



August 2023

Expansion of Pfizer’s Defined Distribution Network for Vyndamax® (tafamidis) and Vyndaqel® (tafamidis meglumine) effective November 1, 2023

Dear 340B Covered Entity and Valued Partners,

Pfizer is providing information about a change in the process to acquire Vyndamax® and Vyndaqel® at the 340B ceiling price beginning November 1, 2023. Additionally, this letter provides information regarding Pfizer’s defined distribution policy that will apply to Vyndamax and Vyndaqel as of that date.

Vyndamax and Vyndaqel are prescription medicines, available in the United States since May 2019, indicated for the treatment of the rare disease cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce death and hospitalization related to heart problems.

Product Name	Product Description	NDC-11
Vyndamax®	Vyndamax® (tafamidis) Capsule Rx	00069-8730-30
Vyndaqel®	Vyndaqel® (tafamidis meglumine) Capsules Rx	00069-1975-40

Since launch, Pfizer, Inc. (“Pfizer”) has utilized a distribution network to distribute Vyndamax and Vyndaqel (“VYNDA Network”) to deliver a consistent patient experience that supports appropriate use for all patients across all non-340B dispensing entities. Pfizer’s VYNDA Network includes (i) six national specialty pharmacies and (ii) eligible institutions. To purchase and dispense Vyndamax and Vyndaqel as an eligible institution in the VYNDA Network (a “VYNDA Network Institution”), a non-340B entity must meet certain eligibility requirements. To date, 340B covered entities have not had to meet such eligibility requirements to purchase and dispense Vyndamax and Vyndaqel from their in-house pharmacies.¹ However, to help ensure all patients prescribed Vyndamax or Vyndaqel receive appropriate care and support,

¹ Under the prior VYNDA Network, a 340B covered entity also was permitted to ship product to one of the six specialty pharmacies in the VYNDA Network if the covered entity maintained a contract pharmacy arrangement with the specialty pharmacy.

effective November 1, 2023, Pfizer will apply the VYNDA Network Institution requirements to 340B covered entities on an equal basis as non-340B entities.

Beginning November 1, 2023, to purchase and dispense Vyndamax and Vyndaqel, a 340B covered entity may either (i) apply to have its specialty pharmacy be a VYNDA Network Institution, or (ii) establish a contract pharmacy relationship with a specialty contract pharmacy in the VYNDA Network subject to the requirements discussed below.

Access to VYNDA Network Through a Specialty Contract Pharmacy

If a 340B covered entity is not a VYNDA Network Institution (discussed further below), Pfizer makes 340B priced product available to Covered Entities through any of the VYNDA Network specialty pharmacies with which the covered entity has a contract pharmacy arrangement.

If a covered entity does not currently maintain a contract pharmacy relationship with one of the VYNDA Network specialty pharmacies, the covered entity may contact any of the following specialty pharmacies to establish a contract pharmacy relationship for dispensing Vyndamax and Vyndaqel to their patients:

- Accredo Specialty Pharmacy (phone 866-759-1557)
- Alliance Rx Walgreens Prime (phone 888-347-3416)
- CenterWell Specialty Pharmacy (phone 800-486-2668)
- CVS Specialty (phone 800-237-2767)
- OptumRx Specialty Services (phone 855-427-4682)
- Orsini Healthcare (phone 800-373-1406)

Beginning **November 1, 2023**, Pfizer will make 340B priced product available to covered entities through any of the VYNDA Network specialty pharmacies with which the covered entity has a contract pharmacy arrangement as follows:

- (1) To ensure that all 340B eligible covered entities that are not VYNDA Network Institutions continue to have access to Vyndamax and Vyndaqel at 340B ceiling prices, any 340B covered entity may designate a single approved VYNDA Network specialty contract pharmacy location online via the 340B ESP™ platform:
 - The selected specialty contract pharmacy location(s) in the VYNDA Network must also be registered on the HRSA 340B OPAIS contract pharmacy database at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/opa).
 - Please visit <https://www.340besp.com/designations> on or after **October 2, 2023** to utilize this option.

- (2) 340B covered entities may engage in multiple VYNDA Network specialty contract pharmacy transactions when the covered entity chooses to provide limited claims data² for product dispensed from their VYNDA Network specialty contract pharmacies.
- Claims data must be submitted via the 340B ESP™ platform, and upon receipt Pfizer will enable shipments for those specialty contract pharmacy locations.
 - The selected specialty contract pharmacy location(s) in the VYNDA Network must also be registered on the HRSA 340B OPAIS contract pharmacy database at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/search/contract-pharmacies).
 - Covered Entities may utilize this option on or after **October 2, 2023** by accessing www.340besp.com. Covered Entities may use their existing 340B ESP™ account, or register for an account, to submit 340B VYNDA Network specialty contract pharmacy claims data and upload the data securely to 340B ESP™.

340B covered entity Bill To / Ship To orders and contract pharmacy transactions that do not fit within one of these options will not be honored by Pfizer on or after November 1, 2023 in connection with purchases of Vyndamax or Vyndaqel.

Access to VYNDA Network as a VYNDA Network Institution

A. Covered Entity Specialty Pharmacy Enrollment as a VYNDA Network Institution

340B covered entity specialty pharmacies may choose to apply for eligibility as a VYNDA Network Institution. Pfizer has engaged with three companies to facilitate any eligible institution's request for access to our VYNDA Network. To qualify, institutions must meet eligibility criteria and must engage with one of three VYNDA Network companies to receive shipments of Vyndamax and Vyndaqel at the 340B ceiling price to any specific in-house specialty pharmacy. Please contact any of the below to inquire about participation as a VYNDA Network Institution:

- Acentrus Specialty (phone 469-299-7250)
- Asembia (phone 973-564-8004)
- Shields Health Solutions (phone 781-566-5066)

² Any covered entity that is a Federal grantee and eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K), ("grantee") may continue to use their registered Pfizer VYNDA Network Specialty contract pharmacies and receive Bill To / Ship To deliveries at the 340B ceiling price. No action is needed by federal grantees. "Grantee" 340B Covered Entities are: Black Lung Clinics Program; Consolidated Health Center Program; Title X funded Family Planning; Tribal Contract/Compact with IHS (P.L. 93-638); Federally Qualified Health Center Look-Alikes; Comprehensive Hemophilia Treatment Center; Native Hawaiian Health Care Program; Ryan White Clinics; Sexually Transmitted Diseases; Tuberculosis and Urban Indian.

B. VYNDA Network Institution Wholly-Owned Specialty Contract Pharmacies

After November 1, 2023, a VYNDA Network Institution that is a wholly-owned contract pharmacy of a 340B covered entity³, will remain eligible on a Bill To/Ship To basis to receive 340B priced product, if the covered entity submits an application and receives approval for a “Wholly Owned Pharmacy” exemption at www.340besp.com/wholly_owned_application. VYNDA Network Institutions may apply for a Wholly Owned Pharmacy exemption on or after **October 2, 2023**.

Pfizer takes its obligations under the 340B program seriously and developed its VYNDA Network in an even-handed manner that treats all purchasers equally, and does not discriminate against 340B Covered Entities. Beginning November 1, 2023, the VYNDA Network will be available to all purchasers -- 340B covered entities and non-340B covered entities -- on an equal basis. If you have any questions regarding the distribution of Vyndamax or Vyndaqel or experience any difficulty obtaining these products at the 340B ceiling price for your eligible patients, please contact Pfizer Customer Service and Product Inquiries: 1-800-879-3477.

Thank you for your interest in Pfizer’s products for your patients.

Paul Hiley



Authorizing Official (AO)
Director/Team Leader, Government Contracts

³ The VYNDA Institution wholly-owned pharmacy location must be registered as a contract pharmacy on the HRSA 340B OPAIS contract pharmacy database at [Search Contract Pharmacies \(hrsa.gov\)](http://SearchContractPharmacies(hrsa.gov)).