



September 9, 2024 – Policy Update

AstraZeneca
1800 Concord Pike
Wilmington, Delaware 19803-2910
T: (800) 456-3669
astrazeneca.com

Dear 340B Covered Entity,

Effective October 1, 2024, AstraZeneca will begin mandating the submission of claims data on 340B utilization filled at contract pharmacies. All specified claims data must be submitted on the 340B ESP™ platform within 45 days of the dispense date. This requirement applies to covered entities, without an in-house pharmacy that have designated a single contract pharmacy via the 340B ESP™ platform.

For clarity, if you already have a designated contract pharmacy in place, you do not need to redesignate. Please note there will be no change to the scope of products subject to our contract pharmacy policy – Oncology and Specialty Pharmacy products remain excluded.

As a reminder, effective August 1, 2023, AstraZeneca transitioned the administration of our 340B contract pharmacy program to the 340B ESP™ platform.

Covered entities with an on-site dispensing pharmacy will continue to be able to purchase AstraZeneca product at the 340B price. Covered entities without an in-house dispensing pharmacy may select a single contract pharmacy location using the 340B ESP portal. The FAQs below provide a list of impacted brands and appropriate National Drug Codes.

Covered entities that do not have an in-house pharmacy can make their designations by visiting www.340BESP.com/designations. Users that have registered an account with 340B ESP™ can designate a 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.

Sincerely,



Rod Lauzon (Sep 5, 2024 20:50 EDT)

Rod Lauzon
Executive Director, Contract Operations

Frequently Asked Questions

Q: Are Oncology & Specialty products subject to AstraZeneca's Contract Pharmacy policy?

A: No.

Q: Which products are subject to AstraZeneca's Contract Pharmacy policy?

A: AstraZeneca's contract pharmacy policy applies to AIRSUPRA®, BEVESPI AEROSPHERE®, BREZTRI AEROSPHERE™, BRILINTA®, BYDUREON®, BYETTA®, CRESTOR®, DALIRESP®, FARXIGA®, KOMBIGLYZE® XR, LOKELMA™, NEXIUM®, ONGLYZA®, PULMICORT®, QTERN®, SEROQUEL®, SEROQUEL XR®, SYMBICORT®, SYMLIN®, XIGDUO® XR. The NDC list can be found below.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing AstraZeneca's drugs, but my entity doesn't use it to dispense AstraZeneca's drugs. Can my entity designate one contract pharmacy instead?

A: No, under AstraZeneca's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B purchased products to eligible patients then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different Walgreens pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. AstraZeneca's policy allows qualifying 340B covered entities (i.e., covered entities without an on-site pharmacy) to designate a single contract pharmacy location. 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. Can my covered entity designate a centralized pharmacy replenishment facility as my single contract pharmacy location?

A. No. Centralized pharmacy replenishment facilities or "central-fill pharmacies" are not eligible to be designated as a single contract pharmacy location for a covered entity. Please refer to the FAQs for a listing of Brands and NDC's above.

Q. How does my covered entity change its contract pharmacy designation and how often can it be changed?

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database. Changes to the single contract pharmacy 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. Is AstraZeneca 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 for a covered entity to designate it as its single contract pharmacy. This information is important for AstraZeneca to manage its process with its wholesalers.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: AstraZeneca 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: What are the requirements for submission of 340B claims data?

A: The claims data submission requirement applies to covered entities without an in-house pharmacy that designates one contract pharmacy location. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Updated 9/9/2024

Product Name	NDC
AIRSUPRA®	
90/80MCG PMDI 120D US	00310-9080-12
BEVESPI AEROSPHERE®	
9/4.8 MCG 120 ACT INHALATION	00310-4600-12
BREZTRI AEROSPHERE™	
160/9/4.8MCG	00310-4616-12
160/9/4.8MCG Inst. Pack	00310-4616-39
BRILINTA®	
TAB 90MG UD Inst. Pack	00186-0777-39
TAB 90MG	00186-0777-60
TAB 60MG	00186-0776-60
BYDUREON®	
BCISE AUTOINJECTOR	00310-6540-04
BYETTA®	
PEN 250MCG/ML	00310-6512-01
PEN 250MCG/ML	00310-6524-01
CRESTOR®	
TAB 5MG	00310-7560-90
TAB 10 MG	00310-7570-90
TAB 20 MG	00310-7580-90
TAB 40 MG	00310-7590-30
DALIRESP®	
TAB 250MCG	00310-0088-28
TAB 250MCG Inst. Pack	00310-0088-39
TAB 500MCG	00310-0095-30
TAB 500MCG	00310-0095-90
FARXIGA®	
TAB 5MG	00310-6205-30
TAB 10MG	00310-6210-30
TAB 10MG Inst. Pack	00310-6210-39
TAB 5MG	00310-6205-90
TAB 10MG	00310-6210-90
KOMBIGLYZE® XR	
TAB 5MG/500MG	00310-6135-30
TAB 2.5MG/1000MG	00310-6125-60
TAB 5MG/1000MG	00310-6145-30
LOKELMA™	
ORAL SUSPENSION 5G	00310-1105-30
ORAL SUSPENSION 5G Inst. Pack	00310-1105-39

ORAL SUSPENSION 10G	00310-1110-30
ORAL SUSPENSION 10G Inst. Pack	00310-1110-39
NEXIUM®	
CAPS 20MG	00186-5020-31
CAPS 20MG	00186-5020-54
CAPS 40MG	00186-5040-31
CAPS 40MG	00186-5040-54
IV INJ 40MG/5mL	00186-6040-01
ORAL SUSPENSION 2.5MG	00186-4025-01
ORAL SUSPENSION 5MG	00186-4050-01
ORAL SUSPENSION 10MG	00186-4010-01
ORAL SUSPENSION 20MG	00186-4020-01
ORAL SUSPENSION 40MG	00186-4040-01
ONGLYZA®	
TAB 2.5MG	00310-6100-30
TAB 2.5MG	00310-6100-90
TAB 5MG	00310-6105-30
TAB 5MG	00310-6105-90
PULMICORT®	
RESPULES 0.25 mg/2 ml	00186-1988-04
RESPULES 0.5 mg/2 ml	00186-1989-04
RESPULES 1 mg/2 ml	00186-1990-04
QTERN®	
TAB 5MG/5MG	00310-6770-30
TAB 10MG/5MG	00310-6780-30
SEROQUEL®	
TAB 100MG	00310-0271-10
TAB 200MG	00310-0272-10
TAB 25MG	00310-0275-10
TAB 300 MG	00310-0274-60
TAB 50 MG	00310-0278-10
TAB 400 MG	00310-0279-10
SEROQUEL XR®	
TAB 50 MG	00310-0280-60
TAB 150 MG	00310-0281-60
TAB 200 MG	00310-0282-60
TAB 300 MG	00310-0283-60
TAB 400 MG	00310-0284-60
SYMBICORT®	
80/4.5MCG	00186-0372-20
160/4.5MCG	00186-0370-20
80/4.5MCG Inst. Pack	00186-0372-28
160/4.5MCG Inst. Pack	00186-0370-28

SYMLIN®	
60-PEN 1000mcg/ml	00310-6615-02
120-PEN 1000mcg/ml	00310-6627-02
XIGDUO® XR	
TAB 2.5MG/1000MG	00310-6225-60
TAB 5MG/500MG	00310-6250-30
TAB 5MG/1000MG	00310-6260-60
TAB 10MG/500MG	00310-6270-30
TAB 10MG/1000MG	00310-6280-30