



Amgen USA Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
805.447.1000

March 17, 2023

Customer Name
Street Address
City, State Zip
Attn: Contact Name

Dear Customer Name,

I am writing to inform you that Amgen Inc. (Amgen) is modifying its policy regarding drugs provided at the 340B price. Effective April 11th, 2023, Amgen will provide products purchased at the 340B price exclusively to locations registered as a 340B covered entity or other locations designated in accordance with Amgen's policy, as described further below. Subject to the exceptions described below, pharmacies registered as contract pharmacies will no longer be eligible for Bill To / Ship To orders. Federal grantees will remain eligible to place Bill To / Ship To orders of drugs at the 340B price for their contract pharmacies.

Effective April 11th, 2023:

- To ensure all 340B covered entities can access Amgen products at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location for delivery of 340B-priced drugs within 40 miles of the covered entity parent site.
- A covered entity that does have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy for delivery of 340B-priced drugs if (i) the location of the single contract pharmacy is within 40 miles of the covered entity parent site and (ii) the covered entity provides claims data for both the in-house pharmacy and the designated single contract pharmacy.

Amgen is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. 340B covered entities that haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab. Entities that had designated contract pharmacies based on the previous policy will have to re-designate.

Covered Entities must take action by March 27th, 2023 in order for contract pharmacy location designations to take effect on the effective date of the policy.

Covered entities may also elect to submit 340B claims through 340B ESP™ for all utilization dispensed through in-house and contract pharmacies.

In support of a smooth transition to our new policy, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To orders in advance of the April 11th, 2023 effective date. Subject to the exceptions above, PHS contracts administered by our wholesalers will no longer support distribution of drugs purchased at the 340B price to 340B contract pharmacies after April 11th, 2023.

Best regards,

David Zimmer
Vice President, Value, Coverage & Pricing

USA-CBU-81152

Frequently Asked Questions

Q Which products are subject to Amgen's policy?

A The current policy primarily applies to self-administered, pharmacy benefit Amgen products, specifically Repatha®, Enbrel®, Otezla®, Aimovig®, Tezspire® and Amjevita®.

Q If a covered entity has a contract pharmacy relationship with a pharmacy that is wholly owned or under common ownership with the covered entity's health system, is this pharmacy subject to Amgen's policy?

A Any non-grantee covered entity may elect to designate any contract pharmacy location registered on the HRSA OPAIS database that is within 40 miles of the covered entity's parent site, regardless of ownership interest, as its single contract pharmacy location so long as it complies with the claim submission requirements noted below.

- Any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location for delivery of 340B-priced drugs within 40 miles of the covered entity parent site.
- A covered entity that does have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy for delivery of 340B-priced drugs if (i) the location of the single contract pharmacy is within 40 miles of the covered entity parent site and (ii) the covered entity provides claims data for both the in-house pharmacy and the designated single contract pharmacy

Q If a covered entity has an in-house pharmacy that is capable of purchasing and dispensing Amgen drugs, but the entity doesn't currently use it to dispense Amgen drugs, can the entity designate one contract pharmacy instead?

A Yes, under Amgen's policy, a covered entity that has an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy for delivery of 340B priced drugs if (i) the location of the single contract pharmacy is within 40 miles of the covered entity parent site and (ii) the covered entity provides claims data for both the in-house pharmacy and the designated single contract pharmacy.

Q What happens if a covered entity does not have an in-house pharmacy that is capable of purchasing and dispensing Amgen drugs and does not have a contract pharmacy within the 40-mile radius of the parent site?

A Amgen will allow the use of a contract pharmacy beyond the 40-mile radius if a covered entity shows that (1) it lacks an in-house pharmacy capable of purchasing and dispensing Amgen's drugs and (2) there is no contract pharmacy capable of purchasing and dispensing Amgen's drugs within a 40-mile radius of the covered entity's parent site.

Q If a 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy, can the entity designate all locations of the same pharmacy?

A Amgen’s policy allows 340B covered entities to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA. The only exceptions to the above apply to Federal grantees, which may obtain products at the 340B price through multiple contract pharmacy locations.

Q How can a 340B covered entity change its contract pharmacy designation?

A Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database. 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 Is Amgen requiring covered entities to have a HIN registered for the contract pharmacy 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. This information is important for Amgen to manage its process with its wholesalers.

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

A Amgen 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 without a HIN in 340B ESP™, the system will notify the covered entity of this requirement and provide instructions for how to obtain a HIN.

Q How does a covered entity ensure that its contract pharmacy designation takes effect on April 11th, 2023?

A For a covered entity’s contract pharmacy designation to take effect on April 11th, 2023, its contract pharmacy designation or re-designation needs to be made by March 27th, 2023. After March 27th, please allow 10 business days for the designation to take effect.

Q If a covered entity would like to submit 340B claims for its in-house pharmacy and contract pharmacy and continue purchasing Amgen products at the 340B price, what does the entity need to do to begin submitting claims data?

A 340B covered entities that wish to submit claims data under Amgen’s policy can do so by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting claims for Amgen by navigating to the Claims Data Submission tab.

Q What happens if a covered entity does not provide 340B contract pharmacy claims data by the required date?

A If a covered entity elects not to submit claims data for its contract pharmacy, the covered entity can continue receiving 340B-priced products at the covered entity’s in-house pharmacy. If the covered

entity does not have an in-house pharmacy capable of dispensing products purchased at the 340B price, the covered entity may designate a single contract pharmacy in accordance with Amgen's policy.

Q Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing, once eligibility for our contract pharmacy designation has been processed by our wholesaler?

A All contract pharmacy replenishment orders for all covered entities registered with 340B ESP™ will be honored for prescriptions dispensed to eligible 340B patients within forty-five (45) days of each data submission to 340B ESP™. Please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your initial Amgen claims submission to 340B ESP™.