Biogen 340B In-House Pharmacy Claims Level Data (CLD) Policy

May 1, 2026

Dear 340B Covered Entity,

In order to help identify duplicate discounts and other 340B program abuses, preserve our ability to initiate good faith inquiries and audits, and expand transparency, effective for dispenses on or after June 1, 2026, Biogen will require covered entities to submit claims level pharmacy dispense data (CLD) for **all** 340B dispenses of specified products, including in-house pharmacy dispensing and dispenses by contract pharmacies.

Effective June 1, 2026, except as specified on Exhibit A, all covered entity types will be required to provide CLD for pharmacy dispenses of AVONEX® (interferon beta-1a), PLEGRIDY® (peginterferon beta-1a), TECFIDERA® (dimethyl fumarate), and VUMERITY® (diroximel fumarate) to the 340B ESP™ platform within 45 days of product dispense. Failure to provide timely, complete, and accurate data for products dispensed at 340B ceiling prices may result in loss of access to 340B pricing until such time as the outstanding data is provided.

The 340B ESP platform is the only way a covered entity can submit CLD under Biogen's policy. Covered entities can register for an account at www.340BESP.com. Please complete the registration promptly to be ready to submit data within the above timelines for dispenses made on or after June 1, 2026.

Biogen's 340B Purchase Policy (establishing contract pharmacy limitations for certain products), available on the 340B ESP platform, is not changed or altered by this notice. Biogen will allow distribution of 340B ceiling-priced applicable products directly to covered entities and their child sites only, with limited exceptions.

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 if the covered entity provides the minimal, standard business information outlined in this notice. 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 this notice.

Best Regards,

Signed by:
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Jason Hawbecker
Head of US Market Access & Reimbursement

Frequently Asked Questions

Q: What are the requirements for submitting claims data?
A: 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. 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. CEs can email support@340BESP.com with any questions.

Q: Which products are subject to Biogen's 340B Claims Level Data Policy?
A: Biogen's 340B Claims Level Data Policy applies to AVONEX® (interferon beta-1a), PLEGRIDY® (peginterferon beta-1a), TECFIDERA® (dimethyl fumarate), and VUMERITY® (diroximel fumarate).

Q: If my covered entity is currently submitting data to 340 ESP, do I need to take any action?
A: If your covered entity has access to both in-house and contract pharmacies and is only submitting CLD for the contract pharmacy dispenses, please contact 340B ESP to begin the claims submission process for in-house pharmacy dispenses. All covered entities must submit CLD for all pharmacy dispenses occurring on or after June 1, 2026 to maintain access to 340B pricing.

Q: How will Biogen use the 340B claims data that we provide through 340B ESP™?
A: Data uploaded by 340B covered entities will be used to monitor for ineligible duplicate discounts, monitor for potential diversion or other 340B program integrity concerns, substantiate good faith inquiries and audits of covered entities where applicable, and for other purposes set forth in the 340B ESP Covered Entity Portal Terms of Use.

Q: Will CEs be able to register and begin submitting claims level data prior to June 1, 2026?
A: The 340B ESP platform will be configured to support 340B claims level data submissions for in-house pharmacies and CPs beginning June 1, 2026. Prior to June 1, 2026, CEs may register on the 340B ESP platform and familiarize themselves with the claims level data submission process.

Q: My covered entity dispenses exclusively through in-house dispensing and does not use contract pharmacies. Am I impacted by this notice?
A: Yes. Beginning with dispenses on or after June 1, 2026, in-house pharmacy dispensing claims data is required to be submitted to maintain access to AVONEX® (interferon beta-1a), PLEGRIDY® (peginterferon beta-1a), TECFIDERA® (dimethyl fumarate), and VUMERITY® (diroximel fumarate) at 340B ceiling prices. Contact www.340BESP.com to register and set up the claims submission process, if not currently submitting data.

Q: What training and resources will be provided to CEs to help with this transition?
A: Detailed information and tutorials on how to use the 340B ESP platform can be found on the 340B ESP platform FAQs. In addition, CEs can email support@340BESP.com with any 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 Claims Level Data (CLD) Policy:

- West Virginia (effective June 1, 2026)
- Nebraska (effective June 1, 2026)
- Utah (effective June 1, 2026)
- Vermont (effective June 1, 2026)
- Tennessee (effective June 1, 2026)
- South Dakota (effective June 1, 2026)
- North Dakota (effective June 1, 2026)
- Colorado (effective June 1, 2026)
- Maine (effective June 1, 2026)
- Oregon (effective June 1, 2026)
- Rhode Island (effective June 1, 2026)
- Washington (effective June 1, 2026)

B. Effective June 1, 2026, Biogen will exempt "applicable entities" in New Mexico as specified below from the Biogen 340B Claims Level Data Policy. For purposes of this exemption, "applicable entity" means an organization that is located in New Mexico, receives federal grant funding, and is recognized by the federal health resources and services administration (HRSA) as a federally qualified health center or a federally qualified health center lookalike. Specifically, this includes the following types of covered entities as designated by HRSA on its Office of Pharmacy Affairs Information System (OPAIS) database: HRSA-Funded Health Center (abbreviation CH) Health Center Program Look-Alike (abbreviation FQHCLA) Tribal Contract/Compact with IHS (abbreviation FQHC638) Urban Indian (abbreviation UI) Native Hawaiian Health Care Program entities (abbreviation NH).