



Dear 340B Covered Entities,

I am writing to inform you that Liquidia is implementing a policy for distributing products purchased at the 340B price. Effective April 1, 2024, and subject to getting final approval from the FDA, Liquidia will ship the product Yutrepia™ (treprostini) inhalation powder purchased at the 340B price exclusively to locations registered as a 340B covered entity or eligible child site location affiliated with that covered entity. Covered entity and Federal Grantee contract pharmacies will no longer be eligible recipients for Bill To / Ship To replenishment orders.

To ensure all 340B covered entities can access Yutrepia™ 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 Accredo or Caremark/CVS Specialty contract pharmacy location. The covered entity must agree to provide claims data for the designated single contract pharmacy within 45 days of the date of dispense. Liquidia is utilizing the 340B ESP™ platform to support this designation and claims submission. 340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™, can make their designations by visiting [www.340besp.com/designations](http://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 this policy, please contact us at [support@340Besp.com](mailto:support@340Besp.com).

To ensure a smooth implementation and timely access to Yutrepia™ 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders in advance of the effective date of this notice.

Best regards,

*Frank Bartolini*

**Frank Bartolini**

Sr. Vice President Market Access





## **Frequently Asked Questions**

### **Q: Which products are covered under Liquidia's contract pharmacy policy?**

A. Currently, Liquidia does not have any FDA-approved products in the market. Upon receiving final approval by the FDA, Yutrepia™ will be the only product covered under Liquidia's contract pharmacy policy. Liquidia reserves the right to add additional products to this policy in the future.

### **Q: Which covered entities are subject to Liquidia's new contract pharmacy policy?**

A. All eligible 340B covered entities, including federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K), are subject to this new contract pharmacy policy.

### **Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy company. Can my entity designate all locations of the same pharmacy company?**

A. If a hospital covered entity does not have in-house dispensing capabilities, only a single Accredo or Caremark/CVS Specialty contract pharmacy location can be designated via the Designations form on [www.340besp.com/designations](http://www.340besp.com/designations).

### **Q. How often can a covered entity change its contract pharmacy location designation?**

A. A covered entity can change its contract pharmacy location designation once every twelve (12) months. A covered entity may change its contract pharmacy location designation within a 12-month period only if the designated contract pharmacy location is terminated as a contract pharmacy of the covered entity from the 340B OPAIS database.

### **Q. How would a covered entity change its contract pharmacy location designation?**

A. Changes to a contract pharmacy location designation can be made at [www.340besp.com/designations](http://www.340besp.com/designations).

### **Q. How does a covered entity ensure its contract pharmacy designation will be in effect on April 1st?**

A. If a hospital covered entity does not have in-house dispensing capabilities, it may complete the form to designate a single contract pharmacy location at [www.340besp.com/designations](http://www.340besp.com/designations). To ensure the single contract pharmacy designation will take effect on April 1<sup>st</sup>, you must designate by March 22<sup>nd</sup>. After that date, please allow for up to ten (10) business days to gain eligibility.

### **Q. Is Liquidia 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 Liquidia 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: Liquidia 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](mailto: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: My covered entity would like to submit 340B claims for its contract pharmacy and purchase Yutrepia at the 340B price. What does our entity need to do to begin submitting 340B claims?**

A: 340B covered entities that wish to submit 340B claims under Liquidia's policy can do so by registering an account at [www.340Besp.com](http://www.340Besp.com). Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Liquidia by navigating to the Claims Data Submission tab.