

AstraZeneca's 340B Rebate Model Pilot Program Plan: FARXIGA®

This proposal includes the provision of the 340B price as a unit-based rebate for FARXIGA® dispensed in the outpatient setting by all 340B entity types and their designated contract pharmacies, regardless of payer. The rebate will be administered by the Beacon technology platform. The proposed start date is January 1, 2027, with an announcement date no later than 10/2/26. We propose a quarterly call with the agency to discuss progress.

340B Rebate Model Pilot Program Criteria

A: General Requirements

1. All costs associated with development, implementation, and administration of the Beacon Platform will be borne by AstraZeneca and not passed onto Covered Entities.
2. AstraZeneca will provide 90 calendar days' notice to covered entities, and other impacted stakeholders, before implementation of a rebate model with instructions for registering on the Beacon Platform. Any changes will be submitted to OPA for review and approval prior to implementation.
3. Covered Entities will be able to order FARXIGA® at the Wholesale Acquisition Cost (WAC) under their 340B wholesaler account. AstraZeneca expects Covered Entities to only purchase FARXIGA® packages, that are intended to receive 340B rebates, via this WAC based contract in the 340B account.
4. AstraZeneca will provide technical assistance, customer service, educational resources, and a free entity-user platform that enables search functionality and reconciliation reporting through Beacon – a technology platform operated by Second Sight Solutions. Entities will have opportunities to engage in good faith regarding questions directly through Beacon's customer support team. Certain inquiries may be escalated to AstraZeneca for resolution.
5. AstraZeneca and its partner, Second Sight, provide comprehensive and robust data security. Additional information on Beacon's security protocols can be found here: <https://cm.beaconchannelmanagement.com/pages/trust-center> . The

collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA.

6. The Beacon Platform has mechanisms in place to protect patient identifying information in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws.
7. AstraZeneca's Rebate Model Pilot plan applies to all Covered Entity types.

B: Reporting Requirements

1. Covered Entities will be required to submit the data elements to the Beacon platform within 45 days of the date of the dispense of FARXIGA®. Covered Entities will also be provided an opportunity to resubmit data within the same 45-day window if it was originally denied for incomplete or missing data. Allowances for extenuating circumstances and other exceptions, including adjustments for when a claim status changes to 340B outside of the 45-day window, will be considered according to AstraZeneca's standard business practices.
2. The Beacon Platform will have the capacity to receive data, filter, and use only the data required to effectuate the rebate.
3. The Beacon Platform will have the capability to provide Covered Entities the real-time rebate status for submitted claims and payments. 340B submitted claims in error should be reversed as soon as discovered, and credits for such reversals will be used to offset future 340B rebate payments. This process will be transparent to entities in the Beacon platform, and the Beacon customer support team will be available to resolve inquiries.
4. Each quarter, Beacon will provide all registered Covered Entities with a 340B pricing file containing the 340B ceiling price for each FARXIGA® NDC to assist with Medicaid billing requirements.
5. AstraZeneca will provide periodic reports as specified by OPA.

C: Rebates

1. The calculated FARXIGA® rebate will be the difference between WAC and the 340B ceiling price at the date of dispense.
2. FARXIGA® rebates will be paid at the unit level.
3. AstraZeneca encourages Covered Entities to empty their accumulator prior to January 1, 2027. Covered Entities with eligible unreplenished accumulated dispenses, occurring within 15 calendar days prior to the January 1, 2027 Rebate Model Pilot launch, will be permitted to submit a 340B claim for up to 2 packages. Dispense information for unreplenished accumulated packages may be submitted for up to 45 days after the date of dispense.
4. AstraZeneca will pay rebates via the Beacon platform to the Covered Entity (or deny with supporting documentation) within 10 calendar days of data submission. If the data submission is returned for incomplete data, the 10-day clock for rebate payment will restart when all necessary data is submitted. Examples of valid reasons for denying a rebate include: the NDC on the 340B claim is not one of the NDCs incorporated into AstraZeneca's 340B rebate model pilot, the date of dispense does not occur during the 340B rebate model pilot period (except for the 2 unreplenished accumulated dispenses), the dispensing pharmacy or site of administration is not registered with HRSA as an eligible 340B covered entity location, or the 340B claim has already been submitted by another 340B covered entity.
5. AstraZeneca will use 340B and MFP claims data elements to conduct deduplication. When duplication is identified and the 340B ceiling price is lower than the MFP, the MFP rebate will be denied. No 340B rebate will be denied or adjusted on 340B/MFP duplication grounds where the 340B ceiling price is lower than the MFP. Any denial of a 340B rebate on MFP/340B duplication grounds will occur only where the MFP is lower than the 340B ceiling price. This approach is described further in AstraZeneca's MFP effectuation plans for IPAY 2026/27, as submitted to CMS. Good faith questions/concerns will be addressed by the Beacon customer support team. 340B Rebates will not be rejected due to concerns with diversion, Medicaid duplicate discounts, or insufficient WAC purchases to support rebate requests. AstraZeneca will monitor these issues and raise any concerns to the appropriate Covered Entity and HRSA.

6. AstraZeneca is submitting the Rebate Model Pilot Plan for the below NDC-11s associated with FARXIGA®, as included within the CMS Medicare Drug Price Negotiation Selected Drug List for IPAY 2026:

Product Name	Product Description	NDC
FARXIGA®	TAB 5MG (1BTLX30)	00310-6205-30
	TAB 10MG (1BTLX30)	00310-6210-30
	TAB 10MG HUD BL 3X10	00310-6210-39
	TAB 5MG (1BTLX90)	00310-6205-90
	TAB 10MG (1BTLX90)	00310-6210-90

D: Data

1. AstraZeneca will utilize Beacon to collect the data required by HRSA for purposes of this pilot. This includes Pharmacy and Medical claims data as outlined below. AstraZeneca and Second Sight will restrict use of Rebate Model claims data to pilot purposes only.

Pharmacy Claims Data:

Field Name	Description
Date of Service	Date on which the pharmacy filled the prescription
Date Prescribed	Date the healthcare provider wrote the prescription
Rx Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy
Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of "0" indicates that the prescription has not been filled previously and the current fill is the first one. The first refill would have a value of "1".
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and the commercial package size.
Quantity Dispensed	The number of units dispensed to the patient

340B ID	HRSA assigned identifier of the 340B covered entity that designated the dispense as 340B
Prescriber ID	National provider identifier (NPI) of the healthcare provider that wrote the prescription
Service Provider ID	NPI of the pharmacy that filled the prescription.
Rx BIN	Prescription Drug Bank Identification Number for the primary payer. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement. If a patient is uninsured or a cash payer, mark "999999" in this field.
Rx PCN	Processor Control Number for the primary payer. Identifier used to determine which processor will handle a prescription drug claim. If a patient is uninsured or a cash payer, mark "CASH" in this field. If there is no PCN, mark "NONE" in this field.

Medical Claims Data:

Field Name	Description
Date of Service	Date on which the medication was administered to the patient.
Claim Line Number	Identifies an individual line number on a claim. Line numbers distinguish services that are submitted on the same claim.
Claim Number	The unique identifier for a prescription and claim processor. This value should align with the Patient Control Number or Claim Submission ID, as set within provider systems and included on EDI 837 transmissions to payers (Form 1500 Box 26 or Claim 1450 Box 3)
Unit of Measure	UOM must be consistent with the standardized billing unit as defined by the NCPDP for the NDC-11.
NDC-11	The 11- digit National Drug Code which indicates manufacturer, product, and commercial package size.
Quantity	The quantity of medication administered to the patient. Quantity must reflect standardized billing units as defined by the NCPDP for the NDC-11.
Rendering Physician ID	The NPI of the healthcare provider who rendered or supervised the care reported on the claim.
Service Provider ID	The NPI of the healthcare entity where the patient received the medication administration. For example, this could be the NPI of a hospital outpatient surgery center or the NPI of an outpatient infusion center.
340B ID	The HRSA assigned identifier of the 340B Covered Entity that designated the administration as 340B

Health Plan Name	Name of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.
Health Plan ID	The identifier code of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.
Health Plan ID Qualifier (if available)	The qualifier for the patient's health insurance plan ID.

- **Waste:** As an oral medication, Farxiga does not present a meaningful waste or undispensed unit concern as pharmacies can readily reuse any undispensed pills. Covered Entities that believe a genuine waste situation exists should submit an exception request to AstraZeneca or Beacon for review.
- **Purchase Data:** AstraZeneca will not request purchase or encounter data as part of this pilot.

Any questions regarding AstraZeneca's plan should be directed to 340B@astrazeneca.com.