

GSK Contract and Chargeback Policies and Procedures Puerto Rico (Effective: June 1, 2024)

This GSK Contract and Chargeback Policies and Procedures document may be modified by GlaxoSmithKline LLC ("GSK") with thirty (30) days prior notification. The current version of this document is available at www.GSK-eCS.com.

GSK reserves the right to revoke AD's eligibility to participate in the GSK Contract Price program or terminate as an Authorized Distributor due to noncompliance by the AD with the policies and procedures contained in this document. The policies and procedures contained in this document shall remain in effect until further written notice from GSK.

Definitions

"Authorized Distributor" or **"AD"** is a GSK-designated entity that is qualified to purchase, receive, handle, and sell GSK products to persons other than consumers or patients. GSK reserves the right to select Authorized Distributors at its sole discretion.

"Eligible Member" or **"customer"** is a GSK-authorized health care entity at the "ship-to" level, approved by GSK, that is party to a contract with GSK. GSK reserves the sole right to designate additional Eligible Members and to remove members deemed not eligible based on noncompliance with applicable terms and conditions of sale.

"Covered Entities" (CE) as used herein shall mean 340B/PHS Covered Entities as defined by HRSA on the OPA website.

"Contract Pharmacy" (CP) is herein defined as "any pharmacy, either real, remote, mail-order or virtual, that is not wholly-owned by the Covered Entity. Contract pharmacy shall also include all entities providing pharmacy or pharmacy-like services pursuant to a contract arrangement or agreement with the Covered Entity."

"Specialty Pharmacy" is herein defined as "any pharmacy, either real, remote, mail-order or virtual, that is not wholly-owned by the Covered Entity. Specialty Pharmacy shall also mean and include all entities providing specialty or oncology product pharmacy or pharmacy-like services pursuant to a contract arrangement or agreement with the Covered Entity."

"Contract Pricing" is available to Eligible Members based on the terms of an applicable agreement. Contract Pricing is GSK's Wholesale Acquisition Cost ("WAC") less an agreed upon discount amount; the term "Contract Pricing" does not include Federal Excise Tax or any other additional federal, state, or local taxes or fees.

General Policy

GSK will sell, with certain limited exceptions, directly to Authorized Distributors for distribution of product(s). Except as expressly stated herein, information from third-party sources, if loaded into AD systems, may generate chargeback rejection and denial. GSK products, Eligible Members, and effective dates for Contract Pricing will be solely determined by GSK and loaded into AD systems based only on GSK Bid Award Notifications ("BANs"). AD is required to upload GSK EDI 845 BANs and/or access the GSK eCS web portal to maintain and apply accurate eligibility based on the applicable effective date. Before AD initiates an email inquiry to GSK Contract Operations for member identifier, eligibility, demographic and pricing review, the AD must utilize GSK's eCS web portal for validation. Purchasing is permitted only at the applicable Contract Prices for each Eligible Member -- for example, city, county, state, or non-government hospitals, hospital groups, Federal purchasers, 340B/PHS Covered Entities, and other health care entities designated by GSK. Institutions not specified by GSK as "Eligible Members" are not authorized to access Contract Prices.

In the event of a delayed notification to AD of a new contract or change to current Contract Pricing, or in the event that inaccurate pricing or membership is extended to a GSK end customer, and other than with regard to 340B Covered Entity purchasing, addressed below, the AD is required to credit and re-bill the customer based on the current eligibility at the AD's original invoice date.

340B Drug Discount Program Policies

- Chargebacks.** 340B chargeback claims are adjudicated based on each Eligible Member's contract eligibility date, contract pharmacy eligibility per GSK's 340B policy, invoice number, invoice date, product, and contract number submitted by AD. AD must ensure that original chargeback transactions are submitted for the correct contract and customer trade class. With regard to 340B Program purchases, AD must submit each chargeback with 340B identifier ("ID" or "340B ID") for either the eligible Covered Entity or selected eligible Contract Pharmacy and as applicable a Specialty Pharmacy. To the extent AD is not able to submit a valid 340B ID, the Health Industry Number ("HIN") associated with the Covered Entity's purchase shall be submitted. The following identifiers should NOT be submitted for 340B chargebacks: DEA numbers or Contract Pharmacy identifiers and as applicable Specialty Pharmacy identifiers. Failure to provide either the 340B ID or HIN will result in a denial of the related chargeback claim. GSK has separate accounts for PHS/Apexus; GSK does not reclassify indirect sales that have already been applied to PHS/Apexus contracts, and GSK will not reverse original chargeback transactions due to an incorrect account selection by the customer. Correction of inaccurate pricing to 340B Covered Entities is addressed in Section 4, below.
- Authorized Distributor Systems.** Prior to implementing data additions and changes in GSK's production environment, AD testing is required for submission of chargeback data modifications, including, for example, the 340B ID.

3. **Eligibility and Pricing.** It is the expectation that the Covered Entity placing an order (i.e., the Eligible Member) will select the appropriate account based on contract eligibility for date of sale. Nevertheless, it is the responsibility of the AD to verify active customer eligibility for participation in the 340B Program with HRSA's Covered Entity OPA database. For ViiV products, the AD will need to ensure that the appropriate Bill To / Ship To relationship is defined on the HRSA website for Covered Entity contract pharmacy shipments.

The following applies to all GSK PHS contracted products purchased by PHS Covered Entities:

- If a Covered Entity has an owned pharmacy capable of dispensing GSK products, the Covered Entity is not eligible for a contract pharmacy "Bill To/Ship To" relationship EXCEPT for the following:
 - Contract pharmacies that are wholly owned by a 340B covered entity or have common ownership with a 340B health system, will remain eligible to receive "Bill To/Ship To" replenishment orders of 340B priced drugs.
 - If the Covered Entity does not have an in-house pharmacy capable of dispensing GSK's products, the Covered Entity can designate one eligible contract pharmacy as a shipping location. For GSK specialty/oncology products which are part of a limited pharmacy network, the contract pharmacy designation must be part of GSK's network. Covered entities not able to dispense products subject to GSK's limited pharmacy network may need to designate a single contract pharmacy for each of GSK's limited pharmacy network products. Once the Covered Entity selects a Contract Pharmacy, updates to the selected Pharmacy can be made once every 12 months. GSK reserves the right to alter its 340B Contract Pharmacy eligibility based on state laws.
4. AD must extend accurate 340B pricing to 340B Covered Entities and/or its selected/eligible Contract Pharmacy based solely on electronic BANs, eCS web portal and/or **manual files** received from GSK. Failure to extend 340B pricing to an eligible 340B Covered Entity and/or Covered Entity's eligible/selected Contract Pharmacy for eligible purchases is a violation of GSK's Contract and Chargeback Policies and Procedures. AD shall immediately correct any incorrectly implemented 340B price and eligibility that is identified (regardless of the source of discovery) to ensure correct pricing on a prospective basis from the point of discovery.
 5. **Correction of Inaccurate Pricing to 340B Covered Entities.** GSK works directly with affected 340B Covered Entities in the event of incorrect pricing and will reprocess chargebacks for verified pricing discrepancies identified by AD or GSK. AD may instruct Covered Entity with a self-identified 340B compliance violation to submit repayment requests to: Mary Turner, GlaxoSmithKline, Suite 1700, 2929 Walnut Street, Philadelphia, PA 19104.
 6. **Eligible Contract Pharmacies.** In accordance with HRSA guidelines, AD must support a shipping and billing procedure in which the Covered Entity purchases and maintains title to the drug but under which AD ships product to the selected eligible Contract Pharmacy under contract with the 340B Covered Entity. In particular, under this purchasing framework, AD will bill the Covered Entity for purchased drug but may ship drug directly to the Covered Entity's Owned Pharmacy or eligible Contract Pharmacy defined above in Section 3.
 7. **Addresses.** Shipping and Billing addresses associated with purchases made by eligible Covered Entity, Covered Entity's Owned Pharmacy, selected Contract Pharmacy and as applicable a Specialty Pharmacy shall be verified by AD on HRSA's OPA database prior to shipping GSK products.

Contract Price Policies

1. Sales of products to AD will be at the WAC in effect at the time of the order. GSK reserves the right to change WAC at its sole discretion and without notice.
2. Contract Prices for sales are exclusively for those Eligible Members specifically designated by GSK.
3. Contract Prices offered to Eligible Members are solely determined by GSK. BANs will be sent to ADs on an equal basis unless otherwise specified by the bidding agency or entity. GSK reserves the right to respond directly to organizations soliciting bids and quotes for Contract Pricing. Terms and conditions will be established between the Eligible Member and their selected AD.
4. All GSK product contract commitments will be subject to availability of stock from GSK.
5. GSK's Contract Prices are conditional upon GSK's agreement with the contract holder that all Eligible Members are purchasing products solely for the Eligible Member's "own use" within the meaning of the federal Nonprofit Institution's Act (15 U.S.C. § 13 (c)).
6. AD shall provide GSK with any information it receives that indicates that any other disposition of such products may have occurred. Any sale by an AD to an institution not approved by GSK or in furtherance of a use other than an Eligible Member's "own use" shall be grounds for immediate termination as an Authorized Distributor agreement or BANs.
7. GSK's Contract Prices represent confidential and competitive proprietary information; any attempt to disclose these prices in any form to individuals or organizations that are not covered by the contract is prohibited.

8. GSK reserves the right to change contract terms (e.g., pricing, eligibility, contract termination, etc.) in any way without incurring fees.

9. GSK does not extend BANs to any AD located in states where such contracting could be deemed to violate unitary pricing laws. The provisions of the Contract Policies and Procedures do not apply in such situations.

10. To be eligible for Contract Prices, Eligible Members must be customers in good standing with GSK that have currently identified only one buying group as their primary group affiliation. GSK will only recognize one buying group with the exception of Specialty products such as but not limited to Benlysta, Cabenuva, Jemperli, Nucala and Zejula where members may be aligned to more than one contract and buying group, GSK may deny Contract Prices to non-Eligible Members. GSK also may deny chargebacks to AD for sales made to non-Eligible Members.

Wholesaler/Distributor Prime Vendors

Under "Prime Vendor" and similar programs, organizations designate (1) manufacturers for Contract Prices; and (2) ADs for distribution of the product(s) chosen. Under such programs, GSK, if it elects to respond, will do so directly to the organization by quoting Contract Prices. AD must be designated by the organization to supply GSK products.

Chargebacks

Chargeback adjustments (in the form of credit reconciliation reports via Electronic Data Interchange ("EDI") or pdf) will be provided by GSK to AD making contract sales of GSK products in the amount of the difference between the WAC and the Contract Price for such AD.

Original Chargeback claims: At a minimum, AD shall transmit original claims on a monthly basis in EDI X12 format through GSK approved transmission protocols and channels. To obtain GSK EDI requirements and contact information, please visit www.GSK-eCS.com.

GSK will process original transmitted submissions within ten (10) days of receipt of claims in our chargeback system.

Original Chargeback claims: At a minimum, AD must submit original **manual** claims on a monthly basis in *GSK Manual Header & Chargeback Lines Template* data must be accurate and complete with requested invoice sampling to upload Excel spreadsheet in GSK Chargeback system for processing.

GSK will process original Manual submissions within twenty (20) days of receipt of accurate and complete data to upload in our chargeback system.

Original chargeback claims shall be submitted to GSK within thirty (30) days after the ADs invoice ship date to the Eligible Member. GSK has the right to deny a chargeback received after this time.

Chargeback Resubmissions: AD shall resubmit disputed chargeback claims promptly to the GSK Chargeback Operations Department for resolution within thirty (30) days from the receipt of GSK's chargeback credit memo reconciliation report. GSK has the right to deny a chargeback received after this time. For disputed claims, ADs shall electronically resubmit the chargeback claim either www.GSK-eCS.com or EDI, not both. Testing is required for EDI resubmissions prior to transmitting data in GSK's production environment.

GSK will process resubmissions within thirty (30) days of receipt of claims in our chargeback system.

Required Information

The following information is required for chargeback processing:

- 1) AD Identifier (HIN or DEA number)
- 2) AD Debit Memo Number
- 3) AD must communicate member identifier to GSK (e.g. HIN , DEA, 340B ID, State License)
- 4) Eligible Member Name and Address
- 5) GSK Contract Number and Price Group
- 6) Product Type Code ID (N4 preferred)
- 7) Package Size Only (no partial/split package allowed)
- 8) Quantity (submit only negative and positive, and no partial quantity allowed)
- 9) NDC# 11
- 10) Invoice Ship Date
- 11) Invoice Number
- 12) WAC
- 13) Contract Price
- 14) Chargeback Amount
- 15) Resubmission shall include a Note which must contain member identifier and/or contract number with price group for GSK review.
- 16) If a unique line number for each transaction is not provided on GSK submissions, GSK will auto-assign a unique line number.

Chargeback and Contract Operating Requirements

1. AD shall report/submit to GSK all credits and other invoice adjustments that relate to sales previously claimed for chargebacks as part of its regular chargeback transmissions. Adjustments and credits relating to previously claimed sales must reference the original invoice ship date and invoice number of the original sale, including chargeback contract member product inventory return reversal, credit reversal and re-bill claims. If accurate information is not included, the claim will result in rejection. GSK may perform a reconciliation of positive and negative chargeback claims to adjustments reported via the ADs 867 sales data or hard copy of original sale and adjustment. GSK will notify AD of any discrepancies identified during the reconciliation process.

Note: GSK does not accept chargebacks for returns of expired and/or damaged products. Refer to GSK's Returns Policy.

2. Contract Bid Award Notifications are provided by GSK via EDI 845, NOTE: If the Member update is limited to an identifier, i.e. DEA and HIN, this change is not sent via EDI 845 but can be validated on our eCS web portal. To obtain GSK EDI requirements and contact information, please visit www.gsk-ecs.com as an additional resource for validation of contract eligibility and pricing to download in MS Excel format.

3. Chargeback requests for "net priced products" should not be submitted (and will not be honored if received). Chargebacks should not be submitted for products GSK invoices the AD at contract price; these transactions will be denied.

4. AD must only submit chargeback claims for products purchased solely from GSK.

5. AD shall submit copies of sales invoices with itemization of product pricing upon GSK request; requests may relate to, but are not limited to, the following: chargeback claim comparisons, suspected duplicates, verifying 340B pricing, adjustments, or the request of Eligible Members. Failure to supply GSK with invoice and/or adjustment copies to verify a contract sale will result in denial or reversal of the chargeback claim.

GSK Operating Guidance

1. AD must have the capabilities to offer GSK Contract Pricing to only Eligible Members at the ship to level with appropriate identifier, member name and address aligned with the contract.

2. GSK may request AD certification and/or appropriate documentation for requests that may relate to but are not limited to: 1) GSK Eligible Members not serviced during a specific measurement period, and 2) verification that accurate discounts and Contract Pricing were invoiced and passed along to Eligible Members.

3. 95% of original chargeback requests shall be received based on GSK system receipt date within fifteen (15) days after ADs shipping date to the Eligible Member.

4. Percent of Initial Chargeback Credit vs. Initial Chargeback Claim must be between 95% and 105%, target is greater than or equal to 99%. The percentage shall be determined based on the average of the total chargeback amount paid on original chargeback transactions divided by the total claimed amount on original chargeback transactions for all paid original debit memos for the period being measured.

5. Unauthorized chargeback deductions are not permitted. All chargeback disputes must be resolved through the GSK Chargeback Resubmission process.

6. AD with percent of errors in chargeback submissions greater than or equal to 5% must initiate corrective actions to address data quality issues.

In the event that the AD is no longer a GSK Authorized Distributor, chargebacks may be submitted with invoice dates no greater than sixty (60) days post end date.