



Pfizer Announces Updates to Defined Distribution System for Xeljanz® (tofacitinib) Effective May 1, 2023

Dear 340B Covered Entity and Valued Partners,

Effective May 1, 2023, Pfizer will update the Defined Distribution system for Xeljanz® (in effect since March 1, 2022).

There are no corresponding modifications to Pfizer's Defined Oncology Distribution Network ("DON"). A recap of the current, unchanged processes in effect for Pfizer's oral oncology medicines follows the FAQs at the end of this announcement.

No action is needed by federal grantees. Any covered entities that are Federal grantees¹ 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.

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 continued to monitor and evaluate the wider risk of duplicate discounts and diversion that occur through contract pharmacy transactions. As a result, we write to you today to announce an update to our Defined Distribution system for Xeljanz®.

Pfizer is committed to ensuring that all 340B covered entities are offered Xeljanz® at the 340B-discounted price. This update to our Defined Distribution system represents a continued distribution preference provided to 340B covered entities. Pfizer business practices for non-340B customers do not enable distribution of Xeljanz® not under common ownership with the ordering customer. Our policy is consistent with the decision of the United States Third Circuit Court of Appeals in *Sanofi Aventis U.S. LLC v. HHS*.²

Updated Defined Distribution System for Xeljanz®

Effective May 1, 2023, to ensure that all 340B eligible covered entities and their patients continue to have access to Xeljanz® at 340B ceiling prices, the following will apply:

¹ 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.

² See *Sanofi Aventis U.S. LLC v. HHS*, ___ F.4th ___, 2023 WL 1098017, at *4 (3d Cir. Jan. 30, 2023).

- all 340B hospital covered entities³ 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/search/covered-entities)
- 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 Xeljanz®.
 - 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/search/contract-pharmacies).
 - Please visit <https://www.340bbsp.com/designations> to exercise this option.

Next Steps and Other Updates

- 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®.
- 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 \(340bbsp.com\)](https://www.340bbsp.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 April 15, 2023, for a new one contract pharmacy designation to take effect on May 1, 2023.

Sunset of 340B Hospital Wholly Owned Exemptions on April 30, 2023

Contract pharmacies that are wholly owned by a 340B hospital covered entity or have common ownership with a 340B hospital, will not separately be eligible to receive shipments of Xeljanz® on a Bill To/Ship To basis at the 340B ceiling price.

- All 340B hospital covered entity Pfizer approved “Wholly Owned Pharmacy” exemptions on the 340B ESP™ platform will sunset on April 30, 2023.
- For any impacted 340B hospital covered entity without an in-house pharmacy capable of dispensing 340B priced medicines to its patients, a one contract pharmacy designation remains available (see above). A wholly-owned pharmacy may be selected as a contract pharmacy if it meets the one contract pharmacy requirements.
- No other action is required by impacted 340B hospital covered entities.

Voluntary Submission of Claims Level Data

- A 340B covered entity may continue to voluntarily submit claims data via the 340B ESP™ platform.
- Please see the next steps and FAQ’s below for additional information. You may also visit www.340BESP.com for additional information.

³ 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).

Pfizer is continuing to utilize Second Sight Solutions' 340B ESP™ platform (www.340besp.com) to support the Defined Distribution system for Xeljanz®. 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.

This Defined Distribution policy applies to the following for Xeljanz® :

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

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® in advance of the May 1, 2023 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

FREQUENTLY ASKED QUESTIONS

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

A: Pfizer’s Defined Distribution policy changes effective May 1, 2023 apply just 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

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.

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 Xeljanz® 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 its patients may designate a single contract pharmacy location registered on the HRSA OPAIS database at [Search Contract Pharmacies \(hrsa.gov\)](https://www.hrsa.gov/opa) 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*.⁴

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®. Can I designate one contract pharmacy instead?

⁴ See *Sanofi Aventis U.S. LLC v. HHS*, ___ F.4th ___, 2023 WL 1098017, at *4 (3d Cir. Jan. 30, 2023).

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 Aventis U.S. LLC v. HHS*.⁵

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 Xeljanz®. 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/opa). Our policy is consistent with the decision of the United States Third Circuit Court of Appeals in *Sanofi Aventis U.S. LLC v. HHS*.⁶

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. 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 Xeljanz®, which corresponds to a single contract pharmacy registration with HRSA. Our policy is consistent with the decision of the United States Third Circuit Court of Appeals in *Sanofi Aventis U.S. LLC v. HHS*.⁷

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 Xeljanz® purchases?

A. To voluntarily provide limited contract pharmacy claims data with Second Sight Solutions' 340B ESP™ platform for Xeljanz® purchases, navigate to 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 to learn more about 340B ESP™ and the voluntary data submission process or contact the 340B ESP™ support desk at support@340besp.com.

⁵ See *Sanofi Aventis U.S. LLC v. HHS*, ___ F.4th ___, 2023 WL 1098017, at *4 (3d Cir. Jan. 30, 2023).

⁶ See *Sanofi Aventis U.S. LLC v. HHS*, ___ F.4th ___, 2023 WL 1098017, at *4 (3d Cir. Jan. 30, 2023).

⁷ See *Sanofi Aventis U.S. LLC v. HHS*, ___ F.4th ___, 2023 WL 1098017, at *4 (3d Cir. Jan. 30, 2023).



Defined Distribution for Oral Oncology Medicines In Effect March 1, 2022⁸

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, Pfizer's Defined Oncology Distribution Network ("DON") includes the requirements discussed here, which will enable Pfizer to uphold the integrity of the 340B Program for all stakeholders.

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. 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 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) 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).

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:

⁸ This summary of Pfizer's policy for various non- Xeljanz® products is based on the policy statement that accompanied its introduction for the original effective date of March 1, 2022. Because Xeljanz®, which was part of this policy at that time, is now subject to different requirements, this summary deleted any discussion of that product. For information on Xeljanz®, please see that product-specific policy.

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”⁹) 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 entity¹⁰ 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/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 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/contract-pharmacies).
- 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.

⁹ 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.

¹⁰ 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).

This defined distribution policy 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), Talzenna™ (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
	TALZENNA 0.5MG CAP 1X30 BTL US	00069-1501-30
	TALZENNA 0.75MG CAP 1X30 BTL US	00069-1751-30
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.¹¹

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.¹²

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/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.

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

¹¹ Please see Pfizer's 340B Notice Regarding Defined Distribution Oncology Network at <https://www.hrsa.gov/sites/default/files/opa/files/340bnoticeregardingpfizerdefinedoncology.pdf>

¹² 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.

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 [Second Sight Solutions \(340besp.com\)](http://www.340besp.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 or call Second Sight Solutions at 888-398-5520.

Q: Which products are subject to Pfizer's defined distribution network effective March 1, 2022 ?

A: Pfizer's defined distribution policy effective March 1, 2022 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
	TALZENNA 0.5MG CAP 1X30 BTL US	00069-1501-30
	TALZENNA 0.75MG CAP 1X30 BTL US	00069-1751-30
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 entity¹³ or have common ownership with a 340B hospital, participating in Pfizer’s DON, will remain 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/opa).

¹³ 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 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 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 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 Walgreens pharmacy locations). 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™.