



October 2, 2023

## **Pfizer Provides Updates to Defined Distribution Systems Effective November 1, 2023**

Dear 340B Covered Entity and Valued Partners,

This letter is intended to provide notice of updates to Pfizer's Defined Distribution systems, effective November 1, 2023.

The updates are as follows:

- The Defined Distribution system currently utilized for Xeljanz® and Xeljanz XR® (in effect since May 1, 2023) will now include additional Pfizer products as listed in Exhibit A below.<sup>1</sup>
- As communicated in August 2023, Pfizer will apply its defined distribution policy to Vyndamax® and Vyndaqel® beginning November 1, 2023. A summary of the VYNDA Network processes in effect for purchases at the 340B ceiling price is attached as Exhibit B.

There will be no change to Pfizer's Defined Oncology Distribution Network ("DON"). A summary of the current, unchanged processes<sup>2</sup> in effect for Pfizer's oral oncology medicines is in Exhibit C.

Pfizer is a strong proponent of the 340B program. We wholeheartedly support the goals for which it was created. Our updated Defined Distribution systems described below will continue to ensure that 340B hospital covered entities<sup>3</sup> will have access to all applicable products at the 340B price. Pfizer business practices for non-340B customers do not enable distribution of these

---

<sup>1</sup> No action is needed by federal grantees. Any covered entities that are Federal grantees may continue to use their registered contract pharmacies and receive Bill To / Ship To deliveries at the 340B ceiling price. Federal grantees may have multiple contract pharmacy relationships. Federal grantees are eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K). 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.

<sup>2</sup> Although the process is unchanged, there are two additional Talzena NDCs that have been added to the DON as of June 21, 2023.

<sup>3</sup> The term "340B hospital covered entity" in this letter, refers to those entities eligible for participation in the 340B Drug Pricing Program under 42 U.S.C. §256b(a)(4)(L)-(O).

products not under common ownership with the ordering customer. Our updated policy, which will take effect on November 1, 2023, will continue to permit Bill To/Ship To transactions for applicable products for 340B covered entities subject to the conditions outlined in the attached exhibits. Our policy is consistent with the decision of the United States Third Circuit Court of Appeals in *Sanofi Aventis U.S. LLC v. HHS*.<sup>4</sup>

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

Paul Hiley



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

---

<sup>4</sup> See *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 704 (3d Cir. Jan. 30, 2023).



## EXHIBIT A

### Updated Defined Distribution System Utilized for Xeljanz to Include Additional Products

Dear 340B Covered Entity and Valued Partners,

Pfizer is providing information about a change in the process to acquire the products listed below. Effective November 1, 2023, the following Pfizer products will be incorporated into the Defined Distribution system model currently in place for Xeljanz:

Cibinqo™ (abrocitinib), Estring® (estradiol), Genotropin® (somatropin [rDNA origin]), Inflectra® (infliximab-dyyb), Ngenla® (somatrogon-ghla), Nivestym™ (filgrastim-aafi), Nurtec® (rimegepant), Nyvepria™ (Pegfilgrastim-apgf), Premarin® Tablets and Vaginal Cream (conjugated estrogens), Premphase® and Prempro® (conjugated estrogens/medroxy progesterone acetate), Ruxience™ (rituximab-pvvr), Trazimera™ (trastuzumab-quup), Xeljanz® and Xeljanz XR® (tofacitinib), Zavzpret™ (zavegepant) and Zirabev™ (bevacizumab-bvzr).

#### November 1, 2023 Pfizer Defined Distribution Products by NDC11

Products	NDC 11	Description
Cibinqo™ (abrocitinib)	00069-0235-30	50 mg Tablet
Cibinqo™ (abrocitinib)	00069-0335-30	100 mg Tablet
Cibinqo™ (abrocitinib)	00069-0435-30	200 mg Tablet
Estring® (estradiol)	00013-1042-01	2 mg Vaginal Ring
Genotropin® (somatropin [rDNA origin]) Lyophilized Powder	00013-2626-81	5.0 mg Cartridge
Genotropin® (somatropin [rDNA origin]) Lyophilized Powder	00013-2646-81	12.0 mg Cartridge
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2649-02	0.2 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2650-02	0.4 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2651-02	0.6 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2652-02	0.8 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2653-02	1.0 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2654-02	1.2 mg Syringe

Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2655-02	1.4 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2656-02	1.6 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2657-02	1.8 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2658-02	2.0 mg Syringe
Inflectra® (infliximab-dyyb)	00069-0809-01	20 mL/100 mg Glass Vial
NGENLA® (somatrogon-ghla)	00069-0505-02	24 mg 1.2 mL Prefilled Pen
NGENLA® (somatrogon-ghla)	00069-0520-02	60 mg 1.2 mL Prefilled Pen
Nivestym™ (filgrastim-aafi)	00069-0291-01	300 mcg/0.5 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0291-10	300 mcg/0.5 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0293-10	300 mcg/1.0 mL Single Dose Vial
Nivestym™ (filgrastim-aafi)	00069-0292-01	480 mcg/0.8 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0292-10	480 mcg/0.8 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0294-10	480 mcg/1.6 mL Single Dose Vial
NURTEC® (rimegepant)	72618-3000-02	75mg disintegrating tablet (blister pkg of 8)
Nyvepria™ (Pegfilgrastim-ppgf)	00069-0324-01	6 mg/0.6 mL Single Dose Prefilled Syringe
Premarin® (conjugated estrogens) Intravenous	00046-0749-05	25 mg Vial
Premarin® (conjugated estrogens)	00046-1100-81	0.3 mg Tablet
Premarin® (conjugated estrogens)	00046-1100-91	0.3 mg Tablet
Premarin® (conjugated estrogens)	00046-1101-81	0.45 mg Tablet
Premarin® (conjugated estrogens)	00046-1102-81	0.625 mg Tablet
Premarin® (conjugated estrogens)	00046-1102-91	0.625 mg Tablet
Premarin® (conjugated estrogens)	00046-1103-81	0.9 mg Tablet
Premarin® (conjugated estrogens)	00046-1104-81	1.25 mg Tablet
Premarin® (conjugated estrogens)	00046-1104-91	1.25 mg Tablet
Premarin® (conjugated estrogens) Vaginal Cream	00046-0872-21	0.625 mg/30 gm Tube
Premphase® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-2575-12	0.625 mg/5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1105-11	0.3 mg/1.5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1106-11	0.45 mg/1.5 mg Tablet

Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1107-11	0.625 mg/2.5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1108-11	0.625 mg/5 mg Tablet
Ruxience™ (rituximab-pvvr)	00069-0238-01	100 mg/10mL Vials
Ruxience™ (rituximab-pvvr)	00069-0249-01	500 mg/50 mL Vials
Trazimera™ (trastuzumab-quup)	00069-0308-01	150 mg Single-dose Vial
Trazimera™ (trastuzumab-quup)	00069-0305-01	420 mg Glass Vial
Xeljanz XR® (tofacitinib)	00069-0501-30	11 mg Tablet
Xeljanz XR® (tofacitinib)	00069-0502-30	22mg Tablet
Xeljanz® (tofacitinib ) Oral Solution	00069-1029-02	1 mg/mL (240mL bottle)
Xeljanz® (tofacitinib)	00069-1002-01	10 mg Tablet
Xeljanz® (tofacitinib)	00069-1001-01	5 mg Tablet
ZAVZPRET™ (zavegepant)	00069-3500-02	10 mg Nasal Spray
Zirabev™ (bevacizumab-bvzr)	00069-0342-01	400 mg/16mL Injection
Zirabev™ (bevacizumab-bvzr)	00069-0315-01	100 mg/4mL Injection

Effective November 1, 2023, to ensure that all 340B eligible covered entities and their patients continue to have access to these Pfizer products at 340B ceiling prices, the following will apply:

- all 340B hospital covered entities will continue to receive shipments of the products at 340B prices to locations listed on their OPAIS Covered Entity Parent and Child records as “Shipping Locations”, available at [Search Covered Entities \(hrsa.gov\)](https://www.hrsa.gov/340B/opa).
- any 340B hospital covered entity that does not have an in-house pharmacy capable of dispensing 340B priced medicines to its patients may designate a single contract pharmacy location online via the 340B ESP™ platform for these products.
  - The contract pharmacy location selected must be registered on the HRSA 340B OPAIS contract pharmacy database at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/340B/opa).
  - Please visit <https://www.340besp.com/designations> to exercise this option.

### Next Steps

- No action is required for 340B hospital covered entities that do not have an in-house pharmacy and that currently have a single contract pharmacy designation for Xeljanz®. The same single contract pharmacy designation will automatically apply to all other Pfizer products listed above unless the covered entity designates a different single contract pharmacy.

- 340B hospital covered entities that do not have an in-house pharmacy and have not already registered an account with 340B ESP™ can make their single contract pharmacy designation by visiting [Second Sight Solutions \(340besp.com\)](https://www.340besp.com) and registering an account with 340B ESP™. A single contract pharmacy can be designated by navigating to the Entity Profile tab.
- 340B hospital covered entities should take action by October 20, 2023, for its contract pharmacy designation to take effect on November 1, 2023.

### **Voluntary Submission of Claims Level Data**

- A 340B covered entity may voluntarily submit claims data via the 340B ESP™ platform.
- Please see the FAQ's below on Exhibit A-1 for additional information. You may also visit [www.340BESP.com](https://www.340BESP.com) for additional information.

Pfizer is continuing to utilize Second Sight Solutions' 340B ESP™ platform ([www.340besp.com](https://www.340besp.com)) to support the Defined Distribution system for Pfizer products. 340B ESP™ is a web-based platform made available to covered entities at no cost to designate one contract pharmacy affiliations, and to voluntarily submit contract pharmacy claims data.

In support of a smooth transition to the change in distribution for these products, 340B hospital covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To contract pharmacy orders of these products in advance of the November 1, 2023 effective date.

If you have questions regarding the change in distribution for 340B hospital covered entities, please contact Pfizer at [340BCP@pfizer.com](mailto:340BCP@pfizer.com)

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



**EXHIBIT A-1  
FREQUENTLY ASKED QUESTIONS**

**Q: Which products are subject to the changes in Pfizer’s Defined Distribution networks effective November 1, 2023?**

**A:** Pfizer’s Defined Distribution policy changes effective November 1, 2023 apply to:

- Cibinqo™, Estring®, Genotropin®, Inflectra®, Nivestym™, Nurtec®, Nyvepria™, Premarin®, Premphase®, Prempro®, Ruxience™, Trazimera™, Xeljanz® and Xeljanz XR®, Zavzpret™, and Zirabev™.

**November 1, 2023 Pfizer Defined Distribution Products by NDC11**

<b>Products</b>	<b>NDC 11</b>	<b>Description</b>
Cibinqo™ (abrocitinib)	00069-0235-30	50 mg Tablet
Cibinqo™ (abrocitinib)	00069-0335-30	100 mg Tablet
Cibinqo™ (abrocitinib)	00069-0435-30	200 mg Tablet
Estring® (estradiol)	00013-1042-01	2 mg Vaginal Ring
Genotropin® (somatropin [rDNA origin]) Lyophilized Powder	00013-2626-81	5.0 mg Cartridge
Genotropin® (somatropin [rDNA origin]) Lyophilized Powder	00013-2646-81	12.0 mg Cartridge
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2649-02	0.2 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2650-02	0.4 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2651-02	0.6 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2652-02	0.8 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2653-02	1.0 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2654-02	1.2 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2655-02	1.4 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2656-02	1.6 mg Syringe
Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2657-02	1.8 mg Syringe

Genotropin® (somatropin [rDNA origin]) MiniQuick®	00013-2658-02	2.0 mg Syringe
Inflectra® (infliximab-dyyb)	00069-0809-01	20 mL/100 mg Glass Vial
NGENLA® (somatrogon-ghla)	00069-0505-02	24 mg 1.2 mL Prefilled Pen
NGENLA® (somatrogon-ghla)	00069-0520-02	60 mg 1.2 mL Prefilled Pen
Nivestym™ (filgrastim-aafi)	00069-0291-01	300 mcg/0.5 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0291-10	300 mcg/0.5 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0293-10	300 mcg/1.0 mL Single Dose Vial
Nivestym™ (filgrastim-aafi)	00069-0292-01	480 mcg/0.8 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0292-10	480 mcg/0.8 mL Pre-filled Syringe
Nivestym™ (filgrastim-aafi)	00069-0294-10	480 mcg/1.6 mL Single Dose Vial
NURTEC® (rimegepant)	72618-3000-02	75mg disintegrating tablet (blister pkg of 8)
Nyvepria™ (Pegfilgrastim-apgf)	00069-0324-01	6 mg/0.6 mL Single Dose Prefilled Syringe
Premarin® (conjugated estrogens) Intravenous	00046-0749-05	25 mg Vial
Premarin® (conjugated estrogens)	00046-1100-81	0.3 mg Tablet
Premarin® (conjugated estrogens)	00046-1100-91	0.3 mg Tablet
Premarin® (conjugated estrogens)	00046-1101-81	0.45 mg Tablet
Premarin® (conjugated estrogens)	00046-1102-81	0.625 mg Tablet
Premarin® (conjugated estrogens)	00046-1102-91	0.625 mg Tablet
Premarin® (conjugated estrogens)	00046-1103-81	0.9 mg Tablet
Premarin® (conjugated estrogens)	00046-1104-81	1.25 mg Tablet
Premarin® (conjugated estrogens)	00046-1104-91	1.25 mg Tablet
Premarin® (conjugated estrogens) Vaginal Cream	00046-0872-21	0.625 mg/30 gm Tube
Premphase® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-2575-12	0.625 mg/5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1105-11	0.3 mg/1.5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1106-11	0.45 mg/1.5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1107-11	0.625 mg/2.5 mg Tablet
Prempro® (conjugated estrogens/medroxy progesterone acetate) Tablets Rx	00046-1108-11	0.625 mg/5 mg Tablet
Ruxience™ (rituximab-pvvr)	00069-0238-01	100 mg/10mL Vials
Ruxience™ (rituximab-pvvr)	00069-0249-01	500 mg/50 mL Vials



Trazimera™ (trastuzumab-quup)	00069-0308-01	150 mg Single-dose Vial
Trazimera™ (trastuzumab-quup)	00069-0305-01	420 mg Glass Vial
Xeljanz XR® (tofacitinib)	00069-0501-30	11 mg Tablet
Xeljanz XR® (tofacitinib)	00069-0502-30	22mg Tablet
Xeljanz® (tofacitinib ) Oral Solution	00069-1029-02	1 mg/mL (240mL bottle)
Xeljanz® (tofacitinib)	00069-1002-01	10 mg Tablet
Xeljanz® (tofacitinib)	00069-1001-01	5 mg Tablet
ZAVZPRET™ (zavegepant)	00069-3500-02	10 mg Nasal Spray
Zirabev™ (bevacizumab-bvzr)	00069-0342-01	400 mg/16mL Injection
Zirabev™ (bevacizumab-bvzr)	00069-0315-01	100 mg/4mL Injection

- See Exhibit B for changes to Vyndamax® and Vyndaqel® in the Pfizer VYNDA Network.

**Q: My covered entity already has a single contract pharmacy designation for Xeljanz/XR. Are any changes required on 340BESP for the additional Pfizer products?**

**A:** No. The same single contract pharmacy designation will automatically apply to all other Pfizer products listed above unless the covered entity designates a different single contract pharmacy.

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

**A:** Changes to the single contract pharmacy can be made by visiting <https://www.340besp.com/designations>. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their single contract pharmacy designation.

**Q: How often can my covered entity change its contract pharmacy designation?**

**A:** Covered entities may change their single 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: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy able to engage in Bill To / Ship To transactions?**

**A:** Contract pharmacies that are wholly owned by a 340B hospital covered entity or have common ownership with a 340B hospital, are not separately eligible to receive shipments of these Pfizer products on a Bill To / Ship To basis at the 340B ceiling price.

However, eligible hospital covered entities that do not have an in-house pharmacy capable of dispensing 340B priced medicines to their patients may designate a single contract pharmacy location registered on the HRSA OPAIS database at [Search Contract Pharmacies \(hrsa.gov\)](https://hrsa.gov) regardless of ownership interest, as its single contract pharmacy location. Thus, a wholly owned contract pharmacy can be selected as a single contract pharmacy if compliant with our policy. Our policy is consistent with the decision of the United States Third Circuit Court of Appeals in *Sanofi Aventis U.S. LLC v. HHS* (“*Sanofi*”).<sup>5</sup>

**Q: My covered entity does have an in-house pharmacy that is capable of purchasing and dispensing outpatient drugs, but we don’t use it to dispense one or more of these products. Can I designate one contract pharmacy instead?**

**A:** No. If a covered entity has an in-house pharmacy capable of dispensing 340B priced products, the entity must use that pharmacy and cannot designate a contract pharmacy. Our policy is consistent with the decision of the United States Third Circuit Court of Appeals in *Sanofi*.

**Q: What if our 340B hospital covered entity does not have an in-house pharmacy capable of dispensing 340B priced products?**

**A:** Any hospital covered entity that does not have an in-house pharmacy capable of dispensing 340B priced products may designate a single contract pharmacy location for these products. The contract pharmacy location selected must be registered on the HRSA 340B OPAIS contract pharmacy database at [Search Contract Pharmacies \(hrsa.gov\)](https://hrsa.gov). Our policy is consistent with the decision in *Sanofi*.

**Q: My 340B hospital covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different individual retail pharmacy locations of a retail pharmacy chain). Can I designate all locations of the same pharmacy?**

**A:** No. 340B covered entities that do not have an in-house pharmacy capable of dispensing 340B priced products are permitted to designate only a single contract pharmacy location for these products, which corresponds to a single contract pharmacy registration with HRSA. Our policy is consistent with the decision in *Sanofi*.

**Q: How long does it take for my one contract pharmacy designation to take effect?**

**A:** Please allow 10 business days for the designation to be processed and to take effect.

**Q: How do I voluntarily submit limited contract pharmacy claims data for any of these Pfizer product purchases?**

---

<sup>5</sup> See *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 704 (3d Cir. Jan. 30, 2023).

**A:** To voluntarily provide limited contract pharmacy claims data with Second Sight Solutions' 340B ESP™ platform for Pfizer product purchases, navigate to [www.340BESP.com](http://www.340BESP.com) to register an account. For covered entities that have already registered an account, please navigate to the Claims Data tab of the platform to voluntarily submit claims. For further help, you can visit [www.340BESP.com/FAQs](http://www.340BESP.com/FAQs) to learn more about 340B ESP™ and the voluntary data submission process or contact the 340B ESP™ support desk at [support@340besp.com](mailto:support@340besp.com).

**Q: My covered entity is a federal grantee. May my entity engage in Bill To / Ship To orders?**

**A:** Yes. No action is needed by federal grantees. Federal grantees may continue to engage in Bill To / Ship To orders with multiple contract pharmacies.



## EXHIBIT B

### 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,

As communicated in August 2023, 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 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.<sup>6</sup> However, to help ensure all patients prescribed Vyndamax or Vyndaqel receive appropriate care and support, effective November 1, 2023, Pfizer will apply the VYNDA Network Institution requirements to 340B covered entities on an equal basis as non-340B entities.

---

<sup>6</sup> 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.

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 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. A single contract pharmacy can be designated by navigating to the Entity Profile tab.
  - 340B hospital covered entities should take action by October 20, 2023, for a contract pharmacy designation to take effect on November 1, 2023.

- (2) 340B covered entities may engage in multiple VYNDNA Network specialty contract pharmacy transactions when the covered entity chooses to provide limited claims data<sup>7</sup> for product dispensed from their VYNDNA 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 VYNDNA Network must also be registered on the HRSA 340B OPAIS contract pharmacy database at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/opa).
  - Covered Entities may utilize this option on or after **October 2, 2023** by accessing [www.340besp.com](https://www.340besp.com). Covered Entities may use their existing 340B ESP™ account, or register for an account, to submit 340B VYNDNA 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 VYNDNA Network as a VYNDNA Network Institution**

#### **A. Covered Entity Specialty Pharmacy Enrollment as a VYNDNA Network Institution**

340B covered entity specialty pharmacies may choose to apply for eligibility as a VYNDNA Network Institution. Pfizer has engaged with three companies to facilitate any eligible institution's request for access to our VYNDNA Network. To qualify, institutions must meet eligibility criteria and must engage with one of three VYNDNA 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 VYNDNA Network Institution:

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

---

<sup>7</sup> 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 VYNDNA 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 entity<sup>8</sup>, 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](http://www.340besp.com/wholly_owned_application). VYNDA Network Institutions may apply for a Wholly Owned Pharmacy exemption on or after **October 2, 2023**.

For 340B hospital covered entities that already have a Wholly Owned Pharmacy exemption for an eligible Pfizer DON (Defined Oncology Network) pharmacy, please visit [Second Sight Solutions \(340besp.com\)](http://www.340besp.com/second_sight_solutions) and navigate to the **Entity Profile** tab. If this same Wholly Owned pharmacy is also eligible in Pfizer’s VYNDA Network, no further action is necessary.

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.

In support of a smooth transition to the change in distribution for Vyndamax and Vyndaqel, 340B hospital covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To contract pharmacy orders of these products in advance of the November 1, 2023 effective date.

Please see the FAQs below on Exhibit B-1 for additional information.

If you have questions regarding the change in distribution for 340B hospital covered entities, please contact Pfizer at [340BCP@pfizer.com](mailto:340BCP@pfizer.com)

---

<sup>8</sup> 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://www.hrsa.gov/search/contract-pharmacies).



## EXHIBIT B-1 FREQUENTLY ASKED QUESTIONS

To provide contract pharmacy claims data with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to [www.340BESP.com](http://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 only about 15 minutes.
2. Once your account is activated, you will be able to upload data securely 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. Once your account is set up, the claims upload process takes about 5 minutes.

In addition to the frequently asked questions below, you can visit [Second Sight Solutions \(340besp.com\)](http://SecondSightSolutions.com) 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](http://www.340besp.com/resources/webinars) or call Second Sight Solutions at 888-398-5520.

**Q: Which products are subject to Pfizer's defined distribution VYNDA Network effective November 1, 2023?**

**A:** Pfizer's defined distribution VYNDA Network policy effective November 1, 2023 applies to:

Products	NDC 11	Description
Vyndamax® (tafamidis)	00069-8730-30	61 mg Capsule Blister pac (3x10 Blister Pac)
Vyndaqel® (tafamidis meglumine)	00069-1975-40	20 mg Capsule (4x30 Blister Pac)

**Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system and that pharmacy is a VYNDA Network Institution which already has an approved "Wholly Owned Pharmacy" exemption for Pfizer's DON on 340B ESP™. Is this VYNDA Network Institution specialty contract pharmacy able to engage in Bill To/Ship To transactions for Vyndamax and Vyndaqel?**

**A:** Please visit [Second Sight Solutions \(340besp.com\)](http://SecondSightSolutions.com) and navigate to the **Entity Profile** tab to confirm that the Pfizer DON "Wholly Owned Pharmacy" location is also eligible in the Pfizer VYNDA Network as a VYNDA Network Institution. If this same Wholly Owned pharmacy is also eligible in Pfizer's VYNDA Network, no further action is necessary.



**Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system, but the pharmacy is not in the VYNDA Network of specialty pharmacies. Is this pharmacy able to engage in Bill To/Ship To transactions for Vyndamax and Vyndaqel?**

**A:** No. Only VYNDA Network Institutions or VYNDA Network specialty contract pharmacies may receive shipments of 340B priced products.

**Q: My covered entity is prepared to provide the limited claims data requested by Pfizer. May my covered entity engage in Bill To / Ship To orders with multiple VYNDA Network specialty contract pharmacies for Vyndamax and Vyndaqel?**

**A:** Yes. 340B covered entities may engage in multiple VYNDA Network specialty contract pharmacy transactions when the covered entity chooses to provide limited claims data 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/opa).
- Covered Entities may utilize this option by accessing [www.340besp.com](https://www.340besp.com).

**Q: My covered entity has an in-house pharmacy that is a VYNDA Network Institution that is capable of purchasing and dispensing Vyndamax or Vyndaqel. Can I designate a Pfizer VYNDA network specialty contract pharmacy also?**

**A:** If a covered entity has an in-house specialty pharmacy that is a VYNDA Network Institution, it may designate one or more Pfizer VYNDA Network specialty contract pharmacies only if it provides the requested claims data for each VYNDA Network specialty contract pharmacy via the 340B ESP™ platform. Please visit <https://www.340besp.com> for more information.

**Q: What if our 340B hospital covered entity does not have an in-house pharmacy capable of dispensing 340B priced medicines to our patients?**

**A:** Any hospital covered entity without an in-house pharmacy capable of dispensing 340B priced medicines to its patients may select a single Pfizer VYNDA Network specialty contract pharmacy with which it has a contract pharmacy arrangement. The covered entity's VYNDA Network specialty contract pharmacy location must be registered on the HRSA 340B OPAIS contract pharmacy database. In addition, a covered entity may select multiple Pfizer VYNDA Network specialty contract pharmacy locations for Vyndamax and Vyndaqel, if they register those locations on 340B ESP™ platform and provide the limited claims data.

**Q. My 340B hospital covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different individual pharmacy locations of a retail pharmacy chain). Can I designate all locations of the same pharmacy for VYNDA Network products?**

**A:** Contract pharmacy locations are registered individually on the HRSA 340B OPAIS contract pharmacy database. 340B covered entities that do not have an in-house pharmacy are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA. However, if the covered entity wishes to use multiple specialty contract pharmacies for Vyndamax and Vyndaqel in Pfizer's VYNDA Network, they may do so by registering each of the specialty contract pharmacy locations on the 340B ESP™ platform and providing the limited claims data.

**Q: How long does it take for my Pfizer VYNDA Network eligible specialty contract pharmacy selection to take effect?**

**A:** Please allow 10 business days for the designation to be processed and to take effect.

**Q: What is Pfizer's timeframe to accept replenishment orders of NDC11 package sizes at 340B prices accumulated from prescriptions dispensed to 340B eligible patients at eligible VYNDA Network specialty contract pharmacy locations?**

**A:** Pfizer honors contract pharmacy replenishment orders only for prescriptions dispensed to eligible 340B patients not greater than forty-five (45) days prior to the date of each claims data submission on 340B ESP™.

**Q: My covered entity is a federal grantee. May my entity engage in Bill To / Ship To orders?**

**A:** Yes. Federal grantees may engage in Bill To / Ship To orders for Vyndamax and Vyndaqel with one, or multiple of the VYNDA Network specialty contract pharmacies.



## EXHIBIT C

### Defined Distribution for Oral Oncology Medicines in Effect March 1, 2022<sup>9</sup>

Dear 340B Covered Entity and Valued Partners,

Pfizer is a strong proponent of the 340B program. We wholeheartedly support the goals for which the Program was created. As part of Pfizer's commitment to uphold the integrity of the 340B Program, Pfizer has been reviewing examples of, and evaluating the wider risk of, duplicate discounts and diversion of oncology products that occur through contract pharmacy transactions. However, that process has been hampered by the lack of data transparency in contract pharmacy arrangements. As a result, Pfizer's Defined Oncology Distribution Network ("DON") includes the requirements discussed here, which will enable Pfizer to uphold the integrity of the 340B Program.

Effective March 1, 2022, Pfizer made modifications to Pfizer's DON to require 340B hospital covered entities to submit limited claims data for their contract pharmacy transactions, which remains unchanged. When 340B hospital covered entities choose to provide the limited claims data for these products, Pfizer enables multiple contract pharmacy shipments to those locations for the applicable products. The DON enables Pfizer to more effectively detect duplicate discounts and diversion of oncology products that would otherwise go undetected. This system also represents a continued distribution preference provided to 340B covered entities. Pfizer business practices for non-340B customers do not enable distribution of the oral oncology products to locations not under common ownership with the ordering customer.

Pfizer is utilizing Second Sight Solutions' 340B ESP™ platform ([www.340besp.com](http://www.340besp.com)) to support the defined distribution system for 340B hospitals. 340B ESP™ is a web-based platform made available to covered entities at no cost, to designate contract pharmacy affiliations, and to submit the requested contract pharmacy claims data. Pfizer will use this claims data to help identify ineligible or duplicate discounts and diversion. Information for Pfizer's DON is available on 340B ESP™.

Pfizer is committed to ensuring that all 340B covered entities are offered oral oncology medicines, at the 340B-discounted price. All 340B hospitals continue to receive shipments of oral oncology medicines at 340B prices to their approved Pfizer DON wholly owned specialty pharmacy(ies).

---

<sup>9</sup> Pfizer's original notice to covered entities regarding its Defined Oncology Distribution Network went into effect on March 1, 2022. This Exhibit C summarizes the current policy.

In addition, Pfizer voluntarily continues to permit 340B covered entity bill to orders for shipments to their OPAIS registered contract pharmacies (Bill To / Ship To transactions) for these products in four broad situations:

**First**, any covered entity that is a Federal grantee and eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K), (“grantee”<sup>10</sup>) may continue to use their registered Pfizer DON approved contract pharmacies and receive Bill To / Ship To deliveries at the 340B ceiling price. No action is needed by federal grantees.

**Second**, contract pharmacies that are wholly owned by a 340B hospital covered entity<sup>11</sup> or have common ownership with a 340B hospital, will remain eligible to receive shipments of oral oncology products on a Bill To/Ship To basis at the 340B ceiling price. For oral oncology products, the specialty contract pharmacy must be participating in Pfizer’s DON.

- The specialty contract pharmacy locations must be registered on the HRSA 340B OPAIS contract pharmacy database as a contract pharmacy of their related 340B covered entity at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/search/contract-pharmacies).
- The 340B hospital covered entity will also need to access the 340B ESP™ platform and submit the online application for a “Wholly Owned Pharmacy” exemption.
- Please visit [www.340besp.com/wholly\\_owned\\_application](https://www.340besp.com/wholly_owned_application) to ensure continued deliveries under this wholly owned option.

**Third**, 340B hospital covered entities may engage in multiple contract pharmacy transactions, when they choose to provide limited claims data for product dispensed from their Pfizer DON registered contract pharmacy.

- The 340B covered entity will provide claims data via the 340B ESP™ platform, and upon receipt Pfizer will enable shipments for those locations.
- The contract pharmacy location selected must be one of the specialty pharmacies that are part of the Pfizer DON.

**Fourth**, to ensure that all 340B eligible covered entities and their patients continue to have access to oral oncology products at 340B ceiling prices, any 340B hospital covered entity, which (1) declines to provide the requested limited claims data and (2) does not have an in-house approved Pfizer DON specialty pharmacy in Pfizer’s DON, may designate a single approved Pfizer DON specialty contract pharmacy location online via the 340B ESP™ platform:

- 340B hospital covered entities may designate a single specialty contract pharmacy location participating in Pfizer’s DON for oral oncology products at the 340B price.
- The contract pharmacy location(s) selected 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).

---

<sup>10</sup> 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.

<sup>11</sup> The term “340B hospital covered entity” in this letter, refers to those entities eligible for participation in the 340B Drug Pricing Program under 42 U.S.C. §256b(a)(4)(L)-(O).

- Please visit <https://www.340besp.com/designations> to exercise this option.

340B hospital covered entity Bill to / Ship To orders and contract pharmacy transactions that do not fit within one of these four broad situations will not be honored by Pfizer on or after March 1, 2022 in connection with oral oncology product purchases.

This defined distribution policy applies to the following oncology products:

### **Pfizer's DON Oral Oncology Products by NDC<sup>12</sup>**

Bosulif® (bosutinib), Braftovi® (encorafenib), Daurismo™ (glasdegib), Ibrance® (palbociclib), Inlyta® (axitinib Tablets), Lorbrena® (lorlatinib), Mektovi® (binimetinib), Sutent® (sunitinib malate), Talzenna™ (talazoparib), Vizimpro® (dacomitinib), Xalkori® (crizotinib)

<b>Product Name</b>	<b>Product Description</b>	<b>NDC-11</b>
Bosulif® (bosutinib)	BOSULIF 100MG TAB 120 US	00069-0135-01
	BOSULIF 400MG FCT 1X30 BTL US	00069-0193-01
	BOSULIF 500MG TAB 30 US	00069-0136-01
Braftovi® (encorafenib)	BRAFTOVI CAP 75MG 60	70255-0025-03
	BRAFTOVI CAP 75MG 90	70255-0025-01
Daurismo™ (glasdegib)	DAURISMO 100MG TAB 1X30 BTL US	00069-1531-30
	DAURISMO 25MG TAB 1X60 BTL US	00069-0298-60
Ibrance® (palbociclib)	IBRANCE 100MG CAP 1X21 BTL US	00069-0188-21
	IBRANCE 100MG FCT 3X7 BLS US	00069-0486-03
	IBRANCE 125MG CAP 1X21 BTL US	00069-0189-21
	IBRANCE 125MG FCT 3X7 BLS US	00069-0688-03
	IBRANCE 75MG CAP 1X21 BTL US	00069-0187-21
	IBRANCE 75MG FCT 3X7 BLS US	00069-0284-03
Inlyta® (axitinib)	INLYTA (AXITINIB) 1MG TABLETS	00069-0145-01
	INLYTA (AXITINIB) 5MG TABLETS	00069-0151-11
Lorbrena® (lorlatinib)	LORBRENA 100MG FCT 1X30 BTL US	00069-0231-01
	LORBRENA 25MG FCT 1X30 BTL US	00069-0227-01
Mektovi® (binimetinib)	MEKTOVI TAB 15MG 180	70255-0010-02
Sutent® (sunitinib malate)	SUTENT 37.5MG HFC 1X28 PBTL US	00069-0830-38
	SUTENT CAP 12.5MG 28	00069-0550-38
	SUTENT CAP 25MG 28	00069-0770-38
	SUTENT CAP 50MG 28	00069-0980-38
Talzenna™ (talazoparib)	TALZENNA 0.25MG CAP 1X30 BTL US	00069-0296-30
	TALZENNA 1MG CAP 1X30 BTL US	00069-1195-30
	TALZENNA 0.5MG CAP 1X30 BTL US	00069-1501-30

<sup>12</sup> Two additional Talzenna NDCs have been added to the DON as of June 21, 2023.

	TALZENNA 0.75MG CAP 1X30 BTL US	00069-1751-30
	TALZENNA 0.1 MG CAP 1X30 BTL US	00069-1031-30
	TALZENNA 0.35 MG CAP 1X30 BTL US	00069-1235-30
Vizimpro® (dacomitinib)	VIZIMPRO 15MG FCT 1X30 BTL US	00069-0197-30
	VIZIMPRO 30MG FCT 1X30 BTL US	00069-1198-30
	VIZIMPRO 45MG FCT 1X30 BTL US	00069-2299-30
Xalkori® (crizotinib)	XALKORI (CRIZOTINIB) 200 MG CAPSULES	00069-8141-20
	XALKORI (CRIZOTINIB) 250 MG CAPSULES	00069-8140-20

### **Pfizer’s Defined Oncology Distribution Network (DON)**

Currently, Pfizer relies on the DON to distribute certain oral oncology medications listed above. This distribution model helps to ensure that the small patient populations, who typically have advanced stage cancers, have access to clinicians who are most familiar with our products so that the patients receive the best possible care when prescribed a Pfizer oncology medication.<sup>13</sup>

All 340B hospital covered entity hospitals approved for participation in Pfizer’s defined oncology distribution network remain eligible for 340B ceiling priced oncology products. Orders may be placed by covered entity hospitals with an approved Pfizer DON specialty pharmacy that is a wholly owned pharmacy co-located with the site of patient care.<sup>14</sup>

Any 340B hospital covered entity that is not part of Pfizer’s defined oncology distribution network may apply for participation in the DON. It may also designate a single contract specialty pharmacy in Pfizer’s DON at one shipping address.

- The specialty contract pharmacy location selected 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)
- Please visit <https://www.340bsp.com/designations> to exercise this option.
- In addition, a covered entity may select multiple contract specialty pharmacy locations in the DON if the covered entity registers those locations on the 340B ESP™ platform and provides the limited claims data. Please visit <https://www.340bsp.com> to exercise this option.

Please see the FAQs below for additional information.

---

<sup>13</sup> Please see Pfizer’s 340B Notice Regarding Defined Distribution Oncology Network at <https://www.hrsa.gov/sites/default/files/opa/files/340bnoticeregardingpfizerdefinedoncology.pdf>

<sup>14</sup> Under the existing DON, non-340B hospital customers are permitted to have product purchases shipped only to their wholly owned pharmacies co-located within the site of patient care. In other words, non-340B customers may not have a Bill To/Ship To arrangement where the Ship To location does not have common ownership with the Bill To customer. 340B entities, on the other hand, historically have been given a unique advantage in that they may purchase product at the 340B price and have the product shipped to one of the DON approved specialty pharmacies, even though the specialty pharmacy is not under common ownership with the 340B covered entity.

If you have questions regarding the change in distribution for 340B hospital covered entities, please contact Pfizer at [340BCP@pfizer.com](mailto:340BCP@pfizer.com)

## EXHIBIT C-1 FREQUENTLY ASKED QUESTIONS

To provide contract pharmacy claims data with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

4. Go to [www.340BESP.com](http://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 only about 15 minutes.
5. Once your account is activated, you will be able to upload data securely to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
6. Login to 340B ESP™ and submit your 340B contract pharmacy claims data. Once your account is set up, the claims upload process takes about 5 minutes.

In addition to the frequently asked questions below, you can visit [Second Sight Solutions \(340besp.com\)](http://SecondSightSolutions.com) 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](http://www.340besp.com/resources/webinars) or call Second Sight Solutions at 888-398-5520.

### **Q: Which products are subject to Pfizer's DON?**

**A:** Pfizer's defined distribution policy applies to Pfizer's oral oncology products managed through our Defined Oncology Distribution Network (DON)<sup>15</sup>:

Bosulif® (bosutinib), Braftovi® (encorafenib), Daurismo™ (glasdegib), Ibrance® (palbociclib), Inlyta® (axitinib Tablets), Lorbrena® (lorlatinib), Mektovi® (binimetinib), Sutent® (sunitinib malate), Talzenna™ (talazoparib), Vizimpro® (dacomitinib), Xalkori® (crizotinib)

Name	Product Description	NDC-11
Bosulif® (bosutinib)	BOSULIF 100MG TAB 120 US	00069-0135-01
	BOSULIF 400MG FCT 1X30 BTL US	00069-0193-01
	BOSULIF 500MG TAB 30 US	00069-0136-01
Braftovi® (encorafenib)	BRAFTOVI CAP 75MG 60	70255-0025-03
	BRAFTOVI CAP 75MG 90	70255-0025-01
Daurismo™ (glasdegib)	DAURISMO 100MG TAB 1X30 BTL US	00069-1531-30
	DAURISMO 25MG TAB 1X60 BTL US	00069-0298-60
Ibrance® (palbociclib)	IBRANCE 100MG CAP 1X21 BTL US	00069-0188-21

<sup>15</sup> Two additional Talzenna NDCs have been added to the DON as of June 21, 2023.



	IBRANCE 100MG FCT 3X7 BLS US	00069-0486-03
	IBRANCE 125MG CAP 1X21 BTL US	00069-0189-21
	IBRANCE 125MG FCT 3X7 BLS US	00069-0688-03
	IBRANCE 75MG CAP 1X21 BTL US	00069-0187-21
	IBRANCE 75MG FCT 3X7 BLS US	00069-0284-03
Inlyta® (axitinib)	INLYTA (AXITINIB) 1MG TABLETS	00069-0145-01
	INLYTA (AXITINIB) 5MG TABLETS	00069-0151-11
Lorbrena® (lorlatinib)	LORBRENA 100MG FCT 1X30 BTL US	00069-0231-01
	LORBRENA 25MG FCT 1X30 BTL US	00069-0227-01
Mektovi® (binimetinib)	MEKTOVI TAB 15MG 180	70255-0010-02
Sutent® (sunitinib malate)	SUTENT 37.5MG HFC 1X28 PBTL US	00069-0830-38
	SUTENT CAP 12.5MG 28	00069-0550-38
	SUTENT CAP 25MG 28	00069-0770-38
	SUTENT CAP 50MG 28	00069-0980-38
Talzenna™ (talazoparib)	TALZENNA 0.25MG CAP 1X30 BTL US	00069-0296-30
	TALZENNA 1MG CAP 1X30 BTL US	00069-1195-30
	TALZENNA 0.5MG CAP 1X30 BTL US	00069-1501-30
	TALZENNA 0.75MG CAP 1X30 BTL US	00069-1751-30
	TALZENNA 0.1MG CAP 1X30 BTL US	00069-1031-30
	TALZENNA 0.35MG CAP 1X30 BTL US	00069-1235-30
Vizimpro® (dacomitinib)	VIZIMPRO 15MG FCT 1X30 BTL US	00069-0197-30
	VIZIMPRO 30MG FCT 1X30 BTL US	00069-1198-30
	VIZIMPRO 45MG FCT 1X30 BTL US	00069-2299-30
Xalkori® (crizotinib)	XALKORI (CRIZOTINIB) 200 MG CAPSULES	00069-8141-20
	XALKORI (CRIZOTINIB) 250 MG CAPSULES	00069-8140-20

**Q: My covered entity is a federal grantee. May my entity engage in Bill To / Ship To orders?**

A: Yes. Federal grantees may engage in Bill To / Ship To orders with multiple specialty contract pharmacies participating in Pfizer’s DON.

**Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy able to engage in Bill To/Ship To transactions for oral oncology products?**

A: Yes, specialty contract pharmacies that are wholly owned by a 340B hospital covered entity<sup>16</sup> or have common ownership with a 340B hospital, participating in Pfizer’s DON, will remain

<sup>16</sup> The term “340B hospital covered entity” in this FAQ, refers to those entities eligible for participation in the 340B Drug Pricing Program under 42 U.S.C. §256b(a)(4)(L)-(O).

eligible to receive shipments of oral oncology products on a Bill To/Ship To basis at the 340B ceiling price. The specialty contract pharmacy locations must be registered on the HRSA 340B OPAIS contract pharmacy database as a contract pharmacy of their related 340B covered entity at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/search/contract-pharmacies).

- The 340B hospital covered entity will also need to access the 340BESP™ platform and submit the online application for a “Wholly Owned Pharmacy” exemption.
- Please visit [www.340besp.com/wholly\\_owned\\_application](https://www.340besp.com/wholly_owned_application) to ensure continued deliveries under this wholly owned option.

**Q: My covered entity is prepared to provide the limited claims data requested by Pfizer. May my covered entity engage in Bill To / Ship To orders with multiple contract pharmacies that are not related by ownership to my covered entity for oral oncology products?**

**A:** Yes. 340B hospital covered entities may engage in multiple specialty contract pharmacy transactions, when they choose to provide limited claims data for oral oncology products dispensed from their registered contract pharmacy on their behalf.

- The 340B covered entity will provide claims data via the 340B ESP™ platform, and upon receipt Pfizer will enable shipments for those locations.
- For oral oncology products, the contract pharmacy location selected must continue to be one of the specialty pharmacies that are part of the Pfizer DON.
- Please visit [www.340besp.com](https://www.340besp.com) for additional information.

**Q: My covered entity does have an in-house pharmacy that is capable of purchasing and dispensing outpatient drugs, but we don’t use it to dispense the oral oncology products in the Pfizer DON. Can I designate one Pfizer DON specialty contract pharmacy instead?**

**A:** If a covered entity has an in-house specialty pharmacy in the Pfizer DON the entity must use that specialty pharmacy and cannot designate one or more Pfizer DON specialty contract pharmacies, unless the covered entity provides the requested claims data for each specialty contract pharmacy via the 340B ESP™ platform. Please visit <https://www.340besp.com> for more information.

**Q: What if our 340B hospital covered entity does not have an in-house pharmacy capable of dispensing 340B priced oral oncology medicines to our patients?**

**A:** Any hospital covered entity without in-house pharmacy capable of dispensing 340B priced medicines to its patients may select a single Pfizer DON specialty contract pharmacy location that it has registered on the HRSA 340B OPAIS contract pharmacy database. In addition, a covered entity may select multiple Pfizer DON specialty contract pharmacy locations for oral oncology products if they register those locations on 340B ESP™ platform and provide the limited claims data.

**Q. My 340B hospital covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different individual pharmacy locations of a pharmacy chain). Can I designate all locations of the same pharmacy for oral oncology products?**

A. Contract pharmacy locations are registered individually on the HRSA 340B OPAIS contract pharmacy database. 340B covered entities that do not have an in-house pharmacy are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA. However, if the covered entity wishes to use multiple specialty contract pharmacies for oral oncology products that are eligible in Pfizer's DON, they may do so by registering each of the specialty contract pharmacy locations on the 340B ESP™ platform and providing the limited claims data.

**Q. How long does it take for my Pfizer DON eligible specialty contract pharmacy selection to take effect?**

A. Please allow 10 business days for the designation to be processed and to take effect.

**Q. What is Pfizer's timeframe to accept replenishment orders of NDC11 package sizes at 340B prices accumulated from prescriptions dispensed to 340B eligible patients at eligible DON specialty contract pharmacy locations?**

A. Effective April 15, 2022, Pfizer honors contract pharmacy replenishment orders only for prescriptions dispensed to eligible 340B patients not greater than forty-five (45) days prior to the date of each claims data submission on 340B ESP™.