

June 7, 2022

Via Electronic Mail

Notice to 340B Covered Entities of Exelixis' 340B Program Integrity Initiative

Dear 340B Covered Entity:

As a biotechnology company focused on difficult-to-treat cancers, our core mission is to bring new therapies to patients in need so that they can recover stronger and live longer. We therefore support the goal of the 340B program, which is intended to improve the care of low-income and uninsured patients by facilitating easier access to discounted medicines. At the same time, we have serious concerns that the extraordinary and uncontrolled growth of the 340B program, coupled with the program's lack of transparency, have dramatically increased the risk of duplicate discounts, particularly for products dispensed by contract pharmacies.

To address this, we will be implementing a 340B program integrity initiative for contract pharmacy orders, which will provide much-needed transparency and promote compliance with program requirements. Importantly, this initiative should not restrict patient access to our medicines; our goal is to work together with covered entities to support the mission of the 340B program and ensure that the program is sustainable into the future.

What is changing?

Effective July 6, 2022, Exelixis requests that covered entities provide claims-level data for COMETRIQ[®] and CABOMETYX[®] dispensed by contract pharmacies. Specifically, Exelixis requests that covered entities provide the following limited data elements: Rx Number, prescribed date, fill date, NDC, dispensed quantity, pharmacy ID, prescriber ID, wholesaler invoice number and 340B covered entity ID. Covered entities are asked to submit these data elements through the 340B ESP[™] platform, which is free of charge to covered entities. The data elements will be de-identified through a HIPAA-compliant process before being uploaded to the 340B ESP[™] platform.

Why is it changing?

The extraordinary expansion of the 340B program, coupled with the program's lack of transparency and a complex contract pharmacy system never contemplated by the original drafters of the 340B legislation, have dramatically increased the risk of duplicate rebate claims. Submission of claims-level data will help to improve transparency, with the goal of bolstering the integrity and sustainability of the 340B program.

Next steps

Covered entities can register for the 340B ESP[™] platform at www.340BESP.com, which will be operational beginning June 10, 2022. The administrator of the platform, Second Sight Solutions, will also make a standard Business Associate Agreement (BAA) available to 340B covered entities upon request.¹

¹ Second Sight Solutions, Frequently Asked Questions, <https://www.340besp.com/faqs> (last updated June 2020).

Starting July 6, 2022, Exelixis will permit covered entities (including child sites of hospital covered entities) that submit claims data as described above to utilize “ship to/bill to” arrangements for COMETRIQ[®] and CABOMETYX[®] with contract pharmacy locations that are within the product’s authorized specialty pharmacy network.² A covered entity that elects not to provide this limited claims data and that does not have an in-house pharmacy may designate a single contract pharmacy location within the specialty pharmacy network for the shipment of 340B product. In addition, until further notice, we will not require covered entities to provide claims data for product dispensed by contract pharmacies that are wholly-owned by, or under common ownership with, the covered entity and that dispense products only to patients of the covered entity. Covered entities can self-identify such pharmacies in the 340B ESP[™] platform. Similarly, until further notice, covered entities that are registered as eligible for the 340B program based on receipt of federal grants (“grantee covered entities”) will be excluded from this initiative and may continue to use contract pharmacies within the product’s authorized specialty pharmacy network, without providing claims data for contract pharmacy utilization.³

Exelixis takes seriously our obligations under the 340B program, and we will continue to ensure that our covered outpatient drugs are available to 340B covered entities at the applicable statutory ceiling price. All covered entities will continue to be able to purchase COMETRIQ[®] and CABOMETYX[®] at the 340B ceiling price through their in-house pharmacies or, if they lack an in-house pharmacy, through a contract pharmacy arrangement with a single network specialty pharmacy of their designation, whether or not they provide the requested claims data.⁴ Exelixis’ 340B program integrity initiative thus will not restrict access to 340B-covered products for any covered entity or eligible patient, but will provide important transparency to help ensure compliance with the 340B program requirements. Exelixis reserves all rights to modify further its 340B program integrity initiative in a manner consistent with law in the future.

We look forward to working collaboratively with you on this initiative to further support transparency and the integrity of the 340B program. Please do not hesitate to contact 340B@exelixis.com if you have any questions.

Sincerely,

Darnell Turner
Executive Director, Government Pricing and Market Access Operations
Exelixis, Inc.

² Further information regarding the authorized specialty pharmacy network for COMETRIQ[®] 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[®] is available at <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-distribution-model-cabometyx.pdf>.

³ Grantee covered entities are defined under 42 U.S.C. § 256b(a)(4)(A)-(K).

⁴ Pursuant to the orphan drug exemption in 42 U.S.C. § 256b(e), 340B pricing for CABOMETYX[®] and COMETRIQ[®] is not available to covered entities registered in the 340B Office of Pharmacy Affairs Information System (“OPAIS”) as rural referral centers, sole community hospitals, critical access hospitals, or free-standing cancer hospitals.

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[®] and CABOMETYX[®] 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.⁵

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[®] and CABOMETYX[®] 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.

⁵ Further information regarding the authorized specialty pharmacy network for COMETRIQ[®] 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[®] 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 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® and CABOMETYX® 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™ platform, by visiting https://www.340bsp.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[®] and CABOMETYX[®]. 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[®] and CABOMETYX[®], 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.340bsp.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.