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March 4, 2025 - Policy Update

Dear 340B Covered Entity,

Effective April 1, 2025, AstraZeneca will amend our 340B Contract Pharmacy Policy to include the following products: LYNPARZA®, TAGRISSO®, and TRUQAP®. A list of Frequently Asked Questions addressing this change is included in Attachment A, and an updated list of AstraZeneca products subject to our 340B Contract Pharmacy Policy is included in Attachment B.

For LYNPARZA®, TAGRISSO®, and TRUQAP®, Covered Entities without an in-house dispensing pharmacy, or an in-house pharmacy incapable of dispensing these products, may designate a single specialty pharmacy for each product. This designation will need to be part of the respective product's limited distribution network. For those Covered Entities without an in-house dispensing pharmacy, these specialty pharmacy designations will be in addition to the single contract pharmacy location for AstraZeneca non-specialty products.

Covered Entities with an in-house pharmacy capable of dispensing AstraZeneca products will continue to be able to purchase AstraZeneca products at the 340B price. Covered Entities without an in-house dispensing pharmacy may select a single contract pharmacy location. For clarity, if you already have a designated contract pharmacy in place for AstraZeneca's non-specialty products, you do not need to redesignate.

As a reminder, effective August 1, 2023, AstraZeneca transitioned the administration of our 340B contract pharmacy program to the 340B ESP™ platform. Covered entities that do not have an in-house pharmacy can make their designations by visiting www.340BESP.com/designations.

Additionally, effective October 1, 2024, AstraZeneca requires Covered Entities to submit claims data on 340B utilization filled at all contract pharmacies. All specified claims data must be submitted on the 340B ESP platform within 45 days of the dispense date. The National Drug Codes (NDCs) subject to AstraZeneca's policy can be found on www.340BESP.com.

If you have questions regarding the change in our 340B Contract Pharmacy Policy, please contact us at support@340BESP.com.

Claudia Vainstein

Executive Director, Contract Operations

Attachment A: Frequently Asked Questions

Attachment B: In-Scope Product List



Attachment A: Frequently Asked Questions

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

A: AstraZeneca's contract pharmacy policy applies to the products in Attachment B. AstraZeneca will inform covered entities of any changes to the product list. Both the AstraZeneca contract pharmacy policy and up to date list of included products can be found on www.340BESP.com

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: If I designate one contract pharmacy location to receive orders of product subject to this policy, may I also make a separate designation for a contract pharmacy location to receive AstraZeneca products subject to a limited distribution network?

A: Yes. Due to the limited distribution network associated with LYNPARZA, TAGRISSO, and TRUQAP, Covered Entities are permitted to designate a specific contract pharmacy for each product. This designation will be in addition to the contract pharmacy the covered entity had already selected for AstraZeneca's non-specialty products.

Q: If my in-house dispensing pharmacy is incapable of dispensing AstraZeneca specialty products, can I designate a specialty pharmacy?

A: Yes, to ensure all 340B covered entities can access AstraZeneca products at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location.

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.



Attachment B In Scope Products List

Non-Specialty Products

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

Specialty Products

*LYNPARZA®

*TAGRISSO®

*TRUQAP®

^{*}Added to policy 4/1/2025

^{**} Divested as of 3/31/2025