



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

March 15, 2024

Dear Arkansas 340B Covered Entity,

Biogen has voluntarily updated its 340B purchase policy set forth in the attachment to this notice. Effective March 12, 2024, Biogen will exempt Arkansas covered entities using Arkansas contract pharmacies from such policy. This exemption applies only to 340B-eligible covered entities and contract pharmacies located within Arkansas. We continue to reserve the right to further update our policy at our discretion.

Biogen continues to strongly support the mission of the 340B Program as well as any steps to increase transparency and accountability under the program. Biogen will continue to monitor purchases of its products for compliance with 340B Program requirements.

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

Best Regards,

A handwritten signature in black ink, appearing to read "B. Mangin".

Brendan Mangin
Head of US Market Access & Reimbursement

Attachment



December 1, 2023

Dear 340B Covered Entity,

We appreciate the critical role that 340B covered entities play in providing life-altering medications to underserved populations. Effective December 1, 2023, Biogen is updating its policy with respect to distributing 340B purchases. This policy was initially effective February 1, 2023, and applied to AVONEX® and PLEGRIDY®. Biogen is now updating its policy to add ZURZUVAE™, which will be distributed through a limited pharmacy network.

Effective December 1, 2023, Biogen will ship AVONEX®, PLEGRIDY® and ZURZUVAE™ purchased at the 340B price by hospital covered entities exclusively to locations registered as a 340B covered entity or a child site location, except for the exemptions outlined below.

In an effort to support continued patient access, any 340B hospital covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location to receive 340B purchases of AVONEX® and PLEGRIDY®. Any 340B hospital covered entity that does not have an in-house pharmacy capable of dispensing ZURZUVAE™ may designate a single contract pharmacy location within the ZURZUVAE™ limited distribution pharmacy network to receive 340B purchases of ZURZUVAE™. Hospital 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 via the 340B ESP™ platform at <https://www.340besp.com/designations>.

Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a 340B-eligible health system will remain eligible to receive 'Bill-To / Ship-To' replenishment orders of AVONEX® and PLEGRIDY® at 340B pricing; these pharmacies must be registered with HRSA as a contract pharmacy of the 340B hospital. Hospital covered entities may apply for a wholly owned contract pharmacy exemption at https://www.340besp.com/wholly_owned_application. If a hospital covered entity is granted an exemption for its wholly or commonly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy. Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a 340B-eligible health system will remain eligible to receive 'Bill-To / Ship-To' replenishment orders of ZURZUVAE™ at 340B pricing, so long as the wholly owned pharmacy is within the ZURZUVAE™ limited pharmacy network.

Covered entities that are federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K) are not subject to this policy and will remain eligible to place 'Bill-To / Ship-To' 340B orders of AVONEX®, PLEGRIDY® and ZURZUVAE™.

Biogen strongly supports the mission of the 340B Program as well as any steps to increase transparency and accountability under the program. We will continue to provide 340B pricing to all covered entities in accordance with the 340B statute. Please contact support@340besp.com if you have any questions.

Best Regards,



Brendan Manquin
Head of US Market Access & Reimbursement

Frequently Asked Questions

Q. Which products are covered under Biogen's contract pharmacy policy?

A. AVONEX[®] (interferon beta-1a), PLEGRIDY[®] (peginterferon beta-1a) and ZURZUVAE[™] (zuranolone) CIV.

Q. If a covered entity has already designated a contract pharmacy for AVONEX[®] and PLEGRIDY[®], would the covered entity need to complete a separate designation for ZURZUVAE[™]?

A. Yes. Contract pharmacy designations for ZURZUVAE[™] must be completed separately from any that have been completed for AVONEX[®] and PLEGRIDY[®].

Q. If a covered entity has an approved wholly owned exemption for AVONEX[®] and PLEGRIDY[®], would the covered entity need to submit a separate wholly owned application for ZURZUVAE[™]?

A. There is not a separate wholly owned application for ZURZUVAE[™]. Wholly owned applications for AVONEX and PLEGRIDY will apply to ZURZUVAE[™] if the pharmacy is in the ZURZUVAE[™] limited distribution pharmacy network.

Q. Which covered entities are subject to Biogen's contract pharmacy policy for AVONEX[®], PLEGRIDY[®] and ZURZUVAE[™]?

A. All eligible 340B covered entities, with the exception of 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 contract pharmacy location with respect to AVONEX[®] and PLEGRIDY[®] can be designated via the Designations form on www.340besp.com/designations. With respect to ZURZUVAE[™], only a single contract pharmacy location within the ZURZUVAE[™] limited distribution pharmacy network can be designated via the Designations form on 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 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 OPAS 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.

Q. How does a covered entity designate a contract pharmacy?

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 with respect to AVONEX[®] and PLEGRIDY[®] at www.340besp.com/designations. With respect to ZURZUVAE[™], it may complete the form to designate a single contract pharmacy location within the ZURZUVAE[™] limited distribution pharmacy network at www.340besp.com/designations.

Alternatively, if a hospital covered entity has a wholly owned contract pharmacy, it may complete the Wholly Owned Exemption application at https://www.340besp.com/wholly_owned_application.

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 its single contract pharmacy location or to be approved for a wholly owned contract pharmacy exemption. 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.

December 12, 2022

Dear 340B Covered Entity,

We appreciate the critical role that 340B covered entities play in providing life-altering medications to underserved populations. Beginning February 1, 2023, Biogen is altering its approach of distributing 340B purchases of AVONEX® and PLEGRIDY®.

Historically, although not required, Biogen has voluntarily allowed 'Bill-To / Ship-To' purchases for contract pharmacies registered on the 340B database. Effective February 1, 2023, Biogen will ship AVONEX® and PLEGRIDY® purchased at the 340B price by hospital covered entities exclusively to locations registered as a 340B covered entity or a child site location, except for the exemptions outlined below.

In an effort to support continued patient access, any 340B hospital covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location to receive 340B purchases of AVONEX® and PLEGRIDY®. Hospital covered entities without an in-house pharmacy may designate a single contract pharmacy location via the 340B ESP™ platform at <https://www.340besp.com/designations>.

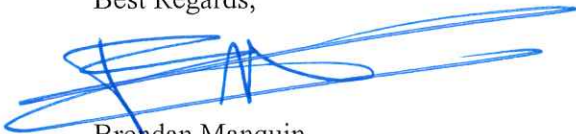
Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a 340B-eligible health system will remain eligible to receive 'Bill-To / Ship-To' replenishment orders of AVONEX® and PLEGRIDY® at 340B pricing; these pharmacies must be registered with HRSA as a contract pharmacy of the 340B hospital. Hospital covered entities may apply for a wholly owned contract pharmacy exemption at https://www.340besp.com/wholly_owned_application. If a hospital covered entity is granted an exemption for its wholly or commonly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy.

To clarify, this change in process impacts only AVONEX® and PLEGRIDY®; no other Biogen products are impacted by this change. Furthermore, covered entities that are federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K) are not subject to this policy and will remain eligible to place 'Bill-To / Ship-To' 340B orders of AVONEX® and PLEGRIDY®.

Affected covered entities are encouraged to work with their contract pharmacy administrators to complete all outstanding contract pharmacy orders in advance of February 1, 2023.

Biogen strongly supports the mission of the 340B Program as well as any steps to increase transparency and accountability under the program. We will continue to provide 340B pricing to all covered entities in accordance with the 340B statute. Please contact support@340besp.com if you have any questions.

Best Regards,



Brendan Manquin
Head of US Market Access & Reimbursement

Frequently Asked Questions

Q: Which products are covered under Biogen's new contract pharmacy policy?

A. AVONEX® (interferon beta-1a) and PLEGRIDY® (peginterferon beta-1a).

Q: Which covered entities are subject to Biogen's new contract pharmacy policy?

A. All eligible 340B covered entities, with the exception of 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 contract pharmacy location can be designated via the Designations form on 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 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.

Q. How does a covered entity ensure its contract pharmacy designation will be in effect on February 1?

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. Alternatively, if a hospital covered entity has a wholly owned contract pharmacy, it may complete the Wholly Owned Exemption application at https://www.340besp.com/wholly_owned_application. Affected covered entities are encouraged to submit designations for approval as soon as possible.

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 its single contract pharmacy location or to be approved for a wholly owned contract pharmacy exemption. 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.