



January 28, 2021

Pfizer Announces Defined Distribution System for Xeljanz® (tofacitinib) and Updates to Our Defined Oncology Distribution Network (DON) for Oral Oncology Medicines Effective March 1, 2022

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 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, we write to you today to announce a defined distribution system for Xeljanz and corresponding modifications to Pfizer's Defined Oncology Distribution Network ("DON"), which will enable Pfizer to uphold the integrity of the 340B Program for all stakeholders.

Effective March 1, 2022, Pfizer will establish a Defined Distribution system (DD) for Xeljanz® and make a corresponding modification to Pfizer's DON, to require 340B hospital covered entities to submit limited claims data for their contract pharmacy transactions. When 340B hospital covered entities choose to provide the limited claims data for these products, Pfizer will enable multiple contract pharmacy shipments to those locations for the applicable products. The defined distribution system will enable Pfizer to more effectively detect duplicate discounts and diversion 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 already do not enable distribution of Xeljanz® or 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) 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 will be available on 340B ESP™ by January 31, 2022, 8:00 AM EST.

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

In addition, Pfizer will voluntarily continue 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 entities that are Federal grantees and eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K), (“grantee”¹) 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. No action is needed by federal grantees.

Second, contract pharmacies that are wholly owned by a 340B hospital covered entity² or have common ownership with a 340B hospital, will remain eligible to receive shipments of Xeljanz® or 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 contract pharmacy locations must be registered on the HRSA 340B OPAIS contract pharmacy database as a contract pharmacy of their related 340B covered entity. [Search Contract Pharmacies \(hrsa.gov\)](#)
- 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 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 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 see the next steps and FAQ’s below for additional information. You may also visit www.340BESP.com for additional information.

Fourth, to ensure that all 340B eligible covered entities and their patients continue to have access to Xeljanz® and 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 pharmacy capable of dispensing 340B priced drugs to its patients, may designate a contract pharmacy location online via the 340B ESP™ platform:

- 340B hospital covered entities may designate a single contract pharmacy location for Xeljanz®
- 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.³
- The contract pharmacy location(s) selected must also be registered on the HRSA 340B OPAIS contract pharmacy database [Search Contract Pharmacies \(hrsa.gov\)](#)
- Please visit <https://www.340besp.com/designations> to exercise this option.

¹ 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.

² The term “340B hospital covered entity” in this letter, refers to those entities eligible for participation in the 340B drug discount program under 42 U.S.C. §256b(a)(4)(L)-(O).

³ A 340B entity may choose a different contract pharmacy location for Xeljanz® and the oncology products. This is because the specialty pharmacies in Pfizer’s DON may not also offer Xeljanz®.

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 no longer be honored by Pfizer on or after March 1, 2022 in connection with Xeljanz® or oral oncology product purchases.

This defined distribution policy applies to the following Xeljanz® products:

Xeljanz® Products by NDC

Products	NDC	Description
Xeljanz® XR (tofacitinib) Tablets	00069-0501-30	11 mg Tablet
	00069-0502-30	22 mg Tablet
Xeljanz® (tofacitinib) Oral Solution	00069-1029-02	1 mg/mL (240mL bottle)
Xeljanz® (tofacitinib) Tablets	00069-1002-01	10 mg Tablet
	00069-1001-01	5 mg Tablet

This defined distribution policy also applies to the following oncology products:

Pfizer's DON Oral Oncology Products by NDC

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

Product 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
	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
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.⁴

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.⁵

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 OPAS contract pharmacy database. [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/opa/contract-pharmacies)
- Please visit <https://www.340besp.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.340besp.com> to exercise this option.

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 Xeljanz® and DON oral

⁴ Please see Pfizer's 340B Notice Regarding Defined Distribution Oncology Network at <https://www.hrsa.gov/sites/default/files/opa/files/340bnoticeregardingpfizerdefinedoncology.pdf>

⁵ 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.

oncology medicines in advance of the March 1, 2022 effective date. Please see the FAQs below for additional information.

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

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



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

NEXT STEPS AND 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 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 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.

Q: Which products are subject to Pfizer's defined distribution network?

A: Pfizer's defined distribution policy effective March 1, 2022 applies to the five NDCs used for Xeljanz® (tofacitinib) products:

Products	NDC	Description
Xeljanz® XR (tofacitinib) Tablets	00069-0501-30	11 mg Tablet
	00069-0502-30	22 mg Tablet
Xeljanz® (tofacitinib) Oral Solution	00069-1029-02	1 mg/mL (240mL bottle)
Xeljanz® (tofacitinib) Tablets	00069-1002-01	10 mg Tablet
	00069-1001-01	5 mg Tablet

Pfizer's defined distribution policy effective March 1, 2022 also applies to Pfizer's oral oncology products managed through our Defined Oncology Distribution Network (DON):

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
	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
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 contract pharmacies.

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: Yes, contract pharmacies that are wholly owned by a 340B hospital covered entity⁶ or have common ownership with a 340B hospital, will remain eligible to receive shipments of Xeljanz® or 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.

⁶ The term "340B hospital covered entity" in this FAQ, refers to those entities eligible for participation in the 340B drug discount program under 42 U.S.C. §256b(a)(4)(L)-(O).

- The contract pharmacy locations must be registered on the HRSA 340B OPAIS contract pharmacy database as a contract pharmacy of their related 340B covered entity. [Search Contract Pharmacies \(hrsa.gov\)](#)
- 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 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?

A: Yes. 340B hospital covered entities may engage in multiple contract pharmacy transactions, when they choose to provide limited claims data for product 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 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 Xeljanz or the oral oncology products in the Pfizer DON. Can I designate one contract pharmacy instead?

A: If a covered entity has an in-house pharmacy capable of purchasing at the 340B price and dispensing, the entity must use that pharmacy and cannot designate a contract pharmacy, unless the covered entity provides the requested claims data for the 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 outpatient, on-site dispensing pharmacy?

A: Any hospital covered entity that does not have an outpatient, on-site dispensing pharmacy may select a single contract pharmacy location that it has registered on the HRSA 340B OPAIS contract pharmacy database. In addition, a covered entity may select multiple contract pharmacy locations 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 Walgreens pharmacy locations). Can I designate all locations of the same pharmacy?

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 contract pharmacies, they may do so by registering each of the contract pharmacy locations on the 340B ESP™ platform and providing the limited claims data.

Q. How long does it take for my contract pharmacy selection to take effect?

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