



October 2, 2023

Dear Covered Entity,

I am writing to inform you that Eisai Inc. (“Eisai”) is implementing the procedures described herein regarding orders of Eisai covered outpatient drugs at the 340B ceiling price for dispensing through contract pharmacies.

These procedures are aimed at addressing abuses of the 340B program, including diversion and duplicate discounting. As a researched-based human health care company with a focus on neurology and oncology, Eisai strives to meet unmet patient needs. Therefore, we support the 340B program, which aims to improve vulnerable patients’ access to discounted outpatient drugs. We are concerned, however, that the rapid growth in 340B contract pharmacy arrangements has substantially raised the risk and incidence of duplicate discounts and drug diversion. The procedures described herein will help promote compliance with program requirements, including the statutory prohibitions on diversion and duplicate discounts. These procedures will apply to the products listed in Exhibit A.

Specifically, Eisai is adopting the following procedures:

- All Covered Entities will continue to be able to purchase Eisai covered outpatient drugs at the 340B price for delivery to locations registered as part of the Covered Entity on the HRSA Office of Pharmacy Affairs Information System (OPAIS) database.
- Federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K) will continue to be eligible to place bill to/ship to orders of 340B priced drugs for all of their contract pharmacies. The contract pharmacy must be a pharmacy within the drug’s limited pharmacy distribution network, if applicable.
- Any hospital Covered Entity that does not have an in-house pharmacy capable of dispensing 340B drugs to its patients may designate one (1) contract pharmacy for delivery of 340B priced drugs. The designated contract pharmacy must be a pharmacy within the drug’s limited pharmacy distribution network, if applicable.
- Any hospital Covered Entity that has an in-house pharmacy capable of dispensing 340B drugs to its patients will not be eligible to place bill to/ship to orders of Eisai covered outpatient drugs for delivery to contract pharmacies.
- Hospital Covered Entities are encouraged to contact Eisai to determine whether additional contract pharmacy options may be available pursuant to Arkansas and Louisiana state law.

Eisai is utilizing the 340B ESP platform to support the contract pharmacy designation process. 340B Covered Entities can make their designations by visiting www.340besp.com/designations. Eisai requests that covered entities without an in-house pharmacy capable of dispensing Eisai’s covered outpatient drugs designate a contract pharmacy by October 22, 2023 in order for the designation to be active on November 1, 2023. 340B Covered Entities should endeavor to process any outstanding bill to/ ship to orders in advance of the November 1, 2023 effective date.

Eisai takes seriously our obligations under the 340B program and is committed to ensuring that our covered outpatient drugs are available to 340B covered entities at the 340B ceiling price. Under these procedures, all covered entities will continue to be able to purchase all Eisai medicines at the applicable 340B ceiling price through their in-house pharmacy, or if they do not have an in-house pharmacy, then through a single contract pharmacy.

Attached as Exhibit B is a Frequently Asked Questions document with additional detail. Please contact support@340bsp.com if you have any questions regarding this letter or how to access Eisai's medicines at the 340B ceiling price.

Best regards,

Paula Martins
Director, Government Pricing & Contract Operations

**EXHIBIT A
Product List**

NDC	Product Name
62856-0245-30	Aricept 5mg
62856-0246-30	Aricept 10mg
62856-0247-30	Aricept 23 mg
62856-0582-52	Banzel 200mg
62856-0583-52	Banzel 400mg
62856-0584-46	Banzel 40mg/mL x 460mL Oral Suspension
62856-0405-30	Dayvigo 5mg
62856-0410-30	Dayvigo 10mg
62856-0389-01	Halaven 1mg/2mL solution x 5mL Vial
62856-0704-30	Lenvima 4mg
62856-0708-30	Lenvima 8mg
62856-0710-30	Lenvima 10mg
62856-0712-30	Lenvima 12mg
62856-0714-30	Lenvima 14mg
62856-0718-30	Lenvima 18mg
62856-0720-30	Lenvima 20mg
62856-0724-30	Lenvima 24mg
62856-0212-01	Leqembi 200mg/2ml
62856-0215-01	Leqembi 500mg/5ml

EXHIBIT B
Frequently Asked Question

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 contract pharmacy location can be designated via the Designations form on www.340besp.com/designations.

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

A: No, subject to the exceptions set forth in this communication, 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 in-house pharmacy and cannot designate a contract pharmacy instead.

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 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. 340B covered entities can elect a single contract pharmacy every twelve (12) months. 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. How does a covered entity ensure its contract pharmacy designation will be in effect on November 1, 2023?

A. For a covered entity's eligible contract pharmacy locations to take effect on November 1st, 2023, the entity must designate by October 22th, 2023. After October 22st, 2023, please allow 10 business days for the eligible contract pharmacy locations to take effect must.

Q. Is Eisai requiring covered entities to have a HIN registered for the contract pharmacy location 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 location or to be approved for a wholly owned contract pharmacy exemption. This information is important for Eisai to manage its process with its wholesalers.

Q. If the contract pharmacy a covered entity wants to designate doesn't have a HIN, how can one be obtained?

A. Eisai will not register a HIN on behalf of a covered entity; however, if a covered entity needs guidance or more information on how to get a HIN assigned to a contract pharmacy, please reach out to support@340besp.com. If a covered entity tries to designate a contract pharmacy location without a HIN in 340B ESP™, the system will notify it of this requirement and provide instructions for how to obtain a HIN.