

## Exelixis' 340B Program Integrity Initiative Frequently Asked Questions

June 7, 2022

### **1. Which covered entity types are subject to Exelixis' 340B program integrity initiative?**

Exelixis is requesting that hospital covered entities (including their child sites) provide claims level data for COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> dispensed by contract pharmacies. Until further notice, covered entities that are registered as eligible for the 340B program based on receipt of federal grants (as defined under 42 U.S.C. § 256b(a)(4)(A)-(K)) may continue to use contract pharmacies that are within the product's specialty pharmacy network without submitting claims data.<sup>1</sup>

### **2. How does a covered entity register with 340B ESP™?**

Exelixis requests that covered entities register with 340B ESP™ platform by visiting <https://www.340besp.com/register>. The initial registration includes an onboarding module that guides users through each step of the registration process. The registration process takes approximately 15 minutes, and will be operational beginning June 10, 2022. Registration and utilization of the 340B ESP™ platform is free of charge for covered entities.

### **3. How does a covered entity upload data?**

Once a covered entity's 340B ESP™ account is activated, the entity will be able to upload claims-level data by visiting the "Claims Data Submission" tab. Covered entities that elect to participate and provide the requested data elements will be able to continue using bill to/ship to arrangements for COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> with contract pharmacy locations that are within the product's specialty pharmacy network.

Exelixis requests that covered entities begin submitting data starting June 10, 2022, but no later than June 20, 2022, in order for a covered entity's eligible contract pharmacy locations to take effect on July 6, 2022. Subsequent submissions should be uploaded twice per month. Covered entities will receive periodic notifications from 340B ESP™ of upcoming data submission deadlines.

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<sup>1</sup> Further information regarding the authorized specialty pharmacy network for COMETRIQ<sup>®</sup> is available at <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/updated-notice-distribution-model-cometriq.pdf> and further information regarding the authorized specialty pharmacy network for CABOMETYX<sup>®</sup> is available at <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-distribution-model-cabometryx.pdf>.

**4. What happens if a covered entity does not provide 340B claims data by the required date? May a covered entity elect to do so at a later date and gain access to 340B pricing for contract pharmacies?**

Subject to the exceptions noted herein, covered entities that elect not to provide claims data will no longer be eligible for ship to/bill to orders for their contract pharmacies on or after July 6, 2022.

A covered entity can elect to provide claims data after July 6, 2022. After July 6, 2022, covered entities should allow up to 10 business days for their eligible contract pharmacy locations to take effect.

**5. Which data elements are requested?**

Exelixis is requesting the following limited data elements: Rx Number, prescribed date, fill date, NDC, quantity, pharmacy ID, prescriber ID, wholesaler invoice number and 340B covered entity ID.

**6. Are there any privacy protections for the submitted claims data?**

Claims data is deidentified through a HIPAA-compliant process before it is uploaded to 340B ESP™. 340B ESP™ does not collect any protected health information (PHI).

The administrator of 340B ESP™, Second Sight Solutions, makes a standard Business Associate Agreement (BAA) available to 340B covered entities that require a BAA be in place prior to submitting data. To request a BAA, email [baarequest@340besp.com](mailto:baarequest@340besp.com) or complete the BAA request form at <https://340besp.com/baa>.

**7. How will Exelixis use the 340B claims data that covered entities provide through 340B ESP™?**

Exelixis will use claims data solely to identify and resolve duplicate discounts and ineligible rebates under Medicaid and under Medicare Part D and commercial agreements.

**8. Does Exelixis provide 340B pricing on COMETRIQ® and CABOMETYX® to rural referral centers, sole community hospitals, critical access hospitals, or free-standing cancer hospitals that participate in Exelixis' 340B contract pharmacy program integrity initiative?**

No. COMETRIQ® and CABOMETYX® are designated as orphan drugs by the U.S. Food and Drug Administration. Notwithstanding Exelixis' 340B program integrity initiative and consistent with 42 U.S.C. § 256b(e), Exelixis does not provide

voluntary 340B discounts on COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> to covered entities registered in 340B Office of Pharmacy Affairs Information System as rural referral centers, sole community hospitals, critical access hospitals, or free-standing cancer hospitals.

**9. Are wholly-owned contract pharmacies subject to Exelixis' policy?**

Contract pharmacies that are wholly-owned by, or under common ownership with, a covered entity and that dispense products only to patients of the covered entity are not subject to this policy. Pharmacies that meet this criteria can self-identify in the 340B ESP<sup>™</sup> platform, by visiting [https://www.340besp.com/wholly\\_owned\\_application](https://www.340besp.com/wholly_owned_application).

**10. If a covered entity is eligible to designate a single contract pharmacy, how does the covered entity make its designation?**

A covered entity that does not provide claims data and that does not have an in-house pharmacy may designate a single contract pharmacy location within the product's authorized specialty pharmacy network for the shipment of COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup>. The covered entity cannot designate multiple locations of the same pharmacy chain.

If the covered entity has an in-house pharmacy that is capable of dispensing COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup>, but does not use it, the covered entity cannot designate a contract pharmacy location.

Covered entities may designate a single contract pharmacy location by visiting <https://www.340besp.com/designations>. A covered entity may change its contract pharmacy designation once every 12 months from the date of first designation.

**11. Who should I contact if I have any other questions about Exelixis' 340B contract pharmacy program integrity initiative?**

Please contact 340B@exelixis.com if you have any other questions.