NOTICE TO 340B COVERED ENTITIES
REGARDING UPDATE TO BIOGEN 340B PURCHASE POLICY

December 19, 2024

Dear 340B Covered Entity,

We appreciate the critical role that 340B covered entities play in providing life-altering medications to underserved populations. To support continued and appropriate patient access under the 340B program, Biogen is updating its policy with respect to AVONEX®, PLEGRIDY®, and ZURZUVAE® 340B contract pharmacy arrangements, effective January 20, 2025, as follows:

BIOGEN 340B PURCHASE POLICY

This AVONEX®, PLEGRIDY®, and ZURZUVAE® 340B contract pharmacy policy applies to all 340B covered entities, including hospital covered entities and federal grantee covered entities ("340B covered entity" or" entities"), and to all contract pharmacies, including contract pharmacies that are wholly owned by a covered entity or have common ownership with a 340B-eligible health system.

Except as set forth below or on Exhibit A, AVONEX®, PLEGRIDY®, and ZURZUVAE® may only be purchased at 340B prices by entities registered as 340B covered entities or child site locations, and, if purchased at 340B prices, may only be shipped to a registered 340B covered entity or child site location.

If all of the requirements of this policy are met, a 340B covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location to receive 340B purchases as follows:

> <u>AVONEX® and PLEGRIDY®</u>: a 340B covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location within 40 miles of the covered entity parent site to receive 340B purchases of AVONEX® and PLEGRIDY®; and
>
> <u>ZURZUVAE®</u>: a 340B covered entity that does not have an in-house pharmacy capable of dispensing ZURZUVAE® may designate a single contract pharmacy location that is both within the ZURZUVAE® limited distribution pharmacy network and within 40 miles of the covered entity parent site to receive 340B purchases of ZURZUVAE®.

To be eligible for designation and use of a contract pharmacy as outlined above, a covered entity must submit to Biogen claims data to substantiate all 340B purchases within 45 days of the date of dispense to the covered entity's patient. Designation of a contract pharmacy must be made via the 340B ESP™ platform at https://www.340besp.com/designations. Covered entities may register for an account with 340B ESP on the 340B ESP™ platform.

As used in this policy an "in-house pharmacy" means any pharmacy, including but not limited to a specialty pharmacy or retail pharmacy, that (i) is owned by the relevant covered entity, (ii) is appropriately licensed or authorized by the applicable state, <u>and</u> (iii) is not listed as a contract pharmacy for the relevant covered entity on OPAIS. "In-house pharmacy" does not include a pharmacy owned by an entity other than the relevant covered entity. Merely listing a non-entity owned pharmacy (i.e., a contract pharmacy) as a ship to address on OPAIS does not confer covered entity-owned status on a pharmacy.

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Biogen strongly supports the mission of the 340B program and will continue to provide 340B pricing for all covered entities in accordance with the 340B statute. Biogen reserves all rights to enforce the requirements of this policy and to change this policy at any time.

Please contact support@340besp.com if you have any questions regarding the change to our 340B purchase policy as described in this notice.

Best Regards,

Brendan Manquin
Head of US Market Access & Reimbursement

FREQUENTLY ASKED QUESTIONS

Q: Which products are subject to Biogen's policy?

A: AVONEX®, PLEGRIDY®, and ZURZUVAE®. Please note, ZURZUVAE® ordering is subject to a limited distribution network.

Q: Am I still able to designate a contract pharmacy location for ZURZUVAE® if my covered entity in- house pharmacy is not in the ZURZUVAE® limited distribution network?

A: If your covered entity's in-house pharmacy is not within the limited distribution network for ZURZUVAE®, you may designate a single contract pharmacy location within the ZURZUVAE® limited distribution pharmacy network to receive 340B purchases of ZURZUVAE®.

Q: If I designate one contract pharmacy location to receive orders of AVONEX® AND PLEGRIDY®, can I also make a separate designation for a contract pharmacy location to receive ZURZUVAE®?

A: Yes, you may separately designate one contract pharmacy location to receive ZURZUVAE®, which is subject to a limited distribution network. Biogen will facilitate bill to/ ship to orders to this designated pharmacy. Currently, this separate contract pharmacy designation is available only for ZURZUVAE®. Accordingly, this pharmacy designation may be in addition to the one permitted contract pharmacy designation for AVONEX® and PLEGRIDY®. Please access the 340B ESP™ platform at https://www.340besp.com/designations to make this selection.

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

A: Yes, under Biogen's 340B contract pharmacy policy, contract pharmacies that are wholly owned by the covered entity or share common ownership with a health system are subject to the same policy requirements as other contract pharmacies. A wholly owned pharmacy can be designated as a covered entity's single contract pharmacy.

Q: I have an in-house pharmacy that is capable of purchasing and dispensing Biogen drugs, but I don't use it to dispense Biogen drugs. Can I designate one contract pharmacy instead?

A: No, under Biogen's policy, if a covered entity has an in-house pharmacy, the entity must use that pharmacy to receive 340B purchases of AVONEX® and PLEGRIDY® and cannot designate a separate contract pharmacy. In addition, if a covered entity has an in-house pharmacy capable of purchasing and dispensing ZURZUVAE®, the entity must use that pharmacy to receive 340B purchases of ZURZUVAE® and cannot designate a separate contract pharmacy.

Q: How often can I change my contract pharmacy designation?

A: 340B covered entities that do not have an in-house pharmacy can designate a single contract pharmacy for AVONEX® and PLEGRIDY® once every twelve (12) months. Similarly, 340B covered entities that do not have an in-house pharmacy capable of purchasing and dispensing ZURZUVAE® can designate a single contract pharmacy for ZURZUVAE® once every twelve (12) months. Changes to a contract pharmacy designation can be made by visiting https://www.340besp.com/designations. Covered entities that have their designated contract pharmacy location terminated will be permitted an additional designation within the twelve (12) months if needed. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their single contract pharmacy designation.

Q: I already designated a single contract pharmacy for Biogen. Do I need to re-designate on 340B ESP™?

A: Covered entities that currently have a designation in place through 340B ESP™ do not need to re-designate provided they have satisfied the requirements of Biogen's updated policy. Covered entities must begin submitting claims data with respect to their designated contract pharmacy and the designated contract pharmacy must be located within 40 miles of the covered entity parent site. If a previously designated contract pharmacy is no longer eligible under the requirements of Biogen's updated policy, the covered entity will need to re-designate.

Q: My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo® pharmacy locations). Can I designate all locations **of the same pharmacy?**

A: No, covered entities without an in-house pharmacy may designate a single contract pharmacy location with respect to AVONEX® and PLEGRIDY® and a single contract pharmacy location with respect to ZURZUVAE® within the ZURZUVAE® limited distribution pharmacy network. Contract pharmacy locations are registered individually on the HRSA database, and a contract pharmacy designation should correspond to a single contract pharmacy registration within the HRSA database.

Q: How do I ensure that my contract pharmacy designation takes effect on January 20, 2025?

A: For a covered entity's contract pharmacy designation to take effect on January 20, 2025, its contract pharmacy selection needs to be made by January 5, 2025. A covered entity that currently has a designation in place through 340B ESP™ does not need to re-designate provided it has satisfied the requirements of Biogen's updated policy. After January 5, 2025, please allow up to 10 business days for designations to take effect.

Q: How can my covered entity identify pharmacy locations within 40 miles of my parent site location?

A: 340B ESP™ will maintain a list of pharmacies within a 40-mile radius of the covered entity parent site location registered on the HRSA 340B OPAIS database.

Q: What if my 340B covered entity does not have a contract pharmacy within a 40-mile radius of my **parent site?**

A: If your covered entity does not have a contract pharmacy registered with HRSA that is within a 40-mile radius of the parent site, please contact support@340Besp.com to find an acceptable alternative pharmacy.

Q: Is Biogen 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 a contract pharmacy location. This information is important for Biogen 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: Biogen 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.

Q: What are the requirements for submission of claims data?

A: The claims data submission requirement applies to a covered entity without an in-house pharmacy that designates a single contract pharmacy location for AVONEX® and PLEGRIDY®, and/or a single contract pharmacy location for ZURZUVAE®. All specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.

The 340B ESP™ platform supports 340B claims uploads. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions.

Exhibit A
State Policies

A. Effective as of the dates specified, covered entities in the states listed below are not subject to the requirements of the Biogen 340B Purchase Policy, if using a contract pharmacy located in the relevant state:

Arkansas (effective March 12, 2024)

West Virginia (effective June 6, 2024)

Louisiana (effective June 11, 2024)

Kansas (effective July 1, 2024)

Maryland (effective July 1, 2024)

Minnesota (effective July 1, 2024)

Mississippi (effective July 1, 2024)

Missouri (effective August 28, 2024)

Nebraska (effective April 10, 2025)

Utah (effective May 7, 2025)

Vermont (effective June 11, 2025)

South Dakota (effective July 1, 2025)

North Dakota (effective August 1, 2025)

Colorado (effective August 6, 2025)

B. Effective July 1, 2025, Biogen will exempt Hawaii covered entities using contract pharmacies located in Hawaii from the Biogen 340B Purchase Policy, so long as the covered entity submits to Biogen claims data to substantiate all 340B purchases within 45 days of the date of dispense to the covered entity's patient. This claims data is necessary so that Biogen may investigate potential diversion, duplicate discounts, or whether a transaction is eligible for a rebate under applicable arrangements between Biogen and third-party payers.