TRODELVY Spoilage Replacement Program

Patient Support: GileadOncologySupport@gilead.com

Only FDA-approved indications will be considered for replacement.

If TRODELVY is purchased for use for an FDA-approved indication, was spoiled, and all eligibility requirements are met, the product may be eligible for replacement through the TRODELVY Spoilage Replacement Program. Product must be returned, Proof of Purchase, Photos of the spoiled product, or a Certificate of Destruction must be furnished to be eligible for the Gilead Spoilage Replacement Program upon request .

For quality or stability-related issues, please contact Gilead Medical Information at 1-866-633-4474.
For expired product returns questions, please contact Gilead Trade Operations at 1-800-939-9009.

Eligibility criteria

- To be eligible for replacement, TRODELVY must have been rendered unusable ("Spoiled Product") after purchase by a licensed healthcare provider ("HCP") and all statements below are true:
    - The Gilead product was dropped or broken by the HCP.
    - The Gilead product (vials) were inappropriately stored due to a catastrophic event or redundant system failure
    - The Gilead product was reconstituted but not administered to the patient due to an unforeseen patient condition or because the patient missed the appointment; or
    - The Gilead product was mixed with the wrong solution

- The Spoiled Product was prescribed for an FDA-approved indication.
- The Spoiled Product was purchased from an authorized distributor or specialty pharmacy.
- **NO** portion of the Product has been administered and **NO** portion of the Product is intended to be administered to any patient.
- The HCP has **not** billed and will not bill for or receive any payment from a payer or patient for **any** portion of the Product.
- For catastrophic events/system failures the facility cannot have insurance to cover the spoiled product.

Process and form completion

Each spoilage incident must be reported separately by completing the Spoilage Replacement Form

Attestation must be provided at the end of the Spoilage Replacement Form by a HCP who has signing authority for the facility

E-mail completed Spoilage Replacement Forms to gileadoncologysupport@gilead.com within thirty (30) calendar days of spoilage; the date of spoilage incident will be required to submit the form

- If approved, a Return Authorization form containing further instructions for returning product or completing a Certificate of Destruction will be provided within five (5) business days of the form submission.
- To avoid any delays, ensure that the Return Authorization form is included with any product being sent back.
- Send one Return Authorization form per return package.
- If you have questions or would prefer a paper form to fax, please email Gilead Oncology Support at gileadoncologysupport@gilead.com with subject line ATTN: Spoilage ;

Important program guidelines

- Each instance of spoilage requires completion of this form and pictures of Spoiled Product, where applicable or requested.
- Gilead will determine whether to provide replacement of Spoiled Product on a case-by-case basis.
- Please retain all original product and packaging and return Spoiled Product in accordance with the instructions provided on the Return Authorization form
- Gilead shall ship replacement product only to licensed healthcare facilities
- Requests are subject to certain limitations and conditions
    - HCP does not have insurance policy coverage that covers the replacement of the Spoiled Product
    - For replacement requests due to dropped, or broken vials; reconstituted product not administer to a patient due to an unforeseen patient condition or patient missed appointment; or mixing errors, each instance of replacement is limited to the actual number of vials affected (but in no instance greater than Trodelvy eight (8) vials)
        - The total number of Spoiled Product replacements in any twelve (12) month period is limited to three (3) replacements per site
    - For replacement requests due to inappropriate storage due to a catastrophic event or redundant system failure, each instance of replacement is limited to the actual number of vials affected (but in no instance greater than the number of vials purchased through an authorized distributor by the site in the last seven (7) calendar days)

- The total number of Spoiled Product replacements in any twelve (12) month period is limited to one (1) replacement per site

Gilead retains the right to make the final decision regarding any spoilage replacement request, as well as request additional documentation. All spoilage requests are subject to review. Returned product is subject to analysis.

Gilead has the right to modify or discontinue the TRODELVY® Spoilage Replacement Program at any time without notice.