



Modified April 11, 2024 To Reflect Update To Takeda's 340B Contract Pharmacy Policy

February 23, 2024

Re: Takeda 340B Contract Pharmacy Policy

Dear Customer,

We write to inform you that effective March 22nd, 2024, Takeda is adding Ninlaro to its 340B Contract Pharmacy Policy that went into effect on January 22nd, 2024, and was updated to include additional products on February 16th, 2024.

Takeda is altering its approach to distributing the Products identified below when purchased under the 340B Drug Pricing Program ("340B"). Takeda's authorized wholesalers and distributors will continue to ship these Products to locations registered as a 340B covered entity or child site location affiliated with that covered entity. However, in accordance with the effective dates listed below, Takeda authorized wholesalers and distributors will not ship specified Products to covered entity contract pharmacies except as described below. As such, some of your contract pharmacies will no longer be eligible recipients for 340B Bill To/Ship To replenishment orders for these Products.

Products included in this policy effective January 22nd, 2024: Entyvio Pen, Entyvio IV, Trintellix, Motegrity, Mydayis, Dexilant, Adderall XR, Pentasa, Vyvanse

Products included in this policy effective February 16th, 2024: Iclusig, Alunbrig, Fruzaqla

Product included in this policy effective March 22nd, 2024: Ninlaro

Except for federal grantees as described below, the following conditions will be applied for these Products under Takeda's 340B Contract Pharmacy Policy beginning on their applicable effective dates:

- Any covered entity that does not have an in-house pharmacy capable of dispensing Products purchased at the 340B price to its patients may designate **a single independent contract pharmacy location OR its Wholly Owned Contract Pharmacy(ies)** to receive Bill To/Ship To replenishment orders of 340B priced Products, as described in this policy.
- Any covered entity that has an in-house pharmacy capable of dispensing Products purchased at the 340B price to its patients may also designate its Wholly Owned Contract Pharmacy(ies) to receive Bill To/Ship To replenishment orders of 340B priced Products, as described in this policy.
- "Wholly Owned Contract Pharmacy(ies)" include contract pharmacies that are **wholly owned** by the covered entity (or have **common ownership** with the entity) and are registered with HRSA as a contract pharmacy for that covered entity.
- Any designated single contract pharmacy location or Wholly Owned Contract Pharmacy must be **within 40 miles** of the covered entity parent site, except as described below.
- For **Entyvio Pen, Iclusig, Alunbrig, Fruzaqla, and Ninlaro**, only pharmacies in Takeda's limited distribution network with access to a specific Product may be designated for the same Product, so the requirement that the designated single contract pharmacy or Wholly Owned Contract Pharmacy(ies) be within 40 miles of the covered entity's parent site may be waived by Takeda.



- The covered entity **must also provide claims data** through 340B ESP™ for the designated single contract pharmacy location or Wholly Owned Contract Pharmacy(ies) to receive 340B discounted pricing.
- Covered entities in states where additional contract pharmacy options may be available will be contacted by Takeda.

Federal grantees remain eligible for Bill To/Ship To arrangements for all Takeda products at the 340B discounted price and do not need to submit 340B claims data through 340B ESP™. Covered entities also remain eligible for Bill To/Ship To 340B arrangements for Takeda products that are not listed in this policy.

Takeda is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. Covered entities impacted by this policy 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 or pharmacies, as appropriate, by navigating to the Entity Profile tab. To submit claims data, covered entities will also need to register an account with 340B ESP™ and must submit the 340B claims within 45 days of the dispense date.

In support of a smooth transition to our new 340B Contract Pharmacy Policy, 340B covered entities impacted by this policy should work with their contract pharmacy administrators and wholesalers/distributors to process any outstanding Bill To/Ship To replenishment orders for the Products in advance of the January 22nd, 2024, February 16th, 2024 and March 22nd, 2024 effective dates. As outlined above, Takeda's authorized wholesalers and distributors will no longer support shipment of these 340B purchased Products to some of your contract pharmacies on or after the applicable effective dates. Please refer to the Next Steps and FAQs below to get started and ensure there is no disruption to your existing pricing.

Best Regards



NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a twice monthly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520.

Frequently Asked Questions

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

A: Covered entities may access the complete list of NDCs at <http://help.340besp.com/en/articles/4455011-what-ndcs-do-we-look-for>.

Q: What happens if a covered entity does not have an in-house pharmacy capable of dispensing these Takeda Products?

A: Takeda will allow the designation of a single independent contract pharmacy location OR any Wholly Owned Contract Pharmacy(ies) within 40 miles of a covered entity's parent site. For Entyvio Pen, Iclusig, Alunbrig, Fruzaqla, and Ninlaro, the designated single contract pharmacy location or Wholly Owned Contract Pharmacy(ies) must be in the applicable Product's limited distribution network, and the requirement that the pharmacy be within 40 miles of the covered entity's parent site may be waived by Takeda. Federal grantees are exempt from this policy.

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

A: Wholly Owned Contract Pharmacies are permitted under Takeda's policy (1) for covered entities that also have an in-house pharmacy, and (2) for covered entities that do not have an in-house pharmacy and choose to designate their Wholly Owned Contract Pharmacy(ies) instead of a single independent contract pharmacy location. Wholly Owned Contract Pharmacy(ies) must be within 40 miles of the



covered entity's parent site, and the covered entity must provide 340B claims data for the pharmacy(ies). Wholly Owned Contract Pharmacy(ies) used to access Entyvio Pen, Iclusig, Alunbrig, Fruzaqla, and Ninlaro at the 340B price must be in the applicable Product's limited distribution network, and the requirement that the designated pharmacy be within 40 miles of the covered entity's parent site may be waived by Takeda. To apply for a Wholly Owned Contract Pharmacy exception, please visit www.340besp.com/wholly_owned_application.

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

A: No. Under Takeda's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B Products to eligible patients, then the covered entity must use that pharmacy and cannot designate an independent contract pharmacy location instead. A covered entity that has an in-house pharmacy may, however, continue to have Products purchased under 340B shipped to their Wholly Owned Contract Pharmacy(ies) within 40 miles of the covered entity's parent site if the covered entity provides 340B claims data for those Wholly Owned Contract Pharmacy(ies).

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

A. No. Takeda's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) 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. Additionally, the designated contract pharmacy must be within 40 miles of the covered entity's parent site and the covered entity must provide 340B claims data for the contract pharmacy.

Q. How often can my 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.

Q. How does my covered entity change its contract pharmacy designation?

A. 340B covered entities can elect a single contract pharmacy location every twelve (12) months. Changes to the single contract pharmacy location 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 Takeda 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. This information is important for Takeda to manage its process with its wholesalers and distributors.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: If you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q. How long does it take for my covered entity's eligible contract pharmacy locations to take effect?

A. Please allow 10 business days for the eligible contract pharmacy locations to take effect. Covered entities should take action by March 8, 2024 to have their contract pharmacy locations in place when Takeda's policy goes into effect on March 22nd, 2024 for Ninlaro.

Q: I have designated my single contract pharmacy and now I need to submit claims for that pharmacy. What does our entity need to do to begin submitting 340B claims?

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

Q: How many days from the date of a drug's dispense does my covered entity have to submit the corresponding claims data?

A: Covered Entities should submit claims within 45 days of the eligible claim's date of service.

FAQs Related to Entyvio Pen

Q: Can a covered entity dispense Entyvio Pen through any contract pharmacy?

A: No, Entyvio Pen can only be dispensed through pharmacies that are within our limited distribution network.

Q: Our 340B covered entity pharmacy is not currently included in the Entyvio Pen limited distribution network. Does this policy mean that our 340B covered entity pharmacy is now approved to dispense this medicine?

A: No. This policy has no effect on which pharmacies are included in the Entyvio Pen limited distribution network.



Q: Does the pharmacy's location that I would like to designate for distribution of Entyvio Pen need to be within 40 miles of my covered entity's location?

A: No. A single contract pharmacy location that a covered entity has chosen to dispense Entyvio Pen must be in the limited distribution network, so the requirement that the designated pharmacy be within 40 miles of the covered entity's parent site may be waived by Takeda.

Q: After designating a single contract pharmacy for distribution of Entyvio Pen, should I submit any additional information through the 340B ESP platform?

A: Once a covered entity has designated a single contract pharmacy location for the purpose of dispensing Entyvio Pen, the covered entity is required to provide claims data for replenishment orders placed at that location through the 340B ESP platform.

Q: Do I need to submit a separate application for a Wholly Owned Contract Pharmacy exception for the purpose of dispensing Entyvio Pen?

A: No. If a covered entity has been approved for a Wholly Owned Contract Pharmacy exception and the approved pharmacy is in the Entyvio Pen limited distribution network, the covered entity will be able to utilize this pharmacy for replenishment orders of Entyvio Pen at the 340B price.

FAQs Related to Iclusig, Alunbrig, Fruzaqla, and Ninlaro

Q: Does my covered entity have to designate the same contract pharmacy for Iclusig, Alunbrig, Fruzaqla, and Ninlaro?

A: No, to the extent needed, covered entities may designate different contract pharmacies for Iclusig, Alunbrig, Fruzaqla, and Ninlaro so long as the pharmacies are within the corresponding limited distribution networks.

Q: Can a covered entity dispense Iclusig, Alunbrig, Fruzaqla, and Ninlaro through any contract pharmacy?

A: No, Iclusig, Alunbrig, Fruzaqla, and Ninlaro can only be dispensed through pharmacies that are within our limited distribution networks.

Q: Our 340B covered entity pharmacy is not currently included in the limited distribution network for Iclusig, Alunbrig, Fruzaqla, or Ninlaro. Does this policy mean that our 340B covered entity pharmacy is now approved to dispense this medicine?

A: No. This policy has no effect on which pharmacies are included in the Iclusig, Alunbrig, Fruzaqla, and Ninlaro limited distribution networks.



Q: Does the pharmacy's location that I would like to designate for distribution of Iclusig, Alunbrig, Fruzaqla, or Ninlaro need to be within 40 miles of my covered entity's location?

A: Yes. A single contract pharmacy location that a covered entity has chosen to dispense Iclusig, Alunbrig, Fruzaqla, or Ninlaro must be within 40 miles of the covered entity's parent location. If your covered entity does not have a contract pharmacy in the limited distribution network within 40 miles of the parent entity and would like to designate a contract pharmacy that is within the limited distribution network but outside of 40 miles of the covered entity's parent location, please contact support@340besp.com.

Q: After designating a single contract pharmacy for distribution of Iclusig, Alunbrig, Fruzaqla, or Ninlaro, should I submit any additional information through the 340B ESP platform?

A: Once a covered entity has designated a single contract pharmacy location for the purpose of dispensing Iclusig, Alunbrig, Fruzaqla, or Ninlaro, the covered entity is required to provide claims data for replenishment orders placed at that location through the 340B ESP platform.

Q: Do I need to submit a separate application for a Wholly Owned Contract Pharmacy exception for the purpose of dispensing Iclusig, Alunbrig, Fruzaqla, or Ninlaro?

A: No. If a covered entity has been approved for a Wholly Owned Contract Pharmacy exception and the approved pharmacy is in the applicable limited distribution network, the covered entity will be able to utilize this pharmacy for replenishment orders of the applicable Product (e.g. Iclusig, Alunbrig, Fruzaqla, and/or Ninlaro) at the 340B price.