Allergan USA, Inc.
LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg REPLACEMENT POLICY

This LILETTA® Replacement Policy applies to LILETTA product sold in the U.S. by Allergan USA, Inc. ("Allergan"). Allergan will, in its sole discretion and judgment, consider all justifiable requests for replacement of a LILETTA system on a unit-by-unit basis, provided that Allergan determines that the conditions stated below are met.

REPLACEMENT CONDITIONS

Product may qualify for replacement if:

(1) Unit has been removed from sterile packaging and contaminated pre-insertion without coming into contact with a patient, and the replacement request is submitted within thirty (30) days of drop or contamination;

(2) Unit has come into contact with a patient, and insertion was unsuccessful, and the replacement request is submitted within thirty (30) days of attempted insertion;

(3) Unit was inserted successfully into a patient and was expelled or removed for medical reasons and the replacement request is submitted within thirty (30) days of the expulsion or removal; or

(4) Customer desires to return unit due to product quality complaint.

To qualify for a replacement, a LILETTA Product Replacement Request Form ("RRF") must be submitted to Allergan regardless of the reason for the request. Follow the instructions below. Note that Allergan requires that the lot number and expiration date of the LILETTA unit sought to be replaced be provided on the RRF. Allergan further requires that units sought to be replaced be returned in accordance with the instructions below before a replacement unit is issued. Replacement requests will be processed within 1-2 weeks upon receipt of the pertinent documents/units.

REPLACEMENT REQUEST PROCESS

(1) Accidentally Dropped or Contaminated Pre-Insertion – A unit may be considered for replacement if it has been accidentally dropped or otherwise inadvertently contaminated prior to insertion into a patient. To request replacement of a unit because it has been dropped or contaminated pre-insertion:

a) Within thirty (30) days following the drop or contamination,

   i. Download a RRF (available under the "Replacement" tab at https://www.lilettaaccessconnect.com/#Resources), then complete, scan, and email the RRF to LILETTASupport@allergan.com. A Return Authorization number ("RA#"), pre-paid shipping label, and instructions on how to return the product will be provided within two (2) business days.

OR

   ii. Contact our Customer Service team at 1.833.246.2386. A Representative will complete the RRF with you over the phone and upon receipt of a signed complete RRF, provide you with a RA#. A pre-paid shipping label and instructions on how to return the product will be provided within two (2) business days.

b) Please return the product as instructed using the shipping label provided within thirty (30) days of receipt of return authorization. Any unit returned after thirty (30) days from receipt of the RA# and shipping instructions may, at Allergan's sole discretion, no longer be eligible for replacement.

c) Your replacement request will be evaluated upon receipt by Allergan, and, if Allergan determines, in its sole discretion, that a replacement is appropriate, a replacement unit will be issued.

d) Any units returned for replacement without the RA# will not be processed for replacement. Allergan reserves the right to return or destroy units that are sent without prior return authorization.

Eff. 1/1/18

(2) Incomplete Insertion – A unit may be considered for replacement if it is contaminated due to an incomplete insertion procedure.

a) Within thirty (30) days following the incomplete insertion,

i. Contact Allergan Quality Complaints at 1-855-LILETTA. An Allergan Quality Complaints Team Member will complete the RRF with you over the phone.

OR

ii. Download a RRF, then complete, scan, and email the RRF to AUS-PSReporting@allergan.com or send it via fax to 1.800.972.2368.

b) Upon receipt of a signed complete RRF, a replacement LILETTA unit will be provided to the requesting Healthcare Practitioner whose associated Healthcare Facility LILETTA AccessConnect℠ Customer Account Number appears above within approximately ten (10) business days.

(3) Expulsion or Removal – A unit may be considered for replacement following expulsion or removal for medical reasons if the replacement request is made within thirty (30) days of the expulsion or removal.

a) Within thirty (30) days after expulsion or removal for medical reasons by a trained medical professional,

i. Contact Allergan Quality Complaints at 1-855-LILETTA. An Allergan Quality Complaints Team Member will complete the RRF with you over the phone.

OR

ii. Download a RRF, then complete, scan, and email the RRF to AUS-PSReporting@allergan.com or send it via fax to 1.800.972.2368.

b) Upon receipt of a signed complete RRF, a replacement LILETTA unit will be provided to the requesting Healthcare Practitioner for the **exclusive use of the patient** whose Patient Initials, associated Healthcare Facility LILETTA AccessConnect Customer Account Number, Expelled/Removed Unit Information, and Date of Birth appear on the RRF within approximately ten (10) business days.

c) In the event that the patient does not present to receive the replacement LILETTA unit, please call 1-855-LILETTA, for information on how to return the unused unit to Allergan.

(4) Product Quality Complaint – A unit may be considered for replacement if a physical or mechanical defect in the product, its packaging, or labeling is suspected. To report a suspected quality defect:

a) Contact Allergan Quality Complaints at 1-855-LILETTA to request a replacement due to suspected physical or mechanical defect and provide descriptive information pertaining to the suspected defect so the RRF can be completed with you over the phone, or download a RRF, then complete, scan, and email the RRF to AUS-PSReporting@allergan.com or send it via fax to 1.800.972.2368.

b) Your replacement request will be evaluated upon receipt of a signed complete RRF by Allergan, and, if Allergan determines, in its sole discretion, that a replacement is appropriate, a replacement unit will be issued.

DESTRUCTION OF RETURNED PRODUCT

Allergan reserves the right to destroy any product returned under this LILETTA Replacement Policy, even if Allergan determines that no replacement can be issued for such product.

PRODUCT NON-RETURNABLE FOR REPLACEMENT

Product is considered to be non-returnable for replacement if:

1) the return of the unit is unauthorized, or otherwise not in compliance with the instructions set forth above;
2) the unit was subjected to improper storage conditions;
3) the unit was damaged by fire, smoke, heat, or water resulting from a casualty occurrence or insurable hazard;
4) any other reason which Allergan determines, in its sole discretion.

RETURNS

This LILETTA Replacement Policy governs requests for replacement units. Customers seeking to return LILETTA units may do so in accordance with the Return Policy of Allergan's U.S. Brand Return Goods Policy, as referenced at https://www.allergan.com/products/key-products/specialty-products, which may be amended from time to time at the sole discretion of Allergan.

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