Chargeback Policy for Eisai Products

Effective November 1, 2023

Listed below, please find Eisai Inc.’s Chargeback policy for Products, which is effective as of November 1, 2023.

A. POLICY

The principal policy requirements for chargeback claim request processing are as follows:

1. Chargeback Claim Submissions—All chargeback debit memo claims must be submitted to Eisai no later than 60 days after the date of distributor's invoice to the end customer. Any chargebacks received after this time will be automatically denied or rejected as “line item too old”, and will not be paid, unless submission is the result of a government audit. Distributor may submit chargebacks greater than 60 days beyond invoice date if these submissions are a result of a government audit. Distributor must identify the submission as being the result of a government audit and the submission must be segregated from normal submissions. All claims must include an accurate primary identifier and secondary identifier (if required.)

2. Chargeback Resubmissions—All chargeback resubmissions must be submitted to Eisai within 120 days of the date of distributor’s invoice to the end customer.

3. Contract Price—Distributor shall administer contracts between Eisai and Customers setting forth the price at which a Customer may purchase Product(s) (the “Contract Price”). Distributor shall limit charges to such Customers to the applicable Contract Price, except for any administrative, handling, or other fees for Distributor's services or discounts, rebates or other price concessions as may be independently agreed upon between Distributor and the Customer; provided, however, that any such fees or amounts shall not be reflected in chargeback claims.

4. Customer Eligibility—Eisai will deny chargeback claims for all sales to entities that are not members of the designated purchasing group at the time of sale, as reflected in Eisai’s records. Eligibility of the membership lists provided from a group purchasing organization to Eisai and to Distributor are subject to Eisai’s final validation of such eligibility. Distributor does not have any entitlement to any adjustment for a denied chargeback if the end customer is determined to be ineligible based on Eisai’s review. Eligibility should be verified by Distributor before submission of chargeback claims.

5. Distributor will be entitled to chargebacks only if all of the following requirements are satisfied:
a. Products are sold only to Customers located in the Territory;
b. Products are sourced solely and directly from Eisai; and
c. Distributor is notified by Eisai that the Customer is entitled to a Contract Price below WAC.

6. Contract Notification-Distributor will be notified by Eisai via 845 EDI transaction set or via email, of the awarded bid or renewal.

7. Chargeback Claim Processing-Eisai will process all chargebacks claims within 10 business days and notify Distributor of the chargeback claim calculation.

8. Chargeback Claim Payment-Chargeback payments will be made via wire transfer to Distributor’s bank account or other form of payment approved in writing by Eisai for the chargebacks claim amount (i.e., credit memo).

9. Customer Credit and Re-bills-Distributor will be responsible for credit and re-bill corrections to the Customer for any discrepancies in administering the Contract Price. These credit and re-bills must be received from Eisai within six months of the original invoice date. If Eisai has made an error regarding the Contract Price for a Customer, Eisai will notify Distributor of the error and Distributor will issue a credit and re-bill to the Customer.

10. Chargeback Claim Reconciliation-Distributor will be notified by Eisai within 10 days of any chargeback claim discrepancies after the original chargeback claim was submitted. Distributor will have 30 days from the notification date to research denial and resubmit additional information. If Eisai does not receive additional detail from Distributor by the end of such 30-day period, Eisai will consider the chargeback closed and paid in full. Distributor will not be authorized to deduct for any chargeback claim discrepancy.

11. Contract Customer Product Returns-For Product returns, Distributor will send a reverse chargeback claim referencing the original invoice number and original invoice date and remit to Eisai. If this information is not provided, Eisai will reject the claim.

B. DISTRIBUTOR SUBMISSION

1. Distributor will submit all chargeback requests in the form of a Debit Memo (DM) via EDI 844. These are interfaced directly into the Eisai contracting system.

2. Eisai will send a EDI 997 (receipt acknowledgement) back to distributor

3. Distributors shall have 60 days from the invoice date to the Customer to submit eligible chargebacks to Eisai.
   a. If Distributor submits a chargeback that is more than 60 days past
the invoice date and is the result of a government audit, Distributor must identify the submission as being the result of a government audit and the submission must be segregated from normal submissions.

4. EDI checks are performed before the DM can be accepted into Eisai’s contracting system. No data is accepted via EDI if:
   a. Distributor’s file cannot be read (if this occurs notification is sent to the EDI Help Desk for follow-up);
   b. sender’s EDI ID is not mapped to an internal ID;
   c. sender's file control numbers are not in sequence (no gaps or duplicates);
   d. count of lines actually received does not match the line count sent with the file; or
   e. other required fields are not populated

5. If the DM does not pass these checks, the EDI administrator will contact Distributor, inform them that the submission failed, and ask for same day or next day resubmission.

C. RESUBMISSIONS

1. Distributor will resubmit chargeback re-submittals to Eisai via EDI. Re-submittals may be made via e-mail only in the event of an EDI failure and if approved by Eisai. The email address for resubmissions is: CB_Membership@eisai.com. In the re-submission, Distributor must include documentation with additional information supporting the acceptance of rejected debit memo (DM) lines.
   a. Eisai requires that Distributor resubmit all information for additional consideration within 120 days of Distributor’s original invoice date to the Customer. Any resubmission after this time is considered stale and no additional credit will be issued.

D. OWN USE

1. Distributor represents and warrants that no Customer is engaged, and no Customer will engage, in retail sales of Eisai specialty drugs, and that all such drugs purchased are exclusively for the own use of each such customer. In accordance therewith, covered products sold under the “own use” restriction may be supplied to:
   a. Inpatients, or emergency room patients being treated by the facility (walk-in buyers not under the care of the hospital or agency are not included, except in emergency).
   b. Former patients, limited to take-home prescriptions given upon
discharge;

c. Employees of the facility and their dependent family members;

d. Staff physicians, for their personal use or the use of their dependent family members (but not for use in private practice unconnected with the facility); and

e. Emergency situations (including those involving a walk-in buyer).

If Distributor fails to observe the terms of this Section, Eisai may, at its option, immediately terminate Distributor and take other action that Eisai deems appropriate.

E. PUBLIC HEALTH SERVICES SUBMISSIONS

1. Verification of 340B Eligibility-Distributor will confirm that a Customer seeking to purchase Product at the 340B Contract Price is registered as a 340B covered entity or child site on HRSA’s OPAIS database, consistent with the 340B statute (“340B Covered Entities”).

2. Limitation of “Bill To/Ship To” Orders to Contract Pharmacies-Subject to the exceptions set forth herein, commencing on November 1, 2023, 340B Covered Entities will not be permitted to purchase certain Products at the 340B Contract Price for delivery to pharmacies that are not registered as a shipping address of the 340B Covered Entity on OPAIS, meaning that Eisai will no longer facilitate “Bill To/Ship To” orders of such Products purchased at the 340B Contract Price to contract pharmacies effective November 1, 2023. This Section E(2) is applicable to ARICEPT®, BANZEL®, DAYVIGO™, HALAVEN®, LENVIMA® and LEQEMBI™. No other Eisai products are impacted by this provision.

3. Exceptions-The following exceptions apply to Section E(2):

   a. Section E(2) applies only to 340B Covered Entities that are registered in OPAIS as disproportionate share hospitals, children’s hospitals, rural referral centers, sole community hospitals, critical access hospitals, or free-standing cancer hospitals (“Hospital Covered Entities”). Federal grantee 340B Covered Entities (i.e., 340B Covered Entities that are not registered in OPAIS as Hospital Covered Entities) are excluded from Section E(2) and will remain eligible to purchase all Products at the 340B Contract Price for delivery to their respective contract pharmacies that are: (i) registered as a contract pharmacy of the 340B Covered Entity in the OPAIS database; and (ii) for orders of LENVIMA and LEQEMBI, included in the limited distribution network for the Product, as communicated in writing by Eisai to Distributor (“Network Pharmacies”).
b. Any Hospital Covered Entity that does not have an in-house pharmacy capable of dispensing 340B products to its patients may designate a single contract pharmacy location for shipment of “Bill To/Ship To” orders of Products purchased at the 340B Contract Price. All such designated contract pharmacies must be: (i) registered as a contract pharmacy of the Hospital Covered Entity in the OPAIS database; and (ii) Network Pharmacies, for orders of LENVIMA and LEQEMBI. Eisai will provide Distributor a spreadsheet listing the addresses of the designated contract pharmacies for Hospital Covered Entities (the “Contract Pharmacy File”). The Contract Pharmacy File will be updated on a weekly basis. Eisai will not honor chargebacks for “Bill To/Ship To” orders to any other addresses for Hospital Covered Entities.

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This policy is subject to change by Eisai at any time without notice. If you have any questions concerning this chargeback policy, please contact Contract Operations - 
CB_Membership@eisai.com.