GALDERMA

EST. 1981

PROGRAM OFFERINGS

EVERSANA™

Table of Content

1 Program Overview

1.1 Operations

Hours of Operation: 8:00am – 8:00pm ET

Warm Transfer:
855-NEMLUVIO

Fax:
844-636-5884

Medical Information Contact:
1-866-735-4137
contactus@galdermasupport.com

Language Line:
855-296-8758
Client code: 2704

Email Address(s):
galdermapatientservices@eversana.com

PO Box:
PO Box 4529
Chesterfield, MO 63017

Pharmacy Benefits Administrator:
1-330-259-0742

1.2 Enrollment

Healthcare Providers (HCPs) may submit an enrollment via **mail**, **fax**, **HCP Portal**, or **eRx**. Form can be used with HUB or SPs.

The enrollment form requests the following information:

Patient demographics & contact information

Patient diagnosis

Product information

Patient consents

HCP demographics & contact information

HCP attestation signature & date

Duplicate Enrollment

When an enrollment form is received for the same patient, it is considered a duplicate enrollment.

- If **no active enrollment** exists, a new one will be created.
- If there is an **active enrollment**:
  - If from the **same HCP**, check if the information is the same.
    - If the same, **attach the duplicate form** to the existing enrollment.
    - If new information, **update the program CRM**. If new benefit verification is needed, cancel the current enrollment and open a new one.
  - If from a **different HCP**, create a new enrollment and contact the patient to decide which enrollment remains active.

Assessing Enrollment Form

- The program carefully **reviews each enrollment form** to ensure all necessary information is included. If the form is **complete**, it will proceed to the **next stage of processing**. However, if any information is **missing**, the program will take **specific actions** to address the gaps.
  - If the form is **signed by the healthcare provider (HCP) but lacks insurance** information, the program will conduct an **eligibility check** to obtain this information.
  - If the insurance details are found, they will be added to the form. If the information cannot be located, the program will continue with the process for handling missing information.
  - If the form is **not signed by the HCP**, the program will also follow the **missing information process**.
- In all cases where information is missing, the program will send a **Missing Information Letter** to the patient via **email** or **mail**, informing them of the required details needed to complete their enrollment.

Processing a Complete Enrollment

- Send an **Intake Complete Letter** to the HCP via **email** or **fax**.
- If the patient has **no insurance**, screen them for eligibility for the **Patient Assistance Program**.
- If the patient **has insurance**, complete a **benefit verification**.

1.3 Benefit Verification

Verifies insurance electronically or by direct contact, determining **coverage status** and necessary actions, including **PAP**, **prior authorization assistance**, or **Copay** program eligibility assessment based on insurance type.

- The program will verify **insurance benefits** for the program product. This verification will cover **primary**, **secondary**, and **tertiary insurance** as needed.
- The process includes an **electronic benefit verification**, focusing on the patient's pharmacy insurance unless the healthcare provider indicates they will handle the product directly (Buy & Bill) or if the product is covered under the medical benefit instead.
- If the benefit information cannot be obtained electronically, the program will contact the insurance company by **phone** or through their **portal/website** to complete the verification.

The case status and details will be updated with the outcome, which could be one of the following:

Not Covered by Insurance

- If there is no option for **authorization**, **exception**, or **appeal**, the patient will be considered **functionally uninsured**. The program will check if the patient is eligible for the **Patient Assistance program**.
- If the patient is already on treatment, then **Bridge program** will be considered.

Covered but PA Required

- If prior authorization, exception, or appeal is needed, the program will assist with this process.

Covered but PA Not Required

- If the patient has only **commercial insurance**, the program will check if the patient is eligible for the **Copay program**.
- If the patient has **government insurance**, the program will look for any available **alternate funds**.

1.4 Prior Authorization

A service that supports patients with **insurance approvals**, including prior authorization, non-formulary exceptions, cost and quantity overrides, advising HCPs, selecting forms, initiating ePA, and ensuring timely submission and follow-ups with payers and HCP offices.

Prior Authorization Process

- The program **advises the HCP** on the authorization assistance process and provides instructions.
- **Plan/drug-specific authorization forms** are selected and pre-populated with patient and HCP demographic information.
- The program attempts to **locate forms** from the payer's website.
- The HCP is responsible for **medical justification** and submitting authorization to the payer.
- The program may initiate an **ePA** if available and not opted out by the HCP.
- The process includes **faxing forms**, **documenting** in the program platform, and **following up** with the HCP and payer.

Up to three levels of appeal assistance offered. Follow-up attempts are made similar to authorization assistance, but timing may vary.

First and Second Attempts

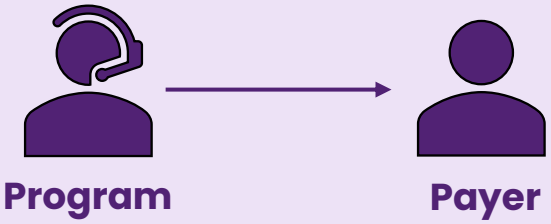
Program → **Payer**

The program will call payer to follow up on authorization status beginning **three (3) business days** after authorization notification was provided to HCP.

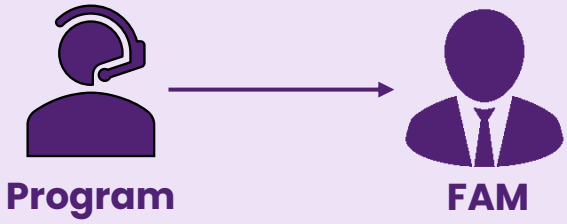
Program → **HCP**

If the authorization is not submitted the program will call the HCP within **one (1) business day**.

Third Attempt

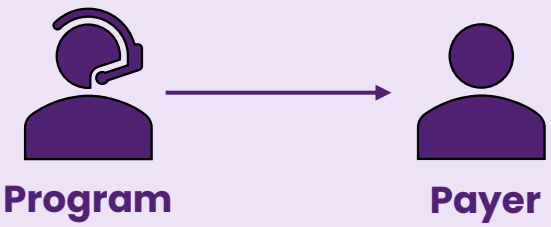


The program will call payer to follow up on authorization status **two (2) business days** after the second attempt.

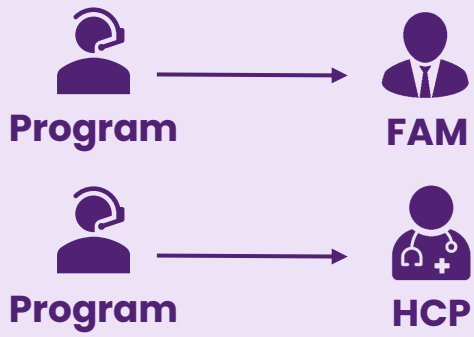


If the authorization is not submitted the program will escalate to the FAM and will not contact the HCP.

Fourth Attempt

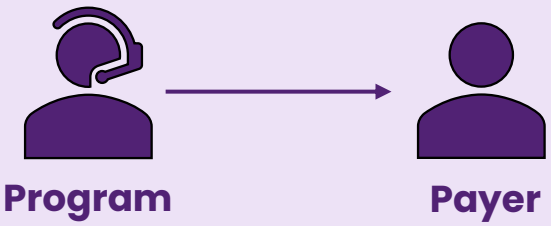


The program will call payer to follow up on authorization status **five (5) business days** after the third attempt.

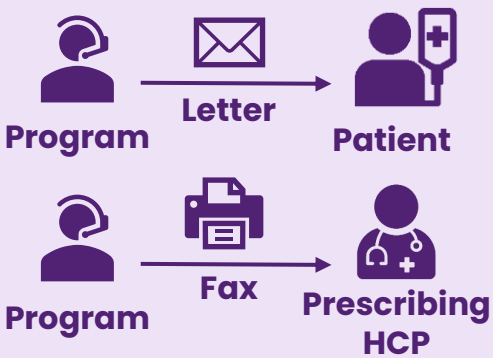


If the authorization is not submitted the program will escalate to the FAM and will contact the HCP **within one (1) business day**.

Fifth Attempt



The program will call payer to follow up on authorization **status five (5) business days** after the fourth attempt.



If HCP office hasn't completed PA submission after **5 attempts**, a final letter will be sent to the patient and fax will be sent to the Prescribing HCP and case will be closed.

Prior Authorization Appeals

- The program offers assistance if Authorization is denied due to **administrative errors or other off-label reasons**.
- The HCP can **resubmit authorization** or proceed with an **appeal**, with the program's guidance.
- Appeals may involve up to **three levels**, including assistance for appeals for medical necessity.
- Similar to the authorization process, the program provides **instructions**, selects **forms**, and assists with **submission**.

Up to three levels of appeal assistance offered. Follow-up attempts are made similar to authorization assistance, but timing may vary.

First Attempt

The program will call payer to follow up on appeal status beginning **five (5) business days** after appeal notification was provided to HCP.

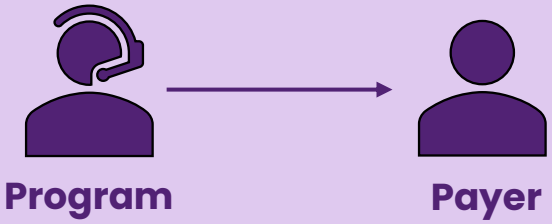
If the appeal is not submitted the program will call the HCP within **one (1) business day.**

Second Attempt

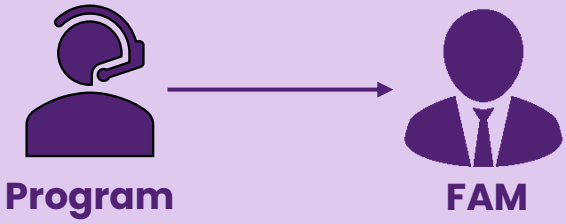
The program will call payer to follow up on authorization status **three (3) business days** after the first attempt.

If the appeal is not submitted the program will call the HCP within **one (1) business day**.

Third Attempt

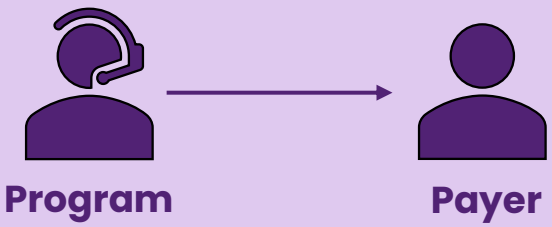


The program will call payer to follow up on appeal status **three (3) business days** after the second attempt.

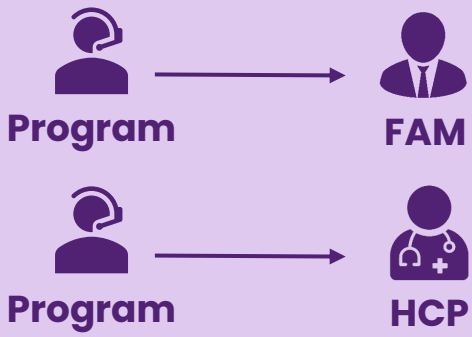


If the appeal is not submitted the program will escalate to the FAM and will not contact the HCP.

Fourth Attempt

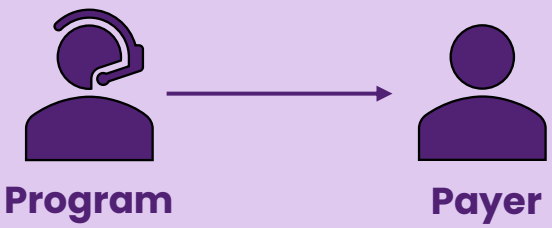


The program will call payer to follow up on appeal status **seven (7) business days** after the third attempt.

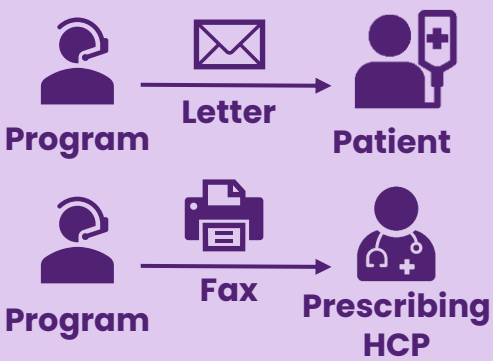


If the appeal is not submitted the program will escalate to the FAM and will contact the HCP within **one (1) business day**.

Fifth Attempt



The program will call payer to follow up on appeal status **seven (7) business days** after the fourth attempt.

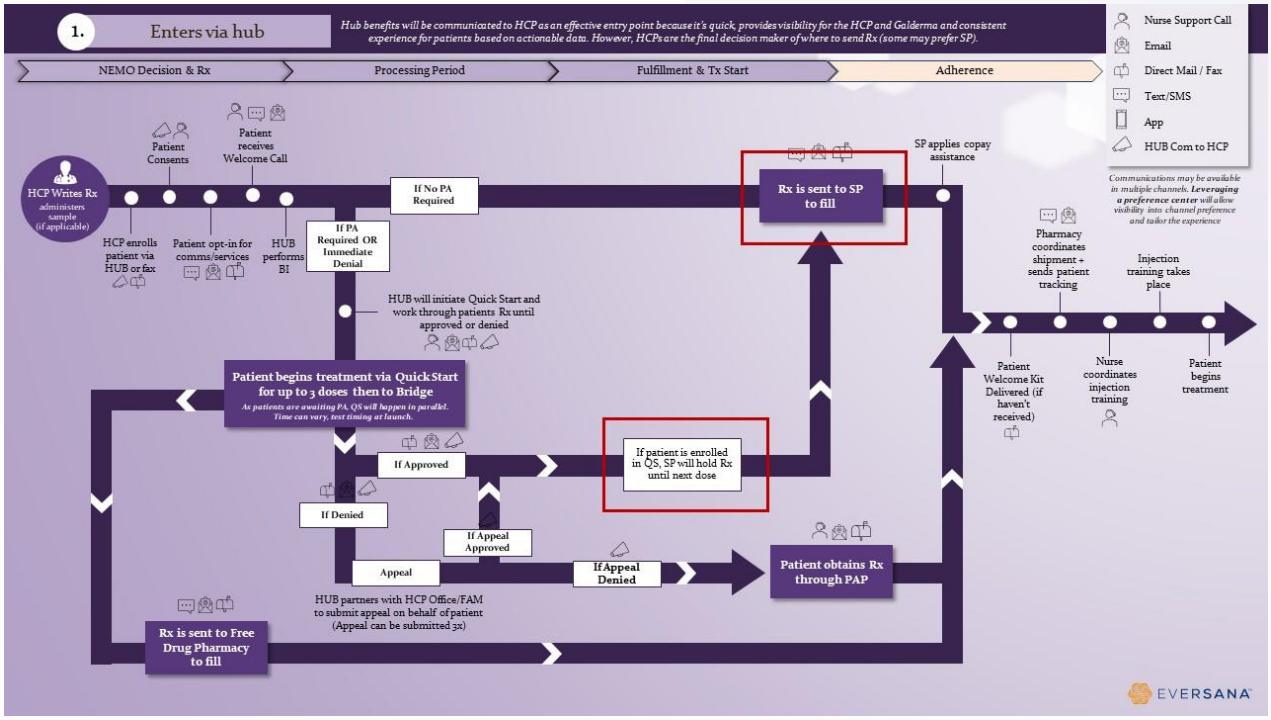


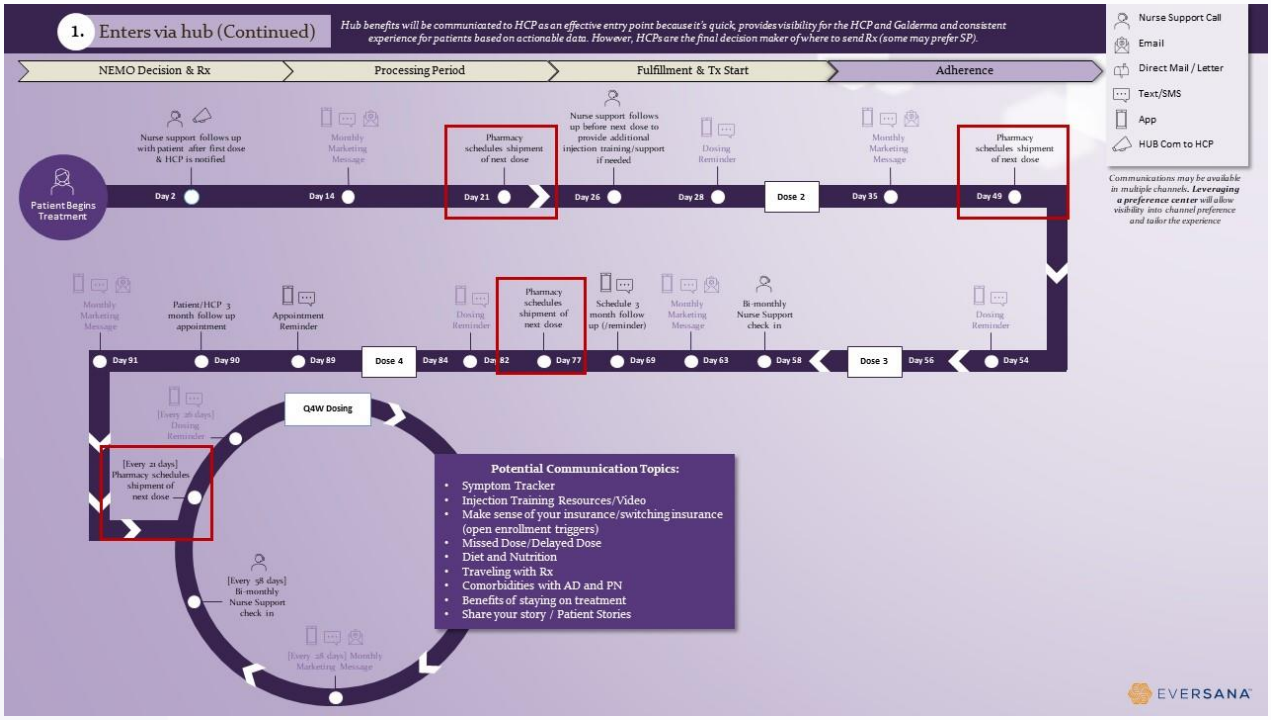
If the HCP office doesn't complete the appeal after **5 attempts**, a final letter will be sent to the patient, a fax will be sent to the prescribing HCP, and the case will be closed.

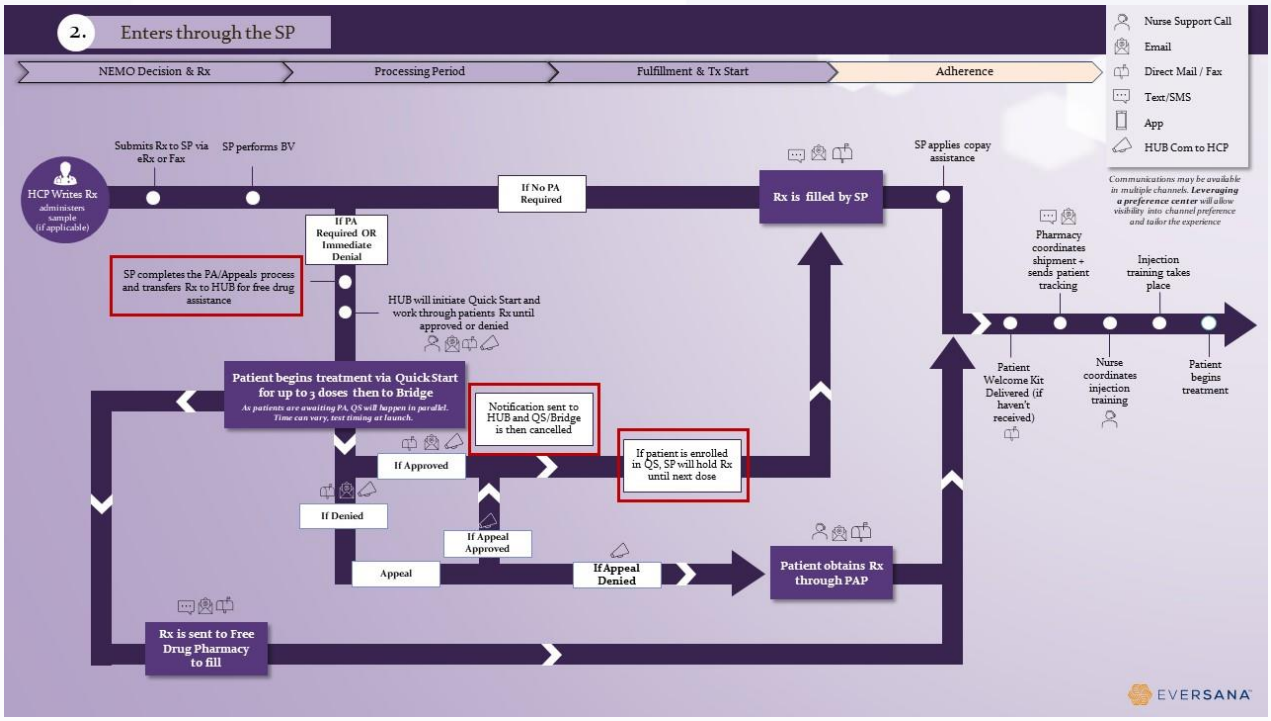
1.5 Program Offerings Eligibility Criteria

	Quick Start	Bridge	Copay	PAP	Sharps	Injection Education	Nurse Educator	Replacement	Welcome Kit
Treated with the program Product	✓	✓	✓	✓					
Reside in the USA	✓	✓	✓	✓	✓	✓	✓	✓	✓
Under care of a US licensed provider	✓	✓		✓					
On-label diagnosis	✓	✓	✓	✓	✓	✓	✓		✓
At least 18 years of age (for PN diagnosis)	✓	✓	✓	✓	✓	✓	✓		✓
Valid commercial Primary insurance plan	✓		✓						
No government-funded programs (Medicare, Medicaid, etc.)	✓		✓						
Adjusted annual income of 600% FPL or less				✓					
Uninsured, functionally uninsured or underinsured				✓					
Naive to program product	✓								
Active on therapy		✓			✓	✓			
Insurance barrier causing treatment gap		✓							
Up to 2 replacements per 12 months								✓	
PQC reported and confirmed by Galderma								✓	
Received product or eligible for shipment					✓			✓	
Actively on therapy or approved to initiate therapy					✓	✓	✓		✓

1.6 Hub Process Flow






2. Enters through the SP
NEMO Decision & Rx
Processing Period
Fulfillment & Tx Start
Adherence
Nurse Support Call
Email
Direct Mail / Fax
Text/SMS
App
HUB Com to HCP
Communications may be available in multiple channels. Leveraging a preference center will allow visibility into channel preference and tailor the experience
HCP Writes Rx
administers sample (if applicable)
Submits Rx to SP via eRx or Fax
SP performs BV
If No PA Required
Rx is filled by SP
SP applies copay assistance
If PA Required OR Immediate Denial
SP completes the PA/Appeals process and transfers Rx to HUB for free drug assistance
HUB will initiate Quick Start and work through patients Rx until approved or denied
Pharmacy coordinates shipment + sends patient tracking
Injection training takes place
Patient Welcome Kit Delivered (if haven't received)
Nurse coordinates injection training
Patient begins treatment
Patient begins treatment via Quick Start for up to 3 doses then to Bridge
As patients are awaiting PA, QS will happen in parallel. Time can vary, test timing at launch.
Notification sent to HUB and QS/Bridge is then cancelled
If patient is enrolled in QS, SP will hold Rx until next dose
If Approved
If Denied
If Appeal Approved
Appeal
If Appeal Denied
Patient obtains Rx through PAP
Rx is sent to Free Drug Pharmacy to fill
EVERSANA

2.1 Quick Start Program

Provides first/loading dose of **nemolizumab** free of charge for eligible patients whose treatment is impacted by an insurance company's prior authorization process.

Eligibility

***To qualify for the Quick Start program, patients must meet these criteria*:**

- **Treatment Compliance:** The patient must be treated with the program Product as per the **full Prescribing Information**.
- **Residency:** The patient must reside in the **United States**, including the **50 states** and **Washington D.C**.
- **Healthcare Provider:** The patient must be under the care of **a US licensed provider** with an established practice in the US.
- **Diagnosis:** The patient must have an **on-label diagnosis**.
- **Age:** The patient must be at least **18 years old** (for PN diagnosis).
- **Insurance:** The patient must have only **commercial insurance**, regardless of the benefit type.
- **Treatment History:** The patient must be **naïve** to the program product (sample patients are eligible if they qualify).
  - If the enrollment form indicates the patient is naïve but there is a record of a dispense, they will not be considered naïve.
  - If there is no record of a dispense and the enrollment form indicates the patient is naïve or does not specify, the patient will be considered naïve unless they report previous therapy.
- **Insurance Authorization:** The patient must have coverage with an **Authorization or Appeal requirement** with their primary insurance.

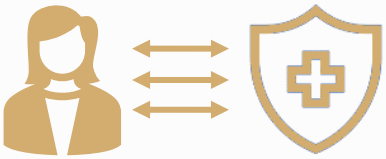
Enrollment

- To enroll in the Quick Start program, patients must be registered by their **healthcare provider (HCP)**. **No patient consent** is needed initially.
- Enrollment can be done by the healthcare provider or through the patient's **Specialty Pharmacy** via fax or transfer.
- The program will gather any missing information and obtain consent through the **Patient Web Application**, mailed form, or brand website.
- After enrollment, patients receive confirmation by **email** or **mail**, and healthcare providers are notified by **email** or **fax**.

Program Terms

- **Doses Provided:** A patient may receive up to 3 free doses of the product.
  - For patients with a PN diagnosis weighing **≤ 90 KG**, this includes up to 2 autoinjectors for a loading dose and 1 autoinjector for each of 2 maintenance doses **(total 4 autoinjectors)**.
  - For patients weighing **> 90 KG**, this includes up to 2 autoinjectors for a loading dose and 2 autoinjectors for each of 2 maintenance doses **(total 6 autoinjectors)**.
- **Second Dose Requirements:** To receive the second dose, the healthcare provider must actively pursue coverage:
  - Authorization or Appeal (if no Authorization is allowed) must be submitted to the Payer.
  - If Authorization is denied before the first dose, an Appeal must be submitted for the second dose.
- **Post-Quick Start Coverage:** If the patient does not have coverage **after 3 Quick Start doses** and the healthcare provider is actively pursuing coverage, the patient may be assessed for **Bridge eligibility**.
  - If all Authorizations and Appeals are exhausted before Quick Start is exhausted, the patient will be referred to **PAP instead of Bridge**.
  - If Authorization or Appeal is approved before Quick Start is exhausted, the patient will be transferred to their **commercial specialty pharmacy**.
    - The patient remains eligible for Quick Start dispense for up to **5 days** after the commercial pharmacy transfer.
    - After 5 days, Quick Start eligibility will terminate.
    - If a commercial dispense is confirmed within the 5-day period, the patient becomes ineligible for additional Quick Start dispenses.

2.2 Bridge Program



Provides medication at no cost to **prevent a gap** in therapy for eligible patients who have a **temporary loss of insurance** coverage.

Eligibility

To qualify for the Bridge program, patients must meet these criteria:

- **Treatment Requirement:** The patient must be treated with the product according to the **full Prescribing Information**.
- **Residency:** The patient must reside in the **United States**, including all **50 states** and **Washington D.C**.
- **Provider:** The patient must be under the care of a **US licensed provider** with an established practice in the US.
- **Diagnosis:** The patient must have an **on-label diagnosis**.
- **Age:** The patient must be at least **18 years old** (for PN diagnosis).
- **Active Therapy:** The patient must be **actively receiving therapy** with the program product.
- **Insurance Barriers:** The patient must face an insurance barrier to therapy through their primary insurance that could result in a treatment gap. This includes situations such as:
  - **Change in insurance** requiring new authorization
  - **New authorization** needed for the same insurance
  - **Exhaustion of Quick Start** program without referral to PAP
  - **Change in specialty pharmacy** causing a treatment gap
- **Coverage Pursuit:** The healthcare provider must be **actively pursuing coverage** (e.g., Prior Authorization submitted).

Enrollment

- Patients must be enrolled by their **HCP**. Consent is not needed, and eligible patients receive program terms and Conditions in the Approval Letter.
- Enrollment can be done through the **HCP** or by **Specialty Pharmacy** via **fax** or **warm transfer**.
- The program captures information verbally and follows up for any details.
- Consent can be given via the **Patient Web Application**, a mailed form, or downloaded from the website.
- Once enrolled, confirmation is sent to both the patient and provider via **email** or **mail**.

Program Terms

- **Product Availability:** Patients may receive **free product** for up to **2 years** from the date of enrollment, provided they continue to meet eligibility criteria and their healthcare provider continues to pursue coverage:
  - **Authorization Requirements:** If an Authorization or Appeal is required (and allowed), it must be submitted within **90 days** of enrollment for continued eligibility.
  - **Insurance Denials:** For each insurance denial, if an Appeal is available (up to 3 levels), it must be submitted within **90 days** of denial for continued eligibility.
  - **PAP Referrals:** If Authorization or Appeal is denied and no further Appeal is available, the patient will be referred to PAP. The patient remains eligible for Bridge product until PAP determination:
    - If **approved for PAP**, Bridge eligibility ends.
    - If **denied for PAP** with commercial insurance only, Bridge eligibility continues for the enrollment period. If denied for PAP with government insurance, Bridge eligibility ends.
- **Approved Authorization or Appeal:** If approved, the patient will be transferred to their **commercial specialty pharmacy**. Bridge eligibility continues for up to **5 days** after transfer. If a commercial dispense occurs within 5 days, Bridge eligibility ends.
- **Coverage Establishment:**
  - As coverage is established, the program will work with the healthcare provider to secure it.
  - When the patient no longer requires Bridge, they may be eligible for additional Bridge enrollments with a new term of up to **2 years** of eligibility. Terms are not cumulative.

2.3 Copay Program

Reduces or eliminates the copay responsibility for **commercially insured** eligible patients who qualify.

Eligibility

To qualify for the Copay program, patients must meet these criteria:

- The patient must be treated with the program product as specified in the full **Prescribing Information**.
- The patient must live in the **United States**, including all **50 states** and **Washington D.C**.
- The patient must have a **diagnosis** that matches the approved uses of the program product.
- The patient must be at least **18 years old** (for PN diagnosis).
- The patient must have a valid **commercial insurance** plan that covers the program product.

Non-Eligibility

Patients are NOT eligible for the Commercial Copay program if:

- They pay for the program product **entirely out-of-pocket**.
- They have insurance that covers the **entire cost** of the program product.
- They have insurance that **declines coverage** for the program product.
- Are enrolled in **any federal or state government-funded program** (e.g., Medicare Part B/Part D, Medicare Advantage Plan, Medicaid, TRICARE, VA, or Indian Health Services).

- The patient must **accept the copay program terms and conditions** during the enrollment process.
- Both the healthcare provider (HCP) and the patient will receive an **Approval Letter** via **email** or **fax**.

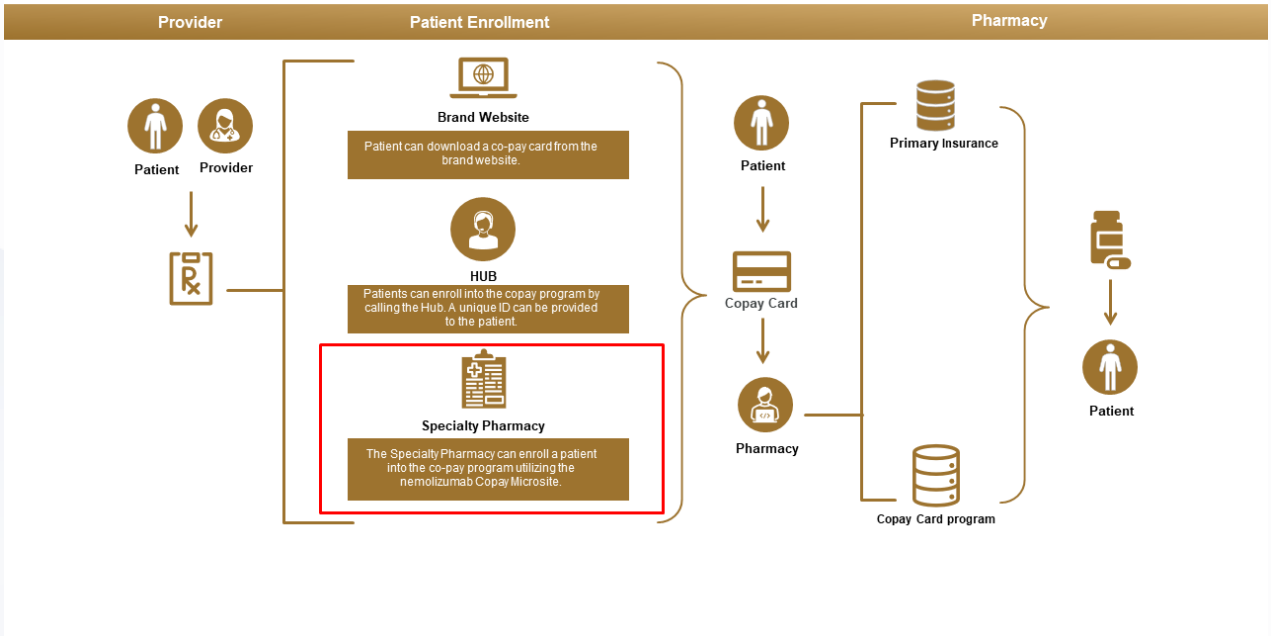
Adjudication Requirements

- The program will cover **prescription-related costs** of the program product, including **deductible**, **copay**, or **coinsurance**, up to the maximum program benefit.
- The program does not cover any related services; it only covers costs associated with the program product.
- Copay Assistance can be applied retroactively to prescription costs incurred up to **90 days before the date of enrollment**.
- Copay may be adjudicated as part of a **secondary point-of-sale claim** at the patient's specialty pharmacy.
- If the claim is not adjudicated as a secondary point-of-sale claim at the specialty pharmacy, and the patient seeks reimbursement for a payment already made, **proof of payment** is required.
- If the program product was secured via **Buy & Bill** by the healthcare provider, and the patient seeks reimbursement for payment already made to the healthcare provider, **proof of payment** is required.

Note: The Program may not make payments directly to an HCP

Copay Process Flow

Galderma offers flexible enrollment channels for patient access into the nemolizumab Copay program.



2.4 Patient Assistance Program

Provides access support for eligible patients who are **uninsured**, **rendered (functionally) uninsured**, or **under-insured** for **nemolizumab** and meet the program requirements.

Eligibility

To qualify for the PAP, patients must meet these criteria:

- **Product Usage:** The patient must be treated with the program product according to the **full Prescribing Information**.
- **Residency:** The patient must reside in the **United States**, including all **50 states** and **Washington D.C**.
- **Diagnosis:** The patient must have an **on-label diagnosis**.
- **Age:** The patient must be at least **18 years old** (for PN diagnosis).
- **Provider Care:** The patient must be under the care of a **US licensed provider** with an established practice in the US.
- **Income:** The patient's **adjusted annual income** must be **600% of the Federal Poverty Level (FPL)** or less.

Insurance Status: Patients must be uninsured, functionally uninsured, or underinsured. Details are as follows:

Uninsured

- No insurance coverage
- Hospital coverage only
- Generic coverage only
- Emergency coverage only

Functionally Uninsured

- Exhausted options for PA and/or denied up to level 3.
- All outpatient medications excluded.
- Program/Benefit exclusion.
- Drug Not Medically Necessary

Underinsured

- Out-of-pocket expense greater than $20 after all other assistance is exhausted, and the patient expresses they cannot afford the expense.

Prescreen Process

- **Initial Contact:** If a patient contacts the program via phone about their eligibility, a Program associate will use the **approved program call guide** to pre-screen the patient.
- **Assessment:** The associate will ask pre-screen questions and record answers in the **EVERSANA CRM**. Eligibility will be verbally assessed based on the information provided.
- **Enrollment Form:** If likely eligible, the patient will be sent a **PAP Enrollment Form** via email or mail.

Enrollment Process

The enrollment form requests the following information:

Patient demographics & contact information

Patient household size and adjusted annual income

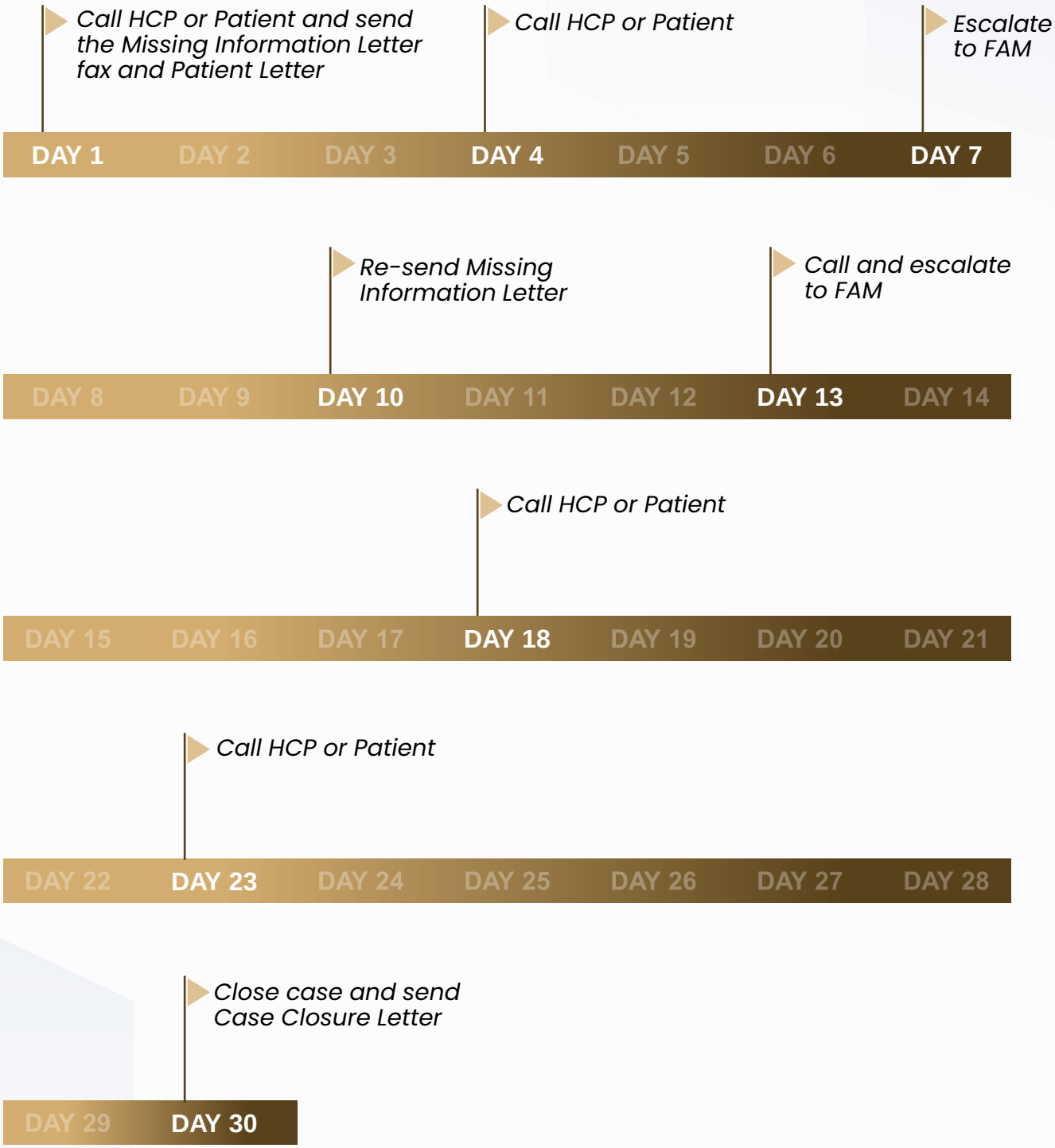
Patient diagnosis

Patient consents

HCP demographics & contact information

Data Intake: The Program will determine if any information is missing.

Follow-up: If information is missing, the Program will contact the HCP or patient and send reminders according to the following schedule:



Eligibility Assessment: Once the enrollment form is complete, the patient's eligibility will be assessed.

Eligibility Reconsideration / Appeal

- **Additional Information:** Patients denied due to income can provide additional information about medical and living expenses.
- **Documentation:** Acceptable documentation includes **pharmacy printouts**, **itemized receipts**, or **EOBs**.
- **Recalculation:** The program will **recalculate income** based on the new documentation.

Denied Patients

- **Notification:** Patients and their HCPs will receive a **Denial Letter**, including information about **alternate assistance** options.
- **Referral:** Patients may be referred back to **Bridge** or other assistance programs.

Approved Patients

- **Approval Period:** Approval duration varies based on insurance status:
  - **Uninsured:** 365 days from the date of approval, with monthly eBV checks.
  - **Commercially Insured**: 365 days from the date of approval.
  - **Government Insured:** Until December 31st of the current year.
- **Notifications:** Both the patient and HCP will receive **Approval Letters**.

Re-Enrollment Process

- **Reminders:** HCPs and patients will receive a re-enrollment reminder **45 days before** the eligibility end date.
- **Submission:** A new enrollment form must be submitted with **updated consent** and **attestation**.
- **Processing:** Re-enrollment forms are processed up to **60 days** before expiration. Government insured patient approvals begin **after January 1st** of the following year.

3.1 Sharps Program

Supplies patients with the proper **disposal containers** and a **mail back option** for proper disposal of the **nemolizumab Auto Injector**.

Eligibility

To qualify for the Sharps program, patients must meet these criteria:

- **Residency:** The patient must reside within the **United States**, including all **50 states** and **Washington D.C**.
- **Diagnosis:** The patient must have an **on-label diagnosis**.
- **Age:** The patient must be at least **18 years old** (for PN diagnosis).
- **Insurance:** Patients, regardless of their insurance type, can receive a Sharps container at no cost if:
  - They are **actively undergoing therapy** with the program product or have been approved to start therapy with it (through insurance, Bridge, Quick Start, or PAP).
  - They **request a Sharps container**, which will be **shipped** to them.

Enrollment

Patients need to be enrolled in the Sharps Program to receive a Sharps container. Enrollment can be done in the following ways:

- **HCP:** The healthcare provider enrolls the patient into the full program. The patient requests a Sharps container **verbally**.
- **Specialty Pharmacy Request:** The patient's Specialty Pharmacy requests Sharps container fulfillment by **faxing an enrollment form** with the patient's consent. Alternatively, the patient can request a Sharps container **verbally** after enrollment.
- **Patient Web Application (PWA):** The patient requests a Sharps container via the PWA with documented marketing consent.

Fulfillment

Upon receiving a request from a patient, the Program will ship a Sharps container under the following conditions:

- **Enrollment and Approval:**
  - The patient is enrolled in the Program.
  - The patient receives insurance approval, and the commercial prescription is transferred to the commercial pharmacy with a confirmed dispense date in the SP data feed.
- **Special Programs:** The patient is enrolled in **Quick Start**, **Bridge**, or **PAP** and receives their **first shipment** of the program product.
- **Web Request:** The patient requested a Sharps container via the **PWA**.
- **Marketing Consent:** Documented marketing consent must be on file.
- **Frequency:**
  - Each patient is eligible to receive **ONE Sharps container every six months.**
  - Patients are not eligible to request another container if one has been provided within the last six months.

3.2 Injection Education

1-on-1 (live or telehealth) **self-injection education** from a **registered nurse** to build confidence with administration

Eligibility

To qualify for the Injection Education, patients must meet these criteria:

- **Residency:** The patient must reside within the **United States**, including all **50 states** and **Washington D.C**.
- **Diagnosis:** The patient must have an **on-label diagnosis**.
- **Age:** The patient must be at least **18 years old** (for PN diagnosis).
- **Insurance:** Patients, regardless of their insurance type, can receive in-home Nurse Injection Education at no cost if they are **actively undergoing therapy** with the program product or have been approved to start therapy with it (through insurance, Bridge, Quick Start, or PAP).

Enrollment

Patients must be enrolled in the program to receive Injection Education. Patients may enroll by:

- Their **HCP**, either **verbally**, in **writing** (including fax or message via the HCP portal), or through the healthcare provider requesting it on the **enrollment form**
- **Specialty Pharmacy** requesting Nurse Injection Education via fax
- Patient requesting Nurse Injection Education via the **PWA** with documented marketing consent.

The program will request a **field nurse** to contact the patient to **schedule a Nurse Injection Education** visit under various conditions, such as when the patient is **enrolled** in the program and receives **insurance approval**, or when the patient's **Specialty Pharmacy** requests Nurse Injection Education via **fax** or **phone**.

3.3 Nurse Education Support

Ongoing **telephonic disease** and **product education & support** in line with patient need and preference

Program

- Opted in patients will receive defined adherence calls from a nurse:
  - **Day 0** (after first injection) to see how patient's injection went (if not observed by injection education nurse)
  - **Day 3-7** (before next injection) to reinforce injection techniques, collect itch scores, etc.
- During **refill reminder calls**, hub will assess **itch & sleep scores** and inquire as to whether the patient has any questions for a nurse. Nurse will be engaged if the patient requests.
- If at any time a patient has questions regarding treatment, disease, handling product, etc., program associate will **warm transfer** patient to a nurse or **arrange a call back**.
- Nurses will not give medical advice. If patient asks questions that where approved responses are not available, patient will be redirected to their HCP.

3.4 Welcome Kit

A kit designed to provide nemolizumab patients with **education and resources** to help them successfully start therapy.

Eligibility

To qualify for the Welcome Kit, patients must meet these criteria:

- **Residency:** The patient must reside within the **United States**, including all **50 states** and **Washington D.C**.
- **Diagnosis:** The patient must have an **on-label diagnosis**.
- **Age:** The patient must be at least **18 years old** (for PN diagnosis).

Enrollment

Patients must be enrolled in the program to receive Welcome Kit. Patients may enroll by:

- **Through Your Healthcare Provider (HCP):** Your healthcare provider can enroll you in the full program with your consent documented.
- **Specialty Pharmacy Request:** Your Specialty Pharmacy can request the Welcome Kit for you by sending a **faxed enrollment form** with your documented consent.
- **Patient Web Application (PWA):** You can request a Welcome Kit directly through the PWA with your documented consent.

Fulfillment

The Program will send out a Welcome Kit when:

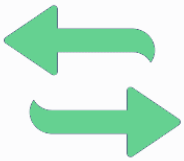
- **Program Enrollment and Insurance Approval:** You are **enrolled**, your insurance has **approved your prescription** and transferred to a **commercial pharmacy**, and a **dispense date** is confirmed.
- **First Shipment of Program Product:** You are enrolled in **Quick Start**, **Bridge**, or **PAP** and have received your first shipment of the product.
- **Specialty Pharmacy Request:** Your Specialty Pharmacy requests a Welcome Kit via **fax** after confirming your shipment.
- **PWA Request:** You request a Welcome Kit through the PWA.

Marketing Consent: Documented marketing consent must be on file to ship a Welcome Kit

One Kit Per Patient: Each eligible patient will receive only one Welcome Kit, regardless of the number of referrals or the frequency of starting and stopping treatment.

Safety Information: An Important Safety Information Letter will be sent to you via email or mail after you request a Welcome Kit.

3.5 Product Replacement



Facilitates requesting a **replacement dose** of nemolizumab due to **damage**, **Quality Complaint** (PQC), or **human error** (ie, misplacement or left in alternate location).

Eligibility

To qualify for the Product Replacement, patients must meet these criteria:

- **Residency:** The patient must reside within the **United States**, including all **50 states** and **Washington D.C**.
- **Replacement Limits:** Patients or HCPs can request up to **2 replacements per patient per 12 months** if eligibility criteria are met, regardless of insurance type.

Criteria for Replacement:

- A **Product Quality Complaint (PQC)** must be reported and confirmed by **Galderma Patient Services**. Events that qualify for PQC include:
  - The product **cannot be administered** due to the PQC.
  - The PQC is due to an **error during self-administration** or by a caregiver.
  - The PQC involves a **malfunctioning** auto-injector.
  - The PQC is due to a **physical appearance issue** of the product.

Exceptions for PQC Reporting:

- The patient never received the product due to a **shipping error** and it was dispensed by the program.
- The product was delivered but **improperly stored by the patient**, rendering it unusable.
- The product was **damaged by patient error**.
- A shipping error occurred by the program **Specialty Pharmacy** for PAP, Quick Start, or Bridge products.

Non-Eligible Instances:

- Shipment errors by a commercial specialty pharmacy.
- Trial and sample products.

Third Replacement Requests: For a third replacement request within a 12-month period, the program will **review the case** to determine if further intervention (e.g., additional Nurse Injection Education) is necessary.

Additional Requests Beyond Limit: Requests beyond the 2 allowable replacements within a 12-month period will be **escalated to Galderma** for review and approval.

Enrollment

Request Submission:

- Patients or HCPs can submit a request **verbally**, **electronically**, or in **writing**.
- Patients can request a replacement **without being enrolled** in full services by their healthcare provider.
- HCPs can request a replacement for a non-enrolled patient by **submitting a form**.

Ways to Request a Replacement:

- Enroll in the full program via HCP and request verbally by phone.
- Submit a **Product Replacement Request Form** on the brand.com website.
- Send a Product Replacement Request Form via **fax** or **mail**.
- **Contact the program** via phone or visit the brand.com website to request a form.
- Be **warm transferred** to the program by **Galderma Patient Services** without needing a form or signature.

PQC Reporting: A PQC will be reported for any replacement request unless already confirmed by Galderma Patient Services on a warm transfer.

Returning Defective Product: The Program will provide a pre-paid shipping label for returning the damaged or questionable product.

Prescription Requirement:

- The program must have an **active**, **valid prescription**.
- Commercial prescriptions intended for transfer to a commercial pharmacy post-insurance approval will not be used for replacements.
- Free product prescriptions on the patient enrollment form can be used for replacing free products.

Requesting a Prescription: If no active prescription is on file, the Program Pharmacy will contact the patient's healthcare provider up to three times as follows: