



**Notice to 340B Covered Entities of the
Addition of Myrbetriq[®] to Astellas Pharma US, Inc.'s
Contract Pharmacy Policy
Effective May 1, 2024**

Dear 340B Covered Entity:

In our ongoing effort to uphold the integrity of the 340B program and address the risk of duplicate discounts and diversion, Astellas Pharma US, Inc. ("Astellas") is modifying its policy regarding contract pharmacies' eligibility to receive Xtandi[®] products at the 340B discount price by adding **Myrbetriq[®] (mirabegron) products** to the policy effective as of **May 1, 2024**.

Under the policy, Astellas will continue to distribute all NDCs of Xtandi[®] and Myrbetriq[®] purchased at the 340B discount price to locations registered as a 340B covered entity or child site on HRSA's OPAIS database, consistent with the 340B statute.

Subject to the exceptions set forth below and in addition to the terms of the policy currently in effect with respect to Xtandi[®] products, commencing on May 1, 2024, 340B covered entities will not be permitted to direct delivery of Myrbetriq[®] products purchased at the 340B discount price to contract pharmacies, meaning that Astellas will no longer facilitate "Bill To/Ship To" orders of Myrbetriq[®] products purchased at the 340B discount price to contract pharmacies.

Exceptions Relative to Myrbetriq[®] Products:

- Federal grantee covered entities are excluded from the policy and will remain eligible to direct delivery of Myrbetriq[®] products purchased at the 340B discount price to their respective contract pharmacies. Accordingly, there is no action required by federal grantees with respect to this policy.
- For covered entities located in the state of Arkansas, Astellas will facilitate "Bill To/Ship To" orders of Myrbetriq[®] products purchased at the 340B discount price to an unlimited number of contract pharmacies located within the state of Arkansas. Accordingly, there is no action required by covered entities located in the state of Arkansas with respect to this policy.
- For covered entities located in the state of Louisiana, Astellas will facilitate "Bill To/Ship To" orders of Myrbetriq[®] products purchased at the 340B discount price to an unlimited number of contract pharmacies located within the state of Louisiana. Accordingly, there is no action required by covered entities located in the state of Louisiana with respect to this policy.



- Any covered entity that does not have an in-house pharmacy capable of dispensing 340B products to its patients may designate a single contract pharmacy location per the instructions below, and Astellas will facilitate “Bill To/Ship To” orders of Myrbetriq® products purchased at the 340B discount price to such designated contract pharmacy location only. The designated contract pharmacy location must be registered in the HRSA 340B contract pharmacy database.

Any 340B covered entity that does not have an in-house pharmacy capable of dispensing Myrbetriq® products purchased at the 340B discount price to its patients must designate a single contract pharmacy location by completing the online form at <https://www.340besp.com/designations>. Astellas is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. Covered entities that have not already registered an account with 340B ESP™, must make their designations by visiting <https://www.340besp.com/designations>. Covered entities that have already registered an account with 340B ESP™ must designate a contract pharmacy by navigating to the Entity Profile tab at <https://www.340besp.com>.

In order for single contract pharmacy designations for **Myrbetriq® products** to take effect as of May 1, 2024, **340B covered entities must take action by April 19, 2024.**

In support of a smooth transition to this policy update, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding “Bill To/Ship To” orders for Myrbetriq® products in advance of May 1, 2024.

Please refer to the attached FAQ for additional information. If you have further questions regarding this policy or utilization of the 340B ESP™ platform, please contact [**support@340BESP.com**](mailto:support@340BESP.com).

Sincerely,

DocuSigned by:

A handwritten signature in black ink that reads "Lei Ding".

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Lei Ding

Senior Vice President, Market Access and Commercial Capabilities
Astellas Pharma US, Inc.



Updated Frequently Asked Questions

Q: Which products are subject to Astellas' contract pharmacy policy?

A: Astellas' contract pharmacy policy applies to all NDCs of Xtandi[®] and Myrbetriq[®].

Q: Does my covered entity have to designate the same contract pharmacy from which to purchase Xtandi[®] products and Myrbetriq[®] products?

A: No. Astellas recognizes that Xtandi[®] is a specialty oncology product and that Myrbetriq[®] is a retail product. If applicable, your covered entity may keep its current contract pharmacy designation for Xtandi[®] products and designate a new contract pharmacy for receipt of "Bill To/Ship To" orders of Myrbetriq[®] products purchased at the 340B discount price. If your current designated contract pharmacy for Xtandi[®] is capable of dispensing Myrbetriq[®], you may designate the same contract pharmacy to receive Myrbetriq[®] products at the 340B discount price if you wish.

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

A: Yes, contract pharmacies that are wholly owned by the covered entity are subject to Astellas' policy. However, a wholly owned contract pharmacy can be designated as the entity's single contract pharmacy, so long as the covered entity does not have an in-house pharmacy.

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

A: No, under Astellas' policy, if a covered entity has an in-house pharmacy capable of dispensing Xtandi[®] products and Myrbetriq[®] products to eligible patients, the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

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

A. No. Astellas' policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location for each of Xtandi[®] products and Myrbetriq[®] products. Contract pharmacy locations are registered individually on the HRSA database and covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.



Q. How often can my covered entity change its contract pharmacy designation?

A. Covered entities may change their contract pharmacy designation for a product once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q. How does my covered entity change its contract pharmacy designation?

A. Changes to the 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. Please allow 10 business days for the eligible contract pharmacy designation to take effect.

Q. Is Astellas 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 that contract pharmacy as its single contract pharmacy. This information is important for Astellas to manage its process with its wholesalers.

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

A: Astellas 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 does my covered entity ensure that its contract pharmacy designation for Myrbetriq® takes effect on May 1, 2024?

A. For a covered entity's eligible contract pharmacy designation to take effect on May 1, 2024, the covered entity must designate a single contract pharmacy by **April 19, 2024**.

Q. How long does it take for my covered entity's contract pharmacy designation for Myrbetriq® to take effect if we do not register by April 19, 2024?

A. Covered entities can take action to comply with Astellas' policy as it applies to Myrbetriq® products after May 1, 2024. After May 1, 2024, please allow 10 business days for the eligible contract pharmacy designation for Myrbetriq® products to take effect.