

**Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO****August 23, 2024**

This notice is to inform 340B end customers of an update to the method by which Johnson & Johnson Health Care System Inc. (JJHCS) shall make the 340B discount available to disproportionate share hospital (DSH) Covered Entities<sup>1</sup> on purchases of STELARA and XARELTO. This policy shall take effect in approximately two months, on October 15, 2024, and JJHCS will provide an additional grace period for rebate claims submission. In total, DSH Covered Entities will have over six months to adjust to the new policy.

**340B Rebate Model**

As of October 15, 2024, JJHCS shall make the 340B discount on STELARA and XARELTO available to DSH Covered Entities through a rebate. To operationalize this rebate model, JJHCS is utilizing the Beacon platform. The Beacon platform is available free of charge, and Covered Entities can obtain detailed instructions on registration and data submission as well as additional information about the platform on the Beacon website at [www.beaconchannelmanagement.com](http://www.beaconchannelmanagement.com).

Pursuant to the rebate method, DSH Covered Entities may purchase STELARA or XARELTO through wholesalers at a commercial price, such as the wholesale acquisition cost (WAC), similar to non-340B customers.<sup>2</sup> Following the dispensing or administration of STELARA or XARELTO to eligible patients, DSH Covered Entities may submit rebate claim data to the Beacon platform. This data will include standard information about the product dispense or administration that Covered Entities collect, report, and maintain in the normal course of business. Specifically, in addition to the limited claims data that non-grantee Covered Entities submit under JJHCS's current Bill To/Ship To policy, DSH Covered Entities will submit medical claims data elements as well as STELARA and XARELTO purchase data (collectively, "Rebate Claim Data"). Except during the initial grace period described below, DSH Covered Entities must timely submit Rebate Claim Data within 45 days of the date of the dispense. This timeline is consistent with the time period by which non-grantee Covered Entities must submit limited claims data under JJHCS's current Bill To/Ship To policy.

**Rebate Claim Validation, Accumulation and Payment**

The Beacon platform will validate the Rebate Claim Data submitted by a DSH Covered Entity to ensure that purchases were made by an eligible DSH Covered Entity, units were dispensed from eligible 340B locations, and Rebate Claim Data was submitted in a timely manner. Upon the accumulation of a sufficient number of validated rebate claims, the Beacon platform will issue a rebate to the bank account designated by the DSH Covered Entity. Rebate payments will be

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<sup>1</sup> Entities qualifying for 340B under 42 USC § 256b(a)(4)(L).

<sup>2</sup> Subject, of course, to the 340B statute's GPO prohibition.

triggered once the number of validated dispensed units equals the number of units in the purchased package size. In general, we expect rebates will typically be paid 7 to 10 days after accumulation of validated rebate claims. However, for STELARA, because the unit of dispense is the same as the number of units in the STELARA package (*i.e.*, 1:1), the accumulation of more than one validated rebate claim is not necessary to trigger a rebate payment. In other words, DSH Covered Entities can seek a 340B rebate immediately upon dispense or administration of STELARA. Similarly, for XARELTO, most 340B utilization is in unit-of-use bottles, which correspond with the most-commonly purchased XARELTO package sizes (*i.e.*, 30:30 and 60:60). Because the unit of dispense also is the same as the number of units in the XARELTO packages in these cases, the accumulation of more than one validated rebate claim is not necessary and DSH Covered Entities can seek a 340B rebate immediately upon dispense for most XARELTO utilization. If a DSH Covered Entity dispenses or administers STELARA or XARELTO shortly after purchase and submits timely Rebate Claim Data, the DSH Covered Entity should be able to obtain 340B rebates on these units before payment is due to wholesalers on the underlying purchase.

The rebate payment will equal the difference between (i) WAC and (ii) the 340B ceiling price, thus allowing the DSH Covered Entity to realize the 340B discount on the purchase. Payment details will be available to DSH Covered Entities within the Beacon platform, which will allow DSH Covered Entities to reconcile and verify rebate amounts received.

## **Effective Date**

This update will take effect on October 15, 2024. As of that date, JJHCS will no longer process wholesaler chargebacks for the 340B ceiling price on purchases of STELARA or XARELTO by DSH Covered Entities. JJHCS believes this nearly 60-day advance notice period will provide sufficient time for DSH Covered Entities to adjust to the rebate model. The Beacon platform also will offer training and support to ensure DSH Covered Entities have the ability to become familiar with the process to obtain STELARA and XARELTO 340B rebates.

## **Additional Grace Period**

Additionally, to further support the transition of DSH Covered Entities to the rebate model, JJHCS will offer a grace period during which time DSH Covered Entities will be permitted to submit Rebate Claim Data outside of the standard 45-day window from the date of the dispense. In effect, this grace period will provide DSH Covered Entities with more than six months to prepare to obtain the 340B discount through the rebate model on purchases of STELARA and XARELTO. Beginning on March 10, 2025, JJHCS will resume the standard 45-day window in which DSH Covered Entities will be required to submit Rebate Claim Data in order to receive 340B rebates on STELARA and XARELTO.

## **Interaction with JJHCS Current Bill To/Ship To Policy for Contract Pharmacies**

JJHCS's current Bill To/Ship To policy for contract pharmacies will remain in effect, except that DSH Covered Entities will no longer submit STELARA and XARELTO limited claims data through the ESP system. Instead, DSH Covered Entities may submit Rebate Claim Data for

STELARA and XARELTO as described herein through the Beacon platform. However, the remaining requirements of the current Bill To/Ship To policy will remain in effect.

In other words, effective October 15, 2024:

- A DSH Covered Entity may continue to designate a contract pharmacy location registered on the HRSA OPAIS database for purchases of STELARA or XARELTO consistent with JJHCS' current Bill to/Ship to policy. This policy applies regardless of whether the DSH Covered Entity has an in-house pharmacy.
- 340B rebates will only be paid on STELARA and XARELTO rebate claims from DSH Covered Entity locations registered on the HRSA OPAIS database and contract pharmacy locations designated in the 340B ESP system.

Additionally, for purchases by (i) all other non-grantee, non-DSH Covered Entities and (ii) DSH Covered Entities for products other than STELARA or XARELTO, JJHCS's current Bill To/Ship To policy will remain in effect without modification. Please refer to that policy announcement for additional details, available here: <https://www.janssen.com/us/policies>.

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JJHCS remains deeply committed to the 340B program. We believe this update will significantly improve program integrity while at the same time enabling covered entities to obtain the 340B price on eligible 340B sales.

Please contact us by email at [340B\\_JJHCS@its.jnj.com](mailto:340B_JJHCS@its.jnj.com) with any questions or with requests for additional information. For questions related to the use of the Beacon platform, please contact [support@beaconchannelmanagement.com](mailto:support@beaconchannelmanagement.com) or 878-788-8907 or visit the Beacon Support Center at <https://beaconchannelmanagement.com/>.

## FREQUENTLY ASKED QUESTIONS

### **To which Covered Entities and JJHCS products does this update apply?**

The update that JJHCS shall make the 340B price available through a rebate model applies to purchases of STELARA and XARELTO by DSH Covered Entities only. DSH Covered Entities may continue to access JJHCS products other than STELARA and XARELTO through JJHCS's current procedures, subject to JJHCS's current Bill To/Ship To policy. Further, Covered Entities other than DSH Covered Entities are not impacted by this update and may continue to access STELARA and XARELTO as well as other JJHCS products through JJHCS's current procedures, subject to JJHCS's current Bill To/Ship To policy.

### **Does this policy apply to all utilization of STELARA and XARELTO or only to utilization dispensed by contract pharmacies?**

This policy applies to all DSH Covered Entity utilization of STELARA and XARELTO, regardless of whether the unit was dispensed or administered in-house or through a designated contract pharmacy.

### **At what price will STELARA and XARELTO be available to DSH Covered Entities?**

STELARA and XARELTO will be available to DSH Covered Entities at the 340B ceiling price, which shall be realized through a rebate following an initial purchase and dispense of the product to eligible patients.

Specifically, DSH Covered Entities may purchase STELARA and XARELTO through wholesalers at a commercial price, such as WAC, similar to non-340B customers.<sup>3</sup> Following the dispense or administration of STELARA or XARELTO on eligible transactions, DSH Covered Entities may submit Rebate Claim Data to the Beacon platform. The Beacon platform will validate the Rebate Claim Data submitted by a DSH Covered Entity to ensure that purchases were made by an eligible 340B DSH Covered Entity, units were dispensed from eligible 340B locations, and Rebate Claim Data was submitted in a timely manner. Upon the accumulation of a sufficient number of validated rebate claims, the Beacon platform will issue a rebate to the bank account designated by the DSH Covered Entity. The rebate payment will equal the difference between (i) WAC and (ii) the 340B ceiling price, thus allowing the DSH Covered Entity to realize the 340B discount on the purchase.

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<sup>3</sup> Subject, of course, to the 340B statute's GPO prohibition.

## **Will DSH Covered Entities be able to purchase STELARA or XARELTO at the 340B ceiling price?**

Effective October 15, 2024, JJHCS will no longer process wholesaler 340B chargebacks for the 340B ceiling price on purchases of STELARA or XARELTO by DSH Covered Entities. Instead, DSH Covered Entities may purchase STELARA or XARELTO through wholesalers at a commercial price, such as WAC, similar to non-340B customers.<sup>4</sup> DSH Covered Entities may then submit STELARA and XARELTO Rebate Claim Data to the Beacon platform in order to receive a 340B rebate.

The Beacon platform will validate the Rebate Claim Data submitted by a DSH Covered Entity to ensure that purchases were made by an eligible 340B DSH Covered Entity, units were dispensed from eligible 340B locations, and Rebate Claim Data was submitted in a timely manner. Upon the accumulation of sufficient validated rebate claims, the Beacon platform will issue a rebate to the bank account designated by the DSH Covered Entity. The rebate payment will equal the difference between (i) WAC and (ii) the 340B ceiling price, thus allowing the DSH Covered Entity to realize the 340B discount on the purchase.

## **What information must DSH covered entities submit to Beacon to receive a 340B rebate?**

DSH Covered Entities will submit standard information about the purchase and dispense or administration of STELARA and XARELTO that Covered Entities collect, report, and maintain in the normal course of business. Specifically, in addition to the limited claims data that non-grantee Covered Entities submit under JJHCS's current Bill To/Ship To policy, DSH Covered Entities will submit medical claims data elements as well as STELARA and XARELTO purchase data. This pharmacy and medical claims information involves data elements routinely reported to payors as a part of standard billing practices. DSH Covered Entities must provide the following Rebate Claim Data:

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<sup>4</sup> Subject, of course, to the 340B statute's GPO prohibition.

## Purchase Data Elements

| Field Name                | Description                                                                                |
|---------------------------|--------------------------------------------------------------------------------------------|
| Invoice Date              | Date the purchase was invoiced to the Covered Entity                                       |
| Invoice Number            | Wholesaler assigned invoice number for the purchase order                                  |
| National Drug Code        | NDC-11 of the product that was purchased by the Covered Entity                             |
| Package Units             | Number of packages of the product ordered                                                  |
| Purchase Account Number   | Wholesaler assigned account number used to place the order                                 |
| Wholesaler Name           | Name of the wholesaler that processed the invoice and shipped the purchase                 |
| 340B ID                   | HRSA-assigned identifier of the 340B Covered Entity that purchased the product             |
| Ship To Pharmacy ID (NPI) | NPI of the pharmacy that received the physical shipment of the product from the wholesaler |

## Pharmacy Claim Data Elements

| Field Name          | Description                                                                                                                                                                                          |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date Of Service     | Date the prescription was filled at the pharmacy                                                                                                                                                     |
| Date Prescribed     | Date the physician wrote the prescription                                                                                                                                                            |
| Rx Number           | Identifier applied to the prescription by the pharmacy                                                                                                                                               |
| Fill Number         | The number of times the prescription has been filled as of the current fill. For example, a value of 2 indicates that the prescription has been filled twice and the current fill is the second one. |
| NDC                 | National Drug Code which is a unique identifier of the drug dispensed to the patient                                                                                                                 |
| Quantity            | Number of units dispensed to the patient                                                                                                                                                             |
| Prescriber Id       | National provider identifier (NPI) of the prescriber that wrote the prescription                                                                                                                     |
| Service Provider ID | NPI of the pharmacy that filled the prescription                                                                                                                                                     |
| 340B ID             | HRSA-assigned identifier of the 340B Covered Entity that designated the prescription as 340B                                                                                                         |
| Rx BIN              | Bank identification number of the primary payer on the claim                                                                                                                                         |
| Rx PCN              | Processor control number assigned by the entity processing payment                                                                                                                                   |

## Medical Claim Data Elements

| Field Name            | Description                                                       |
|-----------------------|-------------------------------------------------------------------|
| Service Provider ID   | ID assigned to a pharmacy or provider                             |
| Product Service ID    | ID of the product dispensed or service provided                   |
| Billed HCPCS quantity | Total quantity being submitted                                    |
| Date of Service       | Date the prescription was filled or professional service rendered |
| Prescriber ID         | ID assigned to the prescriber                                     |
| Claim Number          | Unique identifier for a prescription and claim processor          |
| 340B ID               | Code specifying the 340B Covered Entity                           |
| Plan ID Code          | ID assigned to identify the plan                                  |
| Plan name             | Name of the plan                                                  |

### **Who may submit claim and purchase data on behalf of DSH Covered Entities?**

Beginning on October 15, 2024, validated Beacon account administrators may submit Rebate Claim Data on behalf of a DSH Covered Entity. Administrators may grant access to the DSH Covered Entity's Beacon account to other users, including employees of third-party administrators ("TPAs"), enabling those users to also submit Rebate Claim Data. JJHCS anticipates that in 2025, the Beacon platform will support the submission of data directly from TPAs.

### **How frequently may DSH Covered Entities submit different types of Rebate Claim Data, such as pharmacy and medical claims data and purchase data, to the Beacon platform?**

JJHCS encourages DSH Covered Entities to submit:

- Purchase data immediately following the purchase of STELARA or XARELTO.
- Pharmacy claims data and medical claims data immediately following the dispense or administration of STELARA or XARELTO in an eligible transaction.

There is no limitation on how frequently data may be submitted. Frequent data submission will facilitate the prompt issuance of rebates as described above.

## **By when must Rebate Claim Data be submitted?**

In general, DSH Covered Entities must submit Rebate Claim Data within 45 days of the date of the dispense or administration. This timeline is consistent with the time period by which non-grantee Covered Entities must submit limited claims data today under JJHCS's current Bill To/Ship To policy. However, JJHCS encourages DSH Covered Entities to submit (i) purchase data immediately following the purchase of STELARA or XARELTO and (ii) pharmacy claims data and medical claims data immediately following the dispense or administration of STELARA or XARELTO in an eligible transaction.

DSH Covered Entities must submit all Rebate Claim Data within the 45-day time period from the date of the dispense for rebate claims to be validated and 340B rebates to be paid.

From October 15, 2024 through March 9, 2025, to support the transition of DSH Covered Entities to the rebate model, JJHCS will offer a grace period during which time DSH Covered Entities will be permitted to submit Rebate Claim Data outside of the 45-day window from the date of the dispense. In effect, this grace period will provide DSH Covered Entities with more than six months to prepare to obtain the 340B discount through the rebate model on purchases of STELARA and XARELTO. Beginning on March 10, 2025, JJHCS will resume the standard 45-day window in which DSH Covered Entities will be required to submit Rebate Claim Data.

## **What happens if Rebate Claim Data is submitted outside of the 45-day window?**

Timely submission of Rebate Claim Data is critical to ensuring 340B discounts are not duplicated in other rebate and discount programs. Rebate Claim Data submitted outside of the 45-day window from the date of the dispense will not be eligible for 340B rebates.

## **How specifically will the rebate platform use information provided to validate and approve 340B rebates?**

The Beacon platform will validate that:

- 1) Purchases were made by an eligible 340B DSH Covered Entity;
- 2) Units were dispensed from an eligible 340B DSH Covered Entity registered in the OPAIS database or registered contract pharmacy designated in the ESP system; and
- 3) Rebate Claim Data was submitted in a timely manner.

## **How will rebate claims be accumulated?**

The Beacon platform will validate Rebate Claim Data as it is submitted. Once a sufficient number of rebate claims have been validated, the Beacon platform will issue a rebate to the bank account designated by the DSH Covered Entity. Claim accumulation will be complete so as to trigger a



rebate payment once the number of dispensed units across validated rebate claims equals the number of units in the package size purchased by the DSH Covered Entity.

However, for STELARA, because the unit of dispense is the same as the number of units in the STELARA package (*i.e.*, 1:1), the accumulation of more than one validated rebate claim is not necessary to trigger a rebate payment. In other words, DSH Covered Entities can seek a 340B rebate immediately upon dispense or administration. Similarly, for XARELTO, most 340B utilization is in unit-of-use bottles, which correspond with the most-commonly purchased XARELTO package sizes (*i.e.*, 30:30 and 60:60). Because the unit of dispense also is the same as the number of units in the XARELTO packages in these cases, the accumulation of more than one validated rebate claim is not necessary to trigger a rebate payment, and DSH Covered Entities can seek a 340B rebate immediately upon dispense for most XARELTO utilization. If a DSH Covered Entity dispenses or administers STELARA or XARELTO shortly after purchase and submits timely Rebate Claim Data, the DSH Covered Entity should be able to obtain 340B rebates on these units before payment is due to wholesalers on the underlying purchase.

### **Must a DSH Covered Entity wait until they dispensed all units associated with a package size to eligible patients before submitting Rebate Claim Data for that package size?**

No. JJHCS encourages DSH Covered Entities to submit (i) purchase data immediately following the purchase of STELARA or XARELTO and (ii) pharmacy claims data and medical claim data immediately following the dispense or administration of STELARA or XARELTO in an eligible transaction. The Beacon platform will validate Rebate Claim Data as it is submitted and will issue a rebate payment once the DSH Covered Entity accumulates a sufficient number of validated rebate claim units to equal the number of units in a package size purchased by the DSH Covered Entity.

After the end of the grace period, if a DSH Covered Entity is unable to dispense all of the units affiliated with a package size of STELARA or XARELTO, the Beacon platform will include a mechanism by which the DSH Covered Entity may receive a full rebate for the package size in appropriate circumstances.

### **What will be the amount of a rebate payment?**

A rebate payment will equal the difference between (i) WAC and (ii) the 340B ceiling price for the product, thus allowing the DSH Covered Entity to realize the 340B discount on the purchase.

### **Will rebates be paid on individual dispenses of STELARA or XARELTO?**

No. Rebates will be paid on NDC-11 packages of STELARA or XARELTO, consistent with how 340B prices are determined today. Once a sufficient number of rebate claims reflecting individual dispenses or administrations of STELARA or XARELTO have been validated, the Beacon platform will issue a rebate to the bank account designated by the DSH Covered Entity. Claim

accumulation will be complete so as to trigger a rebate payment once the number of validated dispensed units equals the number of units in the package size purchased by the DSH Covered Entity.

## **When will rebate payments be issued?**

Once a sufficient number of rebate claims have been validated, the Beacon platform will issue a rebate to the bank account designated by the DSH Covered Entity. Claim accumulation will be complete so as to trigger a rebate payment once the number of dispensed units across validated rebate claims equals the number of units in the package size purchased by the DSH Covered Entity. In general, we expect rebates will typically be paid 7 to 10 days after accumulation of validated rebate claims.

However, for STELARA, because the unit of dispense is the same as the number of units in the STELARA package (*i.e.*, 1:1), the accumulation of more than one validated rebate claim is not necessary to trigger a rebate payment. In other words, DSH Covered Entities can seek a 340B rebate immediately upon dispense or administration. Similarly, for XARELTO, most 340B utilization is in unit-of-use bottles, which correspond with the most-commonly purchased XARELTO package sizes (*i.e.*, 30:30 and 60:60). Because the unit of dispense also is the same as the number of units in the XARELTO packages in these cases, the accumulation of more than one validated rebate claim is not necessary to trigger a rebate payment and DSH Covered Entities can seek a 340B rebate immediately upon dispense for most XARELTO utilization. If a DSH Covered Entity dispenses or administers STELARA or XARELTO shortly after purchase and submits timely Rebate Claim Data, the DSH Covered Entity should be able to obtain 340B rebates on these units before payment is due to wholesalers on the underlying purchase.

## **How will DSH Covered Entities identify transactions eligible for the 340B price?**

JJHCS expects that DSH Covered Entities will rely on usual processes consistent with the 340B statute to identify transactions eligible for the 340B price. In other words, the rebate model should not impact the manner by which DSH Covered Entities identify units eligible for the 340B discount.

## **What information will be available to DSH Covered Entities within the Beacon platform?**

DSH Covered Entities will have access to a broad range of resources on the Beacon Support Center website (<https://beaconchannelmanagement.com/>) to support their use of the platform. In addition to training materials and tutorials, DSH Covered Entities can download data submission templates, NDC lists and unit conversion tables to support the data submission process. DSH Covered Entities can access detailed instructions on the registration and data submission processes in the Beacon Support Center as well as operational FAQs on the Beacon platform. The Beacon Support Center also supports direct customer engagement through an in-application chat feature as well as

a call center and email support. DSH Covered Entities can also register for a series of live webinars hosted by the Beacon Support Center beginning on August 28<sup>th</sup>.

## **May DSH Covered Entities dispute rebate claims that are not validated by the Beacon platform?**

Yes. DSH Covered Entities can dispute rebate claim validation through the Beacon platform. Disputes may require the submission of additional documentation.

## **Will JJHCS's contract pharmacy policy continue to apply?**

Yes. JJHCS's current Bill To/Ship To policy will remain in effect, except that DSH Covered Entities will no longer submit limited claims data on STELARA or XARELTO to the ESP system. Instead, DSH Covered Entities may submit Rebate Claim Data on STELARA or XARELTO to eligible patients as described in this notice to the Beacon platform. In other words, effective October 15, 2024:

- A DSH Covered Entity may continue to designate a contract pharmacy location registered on the HRSA OPAIS database for purchases of STELARA or XARELTO consistent with JJHCS' current Bill To/Ship To policy. This policy applies regardless of whether the DSH Covered Entity has an in-house pharmacy.
- 340B rebates will only be paid on STELARA and XARELTO rebate claims from DSH Covered Entity locations registered on the HRSA OPAIS database and contract pharmacy locations designated in the ESP system.

For all other non-grantee and non-DSH Covered Entities, JJHCS's current Bill To/Ship To policy will remain in effect without modification. Thus, DSH Covered Entities may access JJHCS products other than STELARA and XARELTO through JJHCS's current procedures, subject to JJHCS's current Bill To/Ship To policy. Further, types of Covered Entities other than DSH Covered Entities are not impacted by this update and may continue to access STELARA and XARELTO as well as other JJHCS products through JJHCS's current procedures, subject to JJHCS's current Bill To/Ship To policy. Please refer to that policy announcement for additional details, available here: <https://www.janssen.com/us/policies>.

## **Will JJHCS continue to require DSH Covered Entities to submit limited claims data according to its contract pharmacy policy announced February 15, 2023?**

DSH Covered Entities will no longer be required to submit limited claims data on purchases of STELARA and XARELTO to the ESP system. Instead, DSH Covered Entities may submit Rebate Claims Data for STELARA and XARELTO as described in this notice to the Beacon platform.

As it relates to (i) all other non-grantee Covered Entities that are not DSH Covered Entities and (ii) DSH Covered Entities purchasing products other than STELARA or XARELTO, JJHCS's

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current Bill To/Ship To policy will remain in effect without modification, including the requirement to submit limited claims data within 45 days of a dispense to an eligible patient. Please refer to that policy announcement for additional details, available here: <https://www.janssen.com/us/policies>.