 10 Capsules/Carton with HandiHaler
SPIRIVA[®] RESPIMAT[®] (tiotropium bromide)		
Inhalation Spray 2.5mcg	597010051	Box of 1 10 metered actuations
Inhalation Spray 2.5mcg	597010061	Box of 1 60 metered actuations
SPIRIVA[®] RESPIMAT[®] (tiotropium bromide) ASTHMA		
Inhalation Spray 1.25mcg Asthma	597016061	Box of 1 60 metered actuations

DESCRIPTION	NDC #	UNIT PACKAGING
STIOLTO[®] RESPIMAT[®] (tiotropium bromide and olodaterol)		
Inhalation Spray 2.5 mcg/2.5 mcg	597015570	Box of 1 10 metered actuations
Inhalation Spray 2.5 mcg/2.5 mcg	597015561	Box of 1 60 metered actuations
STRIVERDI[®] RESPIMAT[®] (olodaterol)		
Inhalation Spray 2.5mcg	597019261	Box of 1 60 metered actuations
SYNJARDY[®] (empagliflozin and metformin HCL)		
5mg/500mg Tablets	597015960	Bottle of 60
5mg/500mg Tablets	597015918	Bottle of 180
5mg/1000mg Tablets	597017560	Bottle of 60
5mg/1000mg Tablets	597017518	Bottle of 180
12.5mg/500mg Tablets	597018060	Bottle of 60
12.5mg/500mg Tablets	597018018	Bottle of 180
12.5mg/1000mg Tablets	597016860	Bottle of 60
12.5mg/1000mg Tablets	597016818	Bottle of 180
SYNJARDY XR[®] (empagliflozin and metformin HCL)		
5mg/1000mg Tablets	597029074	Bottle of 60
5mg/1000mg Tablets	597029059	Bottle of 180
10mg/1000mg Tablets	597028073	Bottle of 30
10mg/1000mg Tablets	597028090	Bottle of 90
12.5mg/1000mg Tablets	597030045	Bottle of 60
12.5mg/1000mg Tablets	597030093	Bottle of 180
25mg/1000mg Tablets	597029588	Bottle of 30
25mg/1000mg Tablets	597029578	Bottle of 90
TRADJENTA[®] (linagliptin)		
5mg Tablets	597014030	Bottle of 30
5mg Tablets	597014090	Bottle of 90
5mg Tablets	597014061	10 blister cards (10 tabs/card)
TRIJARDY XR[®] (empagliflozin/linagliptin/metformin HCL)		
5 mg-2.5 mg-1000 mg Tablets	597039523	Bottle of 180
5 mg-2.5 mg-1000 mg Tablets	597039582	Bottle of 60
12.5 mg-2.5 mg-1000 mg Tablets	597038586	Bottle of 180
12.5 mg-2.5 mg-1000 mg Tablets	597038577	Bottle of 60
10 mg-5 mg-1000 mg Tablets	597038013	Bottle of 30
10 mg-5 mg-1000 mg Tablets	597038068	Bottle of 90
25 mg-5 mg-1000 mg Tablets	597039071	Bottle of 30
25 mg-5 mg-1000 mg Tablets	597039013	Bottle of 90
VIRAMUNE XR[®] (nevirapine extended-release tablets)*		
400mg Tablets	597012330	Bottle of 30

*Product has been discontinued, divested