

---

PAREXEL®  
*YOUR JOURNEY. OUR MISSION.™*

# ‘How To’ Manual for My Access Programs

## Contents

1.	How to register in My Access Programs.....	4
1.1.	How to fill the Data Collection Statement.....	4
1.2.	How to fill the physician details .....	5
1.3.	How to fill the drug delivery details .....	6
1.4.	How to complete the registration.....	7
2.	First steps once registered .....	8
2.1.	How to login .....	8
2.2.	How to search for your program (for new registrations).....	9
2.3.	How to enter your program after registration .....	11
3.	How to navigate in your program .....	12
3.1.	First steps and how to find necessary information .....	12
3.2.	Document Library.....	12
3.3.	My Site .....	12
3.4.	Patient Management .....	13
3.5.	Shipment Management .....	13
3.6.	How to stay on top of your open tasks .....	13
3.7.	How to exit the current session.....	13
4.	How to grant access for your site users.....	15
4.1.	How to grant access .....	15
4.2.	How to manage site user access .....	15
4.3.	How to update your site details .....	15
5.	How to Complete your patient Registrations .....	17
5.1.	How to initiate new patient registrations .....	17
5.2.	How to access the details of your registered patients .....	20
6.	How to request a drug shipment.....	21
6.1.	How to request a drug shipment for your approved patients (initial and re-supply) 21	
6.2.	How to register a resupply shipment .....	25
7.	How to report an Adverse Event .....	27
8.	How to register required Quarterly Follow Ups.....	27
9.	How to Access and review your data .....	30
9.1.	Site Report .....	30
9.2.	Patient Report .....	30
9.3.	Shipments Report .....	30

## ‘How To’ Manual for My Access Programs

10.	Frequently Asked Questions .....	31
11.	When to contact US.....	32
	11.1. When to contact PAREXEL Clinical Site Manager .....	32
	11.2. When to contact Alexion Local Medical Affairs Manager. ....	32
	11.3. When to contact Technical Support.....	32
12.	APPENDIX .....	33

## Overview of steps in the GATM My Access.

My Access Programs™ (hereafter referenced as My Access) platform is a web-based platform used for physician registration, patient registration, medication ordering and reordering and documenting patient discontinuation. The physician must register but then may delegate access to other site users (e.g. Nurse, coordinator, pharmacist, other physicians). This user-friendly portal will allow your site the ability to easily communicate pertinent program information (i.e. share IRB/EC/RA approval documents, drug orders, safety information, patient status, etc.) to all applicable users. First time users will be provided a confidential username and temporary password for access.

### 1. HOW TO REGISTER IN MY ACCESS PROGRAMS

My Access Programs portal is available via <https://myaccessprograms.parexel.com>.

If you are new to the platform and want to register for the first time, please click on ‘Get Access’ as shown below. The system will guide you through the process for registrations (please see section 1.1 How to fill the Data Collection Statement).

Please note that the registration from outside is only allowed for physicians. Other site users like nurses, pharmacists or sub investigators will get their access granted by the primary treating physician. In those cases, no external self-registration is required / allowed.

If you have already registered please click on ‘Log In’ and proceed to section (see 2 First steps once registered).

#### 1.1. How to fill the Data Collection Statement

The screenshot shows a web form titled "My Access Programs" with a sub-header "SELF-REGISTRATION - DATA COLLECTION STATEMENT". The form contains several paragraphs of text regarding the use of the platform and the processing of personal information. At the bottom of the form, there is a checkbox labeled "I agree on the above mentioned points" and a blue "Cancel" button next to a green "Next" button. Red boxes and arrows highlight the "Next" button (labeled "Step 3") and the checkbox (labeled "Step 2").

Above you see the data collection statement, which has to be agreed to allow self-registration. Please follow the instructions on the screen to complete this step. The tick box at the bottom has to be ticked (Step 2) before you can click on next (step 3). The “Next” button will link you to the physician details page (please see section 1.2 How to fill the physician details).

You can always cancel the registration by using the blue cancel option on the screen. Self-registration can be re-accessed at any time later.

# 'How To' Manual for My Access Programs

If you have questions regarding PAREXEL's terms of service or the privacy policy, please use the link in the footer to get additional information.

## 1.2. How to fill the physician details

**My Access Programs**

**SELF-REGISTRATION - PHYSICIAN CONTACT DETAILS**

\* First Name  
\* Last Name  
\* Medical license number  
\* Phone  
Fax  
\* Email  
\* Re-enter email

**PHYSICIAN ADDRESS DETAILS**

\* Institution  
\* Address  
\* Zip  
\* City  
State  
\* Country -- Select --

If your country is not in the select list, it is currently not accepting registrations. Please contact the program team for further information at [atu-avelumab@parexel.com](mailto:atu-avelumab@parexel.com)

Back Next

Step 4

Step 5

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

The above example shows the physician details page. Please enter your information in the corresponding fields (step 4). All items marked with a red asterisks (\*) are mandatory for your registration. These items have to be populated to continue in the registration process. Once all mandatory information has been entered you can click on 'Next' (step 5) to get to the drug delivery details page (please see 1.3).

The name and address information will be mainly used to identify your site in My Access Programs. Contact details shall be provided to allow the local program teams to contact you in case of any urgent requests.

Your provided email address has two functions in My Access Programs.

- Your username and unique identifier for you as user – the email address can only be used once for a user registration. The system will of course check this at time of new registrations. If you have problems with your registration, please contact PAREXEL [GATM\\_MyAccessSupport@parexel.com](mailto:GATM_MyAccessSupport@parexel.com)
- Main contact route for confirmation emails and reminders – the system sends for all events (patient registration, shipment request etc.) email notifications to you and your assigned site users to inform about actual requests and corresponding updates.

## 1.3. How to fill the drug delivery details

The screenshot displays the 'My Access Programs' registration interface. At the top, a blue header reads 'My Access Programs'. Below it, a grey bar contains the section title 'PHARMACIST CONTACT DETAILS'. A text instruction states: 'Please enter the address where the drug you request in My Access Programs shall be delivered to. The address can be updated later once you are registered to the program.' To the right of this text are 'Back' and 'Next' buttons. The 'Next' button is highlighted with a red box, and a red arrow points from a 'Step 7' label to it. The form fields are: '\* First Name', '\* Last Name', '\* Phone', 'Fax', '\* Email', and '\* Re-enter email'. Below these is another grey bar with the title 'SELF-REGISTRATION - DRUG DELIVERY ADDRESS'. The fields here are: '\* Institution / Pharmacy', '\* Address', '\* Zip', '\* City', and 'State:'. A red box surrounds the 'Institution / Pharmacy' and 'Address' fields, with a red arrow pointing from a 'Step 6' label to the 'Institution / Pharmacy' field. At the bottom of the page, a small disclaimer reads: 'Your use of the information on this site is subject to the Terms of Service and Privacy Policy of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015'.

The above example shows the pharmacy details page. Please enter your delivery address details and contacts. Again, all items marked with a red asterisks (\*) are mandatory for the process. Once the data has been entered (step 6) you are allowed to continue with the registration (step 7). The ‘Next’ button will link you to a review page where you have the chance to review your already entered information (see 1.4 How to complete the registration).

The delivery details are forwarded to the distribution group to ensure the shipments are correctly delivered.

If your delivery or contact details change over time, there is a dedicated functionality in My Access Programs to update your details at a later time point (see 5.2).

## 1.4. How to complete the registration

**My Access Programs**

**SELF-REGISTRATION - REVIEW**

Physician Details		Drug Delivery Details	
Country:	Germany	First Name:	Miriam
First Name:	Max	Last Name:	Musterfrau
Last Name:	Mustermann	Registration Number:	135790
Registration Number:	135790	Institution / Pharmacy:	Musterfrau Pharmacy
Institution:	Muster Clinic	Address:	Mainstreet 1
Address:	Hauptstr. 5	Address 2:	
Address 2:		Address 3:	
Address 3:		Zip:	12349
Zip:	25783	City:	Berlin
City:	Berlin	State:	
State:	Deutschland	Phone:	3030303030
Phone:	+493030303030	Fax:	
Fax:		Email:	musterfrau@muster.muster
Email:	max.mustermann@exampleclinic.com		

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

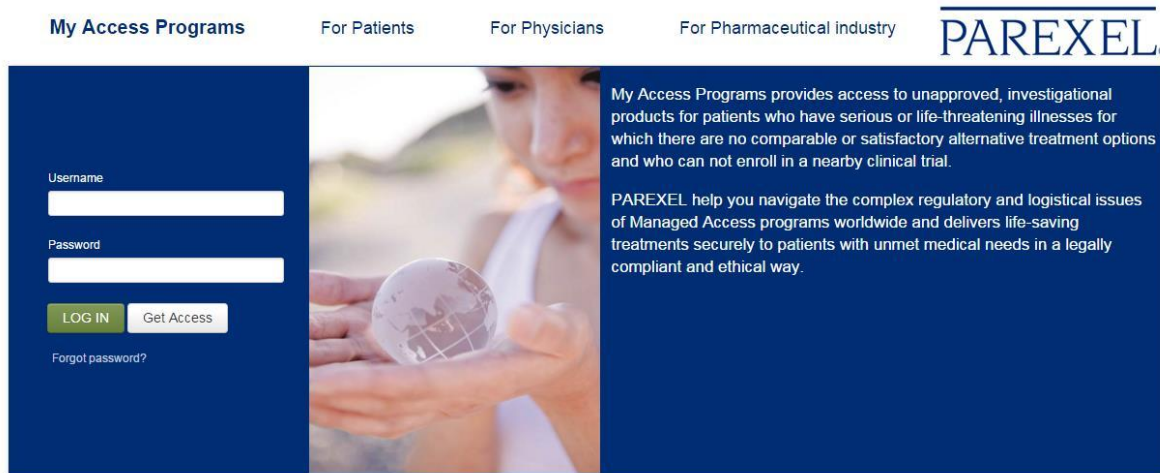
Once you have entered all of your contact and address details the process leads you to a review page, where you can review the previously entered information before the registration gets completed. You can always use the 'Back' button to correct / amend the physician and pharmacy details.

As soon as you click on 'Register' (Step 8), the self-registration process for My Access Programs is completed. The system will send you two different emails to the provided email address under physician details. The emails will contain the username and a temporary password. The temporary password is required for the initial login and the password change.

## 2. FIRST STEPS ONCE REGISTERED

### 2.1. How to login

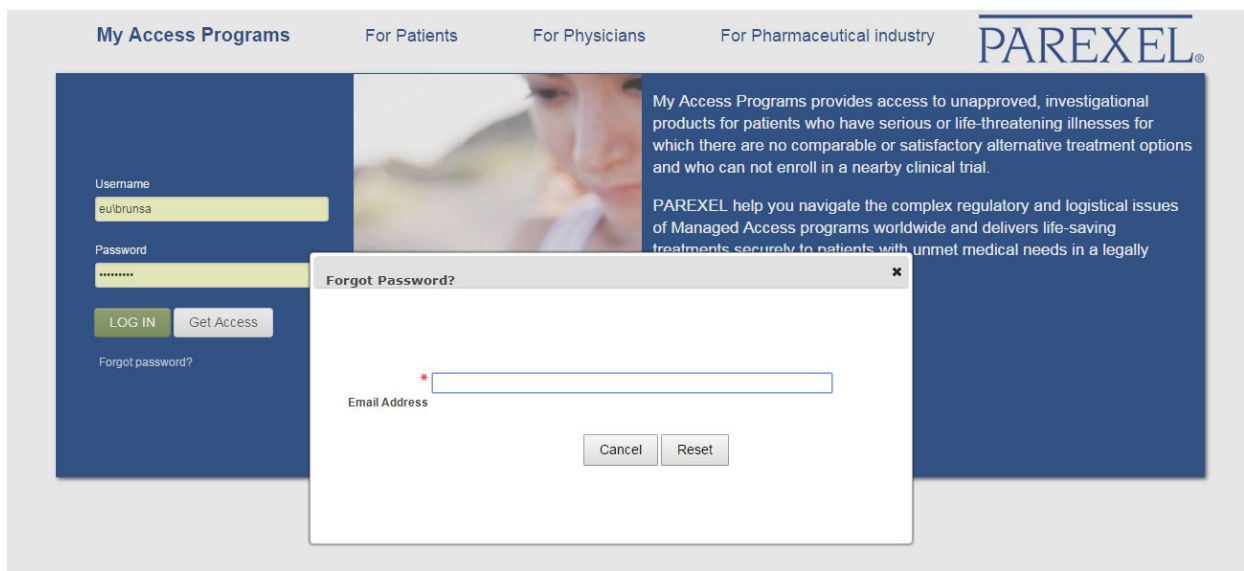
My Access Programs portal is available via <https://myaccessprograms.parexel.com> .



After your registration you have received two automatic emails from the system, one containing your login name which is the email address used during registration and second containing a temporary password.

Please enter your username and the received temporary password into the fields as listed above and click on ‘LOG IN’ button. Once you press ‘Log In’, the system checks your credentials and links you to the internal My Access Programs home page for further selection.

If you have forgotten your password, use the link on the first page to request a new password.



Enter your email address which has been used for the registration of your account to receive a new temporary password.



# ‘How To’ Manual for My Access Programs

Your login name cannot be reset – this will always correspond to the email address used during your initial registration and will not be affected by any future updates in your contact email address.

## 2.2. How to search for your program (for new registrations)

If you have not yet participated in the GATM program, please follow the instructions on how to find the program. If you have the GATM link already available in the list of programs, please continue with section 2.3.

Home

WELCOME TO MY ACCESS PROGRAMS

MY ACCESS PROGRAMS

Search for new Programs

Search for GATM MAP

On the My Access Programs portal you get a list of your already registered programs and the option to search for new programs. To get access to the GATM program use the ‘Search for new MAPs’ functionality shown above.

Home > Search for new MAPs

SEARCH FOR NEW MAPS

Use the search function to find new programs. Therefore, simply start typing what you are looking for - the application will suggest results after entering the first characters. To get more information, click on "Details" to have an overview of the program displayed. You can directly register to the program using the Information page.

Back

GATM Search

Link	MAP Name	MAP Description	Already Registered	Found via
<a href="#">Details</a>	GATM	A Global Access to Medicine-Managed Access Program that has been initiated to provide eligible patients outside the USA, access to Kanuma, Soliris and Strensiq.	No	GATM

1 - 1

New programs can be found using keywords specifically linked with the managed access program. For the GATM program please use the keyword ‘GATM’.

# ‘How To’ Manual for My Access Programs

Via ‘Details’ you can access additional information for the new program.

If you do not find the GATM program please check, if you used the right keyword?



The screenshot displays the 'My Access Programs' web application. The top navigation bar includes the PAREXEL logo, a user profile icon, and the text 'Welcome: GATM-P11@DEMO.DEMO'. Below the navigation bar, the breadcrumb trail reads 'Home > Search for new MAPs > Program Details for GATM'. The main content area features a 'MAP MENU' sidebar on the left and a 'PROGRAM DETAILS FOR GATM' header. The primary text describes the GATM-MAP program, stating it provides access to Kanuma®, Soliris®, and Strensiq® for eligible patients outside the USA. A list of criteria for patient coverage is provided, including being outside clinical settings, in geographies where therapies are unavailable, having a life-threatening condition, or having exhausted alternative therapies. A 'Register for Program' button is highlighted with a red box, and a 'Back' button is also visible. The footer contains a disclaimer about the use of information on the site.

You get a detailed description of the managed access program on the program details page.

Please use the ‘Register for Program’ functionality as highlighted above to register your site for the GATM program.

Once registered, a notification will be sent to the local program team to approve your registration. Your status will be marked as ‘Waiting for approval’. You will be informed, once your program registration has been fully approved.

## 2.3. How to enter your program after registration

The screenshot shows the PAREXEL My Access Programs portal. The top navigation bar includes the PAREXEL logo, a home icon, and user information: 'Welcome: GATMCAN1@DEMO.DEMO' with links for 'Change Password' and 'Logout'. The main content area is divided into two columns. The left column, titled 'WELCOME TO MY ACCESS PROGRAMS', contains a welcome message, a search instruction, a small image of a person, and contact information for the general helpdesk. The right column, titled 'MY ACCESS PROGRAMS', displays a search bar and a list of programs. A red box highlights the 'GATM-MAP' program, which features the Alexion logo. A red arrow points from a box below labeled 'Registered for GATM MAP' to the highlighted program. A footer at the bottom of the page contains a disclaimer about the use of information on the site.

If you see the GATM program in your list of My Access Programs, you are successfully registered. If the program, as shown above, is missing, please follow the steps described in section 2.2 to register for the program. You do not need to enter additional login details to enter the program within the My Access Programs platform.

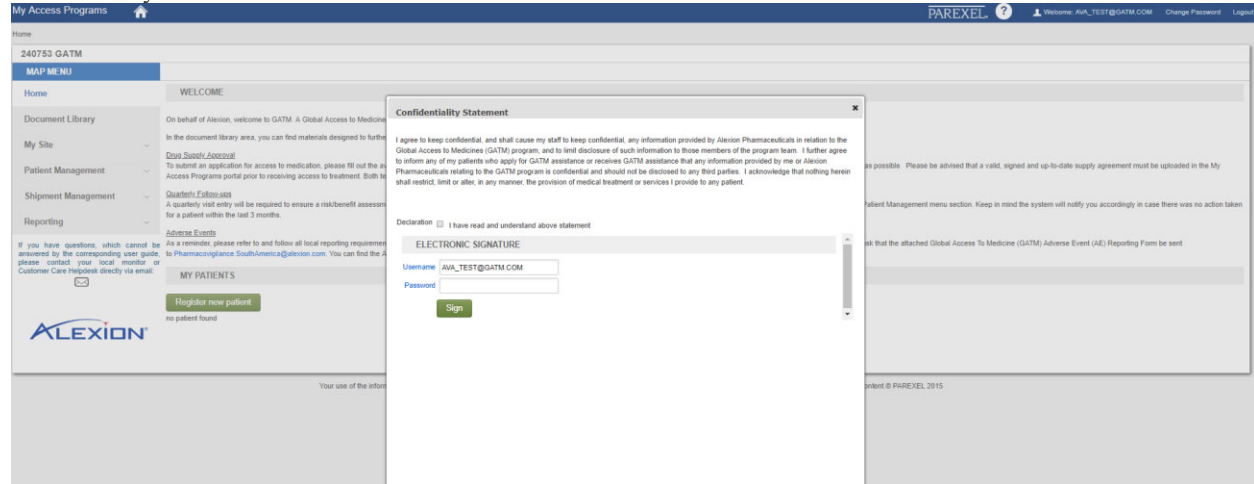
Please note: Once the initial steps are completed your site registration will be reviewed by the team. Without site approval you will not be able to register any patients. In case of any questions the team will reach out to you to complete the registration. Upon approval by the team you will receive a related notification.

# 'How To' Manual for My Access Programs

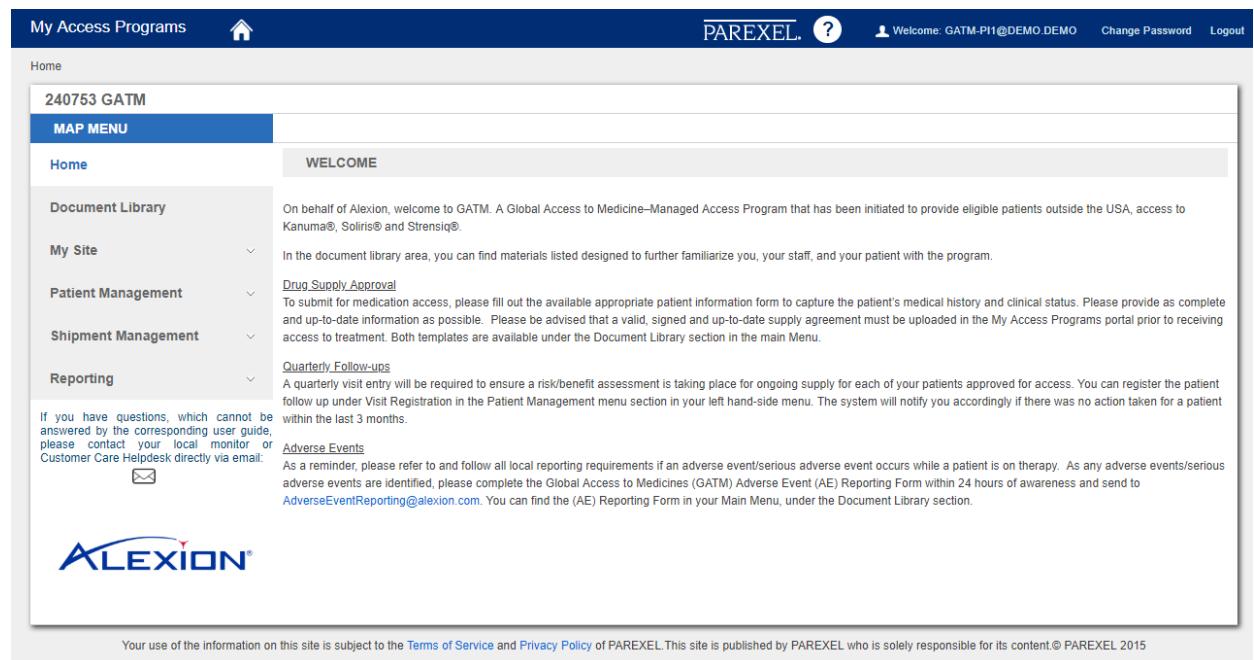
## 3. HOW TO NAVIGATE IN YOUR PROGRAM

### 3.1. First steps and how to find necessary information

The first time you log in to the GATM program, you will be asked to electronically sign the Confidentiality Agreement. You cannot move beyond this point in the system until the Confidentiality Agreement is signed electronically.



Once signed, you can find different menu options on the left-hand side.



### 3.2. Document Library

This section lists all the prepared guidance documents and templates required for the conduct of this Managed Access Program.

### 3.3. My Site

This Section allows you to update the contact / address details as described in section 9. Furthermore you can create user accounts for your site as described in section 5 (How to grant access for your site users)

# 'How To' Manual for My Access Programs

## 3.4. Patient Management

Here you will find all options for your patient management.

## 3.5. Shipment Management

This section brings you to all options linked to shipment requests. For more details please see section 6 (How to request a drug shipment).

## 3.6. How to stay on top of your open tasks

The screenshot shows the home page of the My Access Programs system. The top navigation bar includes 'My Access Programs', a home icon, 'PAREXEL', a help icon, and user information 'Welcome: GATMCAN1@DEMO.DEMO' with 'Change Password' and 'Logout' links. The main content area is titled '240753 GATM-MAP' and features a 'MAP MENU' with options for Home, Document Library, My Site, Patient Management, Shipment Management, and Reporting. A 'WELCOME' message is displayed. Two red boxes highlight key sections: 'Open tasks' and 'My Patients Dashboard'. The 'Open tasks' table lists various tasks such as 'Complete Registration' and 'Request Shipment' with columns for Task, Description, Open Since, Workflow, and Additional Information. The 'My Patients Dashboard' table shows patient details including Patient ID, YOB, Gender, Patient Group, Patient Status, Registration Status, Approval Status, Initial Supply, Resupply, Queries, Last Step, and Next Step.

Task	Description	Open Since	Workflow	Additional Information
Complete Registration	Complete the registration for Patient CAN0030018	13-AUG-2018	Patient Registration	-
Request Shipment	Request initial shipment for Patient CAN0030010	06-AUG-2018	Shipment Request	-
Complete Shipment Request	Complete the shipment request for Patient CAN0030010 Shipment 187125	06-AUG-2018	Shipment Request	-
Complete Registration	Complete the registration for Patient CAN0030017	13-AUG-2018	Patient Registration	-
Request Shipment	Request initial shipment for Patient CAN0030014	13-AUG-2018	Shipment Request	-
Complete Shipment Request	Complete the shipment request for Patient CAN0030010 Shipment 187082	06-AUG-2018	Shipment Request	-

Patient	YOB	Gender	Patient Group	Patient Status	Registration Status	Approval Status	Initial Supply	Resupply	Queries	Last Step	Next Step
CAN0030001	2015	Female	hHUS	Rejected	✓	✗	-	-	-	Patient ineligible (19-JUL-2018)	-
CAN0030002	2015	Female	LAL-D	Rejected	✓	✗	-	-	-	Patient ineligible (19-JUL-2018)	-

On the home page, you get a list of tasks including the necessary details to identify the most urgent items.

You can directly navigate to the corresponding case by clicking on the task name. This way you can jump directly to the action.

The open tasks remain listed until the necessary action has been performed. This allows you to work on tasks and save your progress until you have all required information to proceed.

In addition, the 'My Patients' dashboard informs you about all your patients and their registration milestones. Furthermore, it outlines the last performed step and the next expected step.

## 3.7. How to exit the current session

The screenshot shows the home page of the My Access Programs system. The top navigation bar includes 'My Access Programs', a home icon, 'PAREXEL', a help icon, and user information 'Welcome: GATMCAN1@DEMO.DEMO' with 'Change Password' and 'Logout' links. The 'Logout' link is highlighted with a red box. The main content area is titled '240753 GATM-MAP' and features a 'MAP MENU' with options for Home, Document Library, My Site, Patient Management, Shipment Management, and Reporting. A 'WELCOME' message is displayed.

## ‘How To’ Manual for My Access Programs

My Access Programs allows you to exit and continue later with your patient or drug shipment registration at any time. To exit your current session, close your browser session or use the defined log-out button in the upper right corner.

If you participate in multiple programs, you can also switch between programs by clicking on ‘Portal Home’ in the upper left corner, which brings you back to the My Access Programs platform homepage with the program selection of your already registered programs or back to the search functionality for new programs.

If you stay within the platform to switch between programs, no new authentication is required as you are already logged in.

## 4. HOW TO GRANT ACCESS FOR YOUR SITE USERS

### 4.1. How to grant access

240753 GATM-MAP

MAP MENU

Home ADD SITE USER

Document Library

My Site

Contact / Address Management

Site User Management

Site Documents

Patient Management

Shipment Management

Reporting

Herewith I confirm that insofar I delegate the registration of patients and the placing of shipments related to this MAP to another individual this is a licensed/registered Health Care Professional according to my country legislation. I further confirm that I will stay fully responsible for all actions performed with regards to this MAP and the patient's treatment, including the ones delegated to a licensed/registered Health Care Professional.

\* First name Sandra

\* Last name Ruocco

\* Function Site User (Full)

\* Email Address Sandra.Ruocco@demo.demo

\* Email address re-entry for verification Sandra.Ruocco@demo.demo

Cancel Save

Access details will be sent to the Site User directly by the system.

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email:

ALEXION

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

As treating physician, you are allowed to grant further access for your supporting site users. The system will ask for the mandatory information to grant access. Once completed, your site user will receive email notifications by the system regarding his/her access.

Please consider the correct function level for your new site user. If this is set to 'Patients', it will limit the functionality to patient management tasks. If ordering shipments or Kanuma/Strensiq/Soliris will be the primary task for the new user (i.e., pharmacist), select 'Shipments'. If a team member is responsible for all, please select 'Full'.

Each user needs to be identified via a unique email address. Account sharing is not allowed. Every update in the system is directly linked to the specific user account and therefore requires individual identification.

### 4.2. How to manage site user access

The treating physician has full control of site users and always has the option to remove access or change the level of responsibility for existing site users.

Granting full site user access to a delegate allows the delegate to add/modify other site users.

### 4.3. How to update your site details

Via 'My Site -> Contact / Address Management' you can update your site details. This is required if you have any changes to your contact information or changes affecting your drug delivery address.

All items marked with a red asterisks (\*) are mandatory and need to be populated, even if you just perform an update. The email address listed for the treating physician is linked with the email address to be used for

# 'How To' Manual for My Access Programs

notifications via email. This update will not affect the user name for the login. The user name will remain the email address used for the initial registration. Shared email addresses cannot be used as each registered user must have his/her own individual login credentials.

Please note: If you participate in multiple programs utilizing this My Access Program platform in parallel, any changes to your site details will affect all programs.

The screenshot displays the PAREXEL My Access Programs web interface. The top navigation bar includes the PAREXEL logo, a home icon, and user information: 'Welcome: GATMCAN1@DEMO.DEMO' with links for 'Change Password' and 'Logout'. The breadcrumb trail shows 'Home > My Site - Contact / Address Management'. The main content area is titled '240753 GATM-MAP' and features a 'MAP MENU' on the left with options like Home, Document Library, My Site, Contact / Address Management, Site User Management, Site Documents, Patient Management, Shipment Management, and Reporting. The central form is divided into two tabs: 'CONTACT INFORMATION' and 'DRUG DELIVERY DETAILS'. The 'CONTACT INFORMATION' tab shows fields for Site # (CAN0030), First Name (Mac), Last Name (Anderson), Medical license number (439380), Phone (416-813-1500), Fax, Email (gatmcan1@demo.demo), Institution (The Hospital for Sick Children), Address (555 University Ave), Zip (ON MSG 1X), City (Toronto), State, and Country (Canada). The 'DRUG DELIVERY DETAILS' tab shows fields for First Name (Mac), Last Name (Anderson), Phone (416-813-1500), Fax, Email (gatmcan1@demo.demo), Institution / Pharmacy (SickKids Pharmacy), Address (555 University Avenue), Zip (MSG 1X8), City (Toronto), and State. 'Cancel' and 'Apply Changes' buttons are located at the top right of the form area. The Alexion logo is visible in the bottom left corner. A footer note states: 'Your use of the information on this site is subject to the Terms of Service and Privacy Policy of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015'.



## 5. HOW TO COMPLETE YOUR PATIENT REGISTRATIONS

### 5.1. How to initiate new patient registrations

Patient registration is a task that can be delegated as indicated in section 5.1. It can be completed on the Patient Management screen or from the Home screen.

To register a new patient, you can click on the Register Patient button in your home page or navigate to the patient registration section under patient management on the left-hand side menu.

The screenshot displays the 'My Access Programs' web application. The top navigation bar includes the PAREXEL logo and user information. The left-hand side menu is expanded, showing 'Patient Management' and 'Patient Registration' highlighted with a red box. The main content area features a 'WELCOME' message, a list of 'OPEN TASKS' with columns for Task, Description, Open Since, Workflow, and Additional Information, and a 'MY PATIENTS' table. The 'MY PATIENTS' table has a 'Register new patient' button highlighted in red above it. The table contains two rows of patient data:

Patient	YOB	Gender	Patient Group	Patient Status	Registration Status	Approval Status	Initial Supply	Resupply	Queries	Last Step	Next Step
CAN0030001	2015	Female	aHUS	Rejected	✓	✗	-	-	-	Patient ineligible (19-JUL-2018)	-
CAN0030002	2015	Female	LAL-D	Rejected	✓	✗	-	-	-	Patient ineligible (19-JUL-2018)	-

Enter the patient demographics and select to continue. You will be also requested to select the appropriate patient group for the patient to be registered which will also define the treatment received. You will still be allowed to update them in the following step.

# 'How To' Manual for My Access Programs

Review the demographics entered before and make updates as necessary.

Read through the required data collection for patient registration and provide the corresponding answers.

In most cases, questions can be answered via a dropdown field. Some fields will show up as a text box or as a small calendar for the date collection.

You can save your work at any time by clicking the Save button at the bottom of the screen.

On the right- side of the subheading there is an indicator of all mandatory items per section and your overall progress for the registration.

## ‘How To’ Manual for My Access Programs

Once you have entered 100% of the mandatory data collection items, click the ‘Complete Registration’ button (lower right corner). Once done, the patient registration will be forwarded to PAREXEL for review.

Please retain a copy of the confirmatory email in your study files.

You will not be able to order Kanuma, Strensiq or Soliris until the reviewer confirms the patient is eligible for participation. Your PAREXEL in-house monitor will reach out to you within 2 business days if they have any questions regarding the information entered. Questions will be raised using My Access. You will be notified via email and will see an open query, once logged in. Please use My Access to reply to the reviewer questions.

Remaining subject data and information related to the baseline assessment can be completed before or after the patient is treated (please see section 9.1)

**Please note: If you click on ‘Cancel Registration’ the patient registration will be cancelled and deleted. Please use ‘Cancel Registration’ only if the patient confirmed they will not participate, and registration should be removed. If you are not absolutely sure, please contact the local PAREXEL CSM for further consultation via [GATM\\_MyAccessSupport@parexel.com](mailto:GATM_MyAccessSupport@parexel.com)**

5.2. How to access the details of your registered patients

MY PATIENTS												
Patient	YOB	Gender	Patient Group	Patient Status	Registration Status	Approval Status	Initial Supply	Resupply	Queries	Last Step	Next Step	
DEU0038001	1968	Male	ALS	Active	✓	✓	✓	!	-	Shipment requested (08-JUN-2018)	Shipment Approval required	
DEU0038002	1983	Female	ALS	Discontinued	✓	✓	✓	-	✓	Visit registered (14-JUN-2018)	-	
DEU0038003	2016	Male	ALS	Registered	✓	!	-	-	!	Query raised (14-JUN-2018)	Answer Query by site team	
DEU0038004	1992	Male	ALS	Pending	!	-	-	-	-	Patient Registration started (01-JUN-2018)	Complete Patient Registration by site team	
DEU0038005	1979	Male	ALS	Not Started	✓	✓	!	-	-	Patient approved (08-JUN-2018)	Request Initial Shipment by site team	

✓ Task completed
! Open Site Task
! Open Approver Task
✗ Patient rejected

If you click on the patient number in the My Patients dashboard for a specific patient, you will be linked to the patient details as collected so far.

The patient details page allows you to access, update and or complete previously entered data, including documents uploaded, patient followed-up visits and shipments request. Through this page you have also the ability to request new shipments and register the required quarterly patient follow-up visits.

## 6. HOW TO REQUEST A DRUG SHIPMENT

### 6.1. How to request a drug shipment for your approved patients (initial and re-supply)

Once your patients are approved, you will be notified via email that the initial drug order can be requested. At the same time an open task is listed on your home screen to indicate that an approved patient has not yet been supplied. Please see screenshot below.

Home

240753 GATM-MAP

**MAP MENU**

- Home
- Document Library
- My Site
- Patient Management
- Shipment Management
- Reporting

**WELCOME**


On behalf of Alexion welcome to GATM. A Global Access to Medicine-Managed Access Program that has been initiated to provide eligible patients outside the USA, access to Kanuma®, Soliris® and Strensiq®.


In the document library area, you can find materials listed designed to further familiarize you, your staff, and your patient with the provided treatment.

**Drug Supply Approval**  
In order to review your request, please fill out the available appropriate patient intake form to capture the patient's medical history and clinical status. Please provide as complete and up-to-date information as possible. Please be also advised that a valid, signed and up-to-date supply agreement must be uploaded in My Access prior to receiving access to treatment. Both templates are available under the Document Library section in the main Menu.

**Quarterly Follow-ups**  
A quarterly visit entry will be required to ensure a risk/benefit assessment is taking place for ongoing supply for each of your patients approved for access. You can register the patient follow up under Visit Registration in the Patient Management menu section. Keep in mind the system will notify you accordingly in case there was no action taken for a patient within the last 3 months.

**Adverse Events**  
As a reminder, please refer to and follow all local reporting requirements if an adverse event/serious adverse event occurs while a patient is on therapy. As any adverse events/serious adverse events are identified, we also ask that the attached Global Access To Medicine (GATM) Adverse Event (AE) Reporting Form be sent to [AdverseEventReporting@alexion.com](mailto:AdverseEventReporting@alexion.com).

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email: 





**OPEN TASKS**

Task	Description	Open Since	Workflow	Additional Information
<a href="#">Complete Shipment Request</a>	Complete the shipment request for Patient CAN0030010 Shipment 187082	06-AUG-2018	Shipment Request	-
<a href="#">Complete Shipment Request</a>	Complete the shipment request for Patient CAN0030010 Shipment 187125	06-AUG-2018	Shipment Request	-
<a href="#">Complete Registration</a>	Complete the registration for Patient CAN0030012	06-AUG-2018	Patient Registration	-
<a href="#">Request Shipment</a>	Request initial shipment for Patient CAN0030010	06-AUG-2018	Shipment Request	-
<a href="#">Request Shipment</a>	Request initial shipment for Patient CAN0030014	13-AUG-2018	Shipment Request	-
<a href="#">Complete Registration</a>	Complete the registration for Patient CAN0030017	13-AUG-2018	Patient Registration	-
<a href="#">Complete Registration</a>	Complete the registration for Patient CAN0030018	13-AUG-2018	Patient Registration	-

**MY PATIENTS**

[Register new patient](#)

Patient	YOB	Gender	Patient Group	Patient Status	Registration Status	Approval Status	Initial Supply	Resupply	Queries	Last Step	Next Step
CAN0030001	2015	Female	aHUS	Rejected			-	-	-	Patient ineligible (19-JUL-2018)	-

# 'How To' Manual for My Access Programs

To request a shipment, you can click on the open tasks or navigate to the patient details section (as shown below) or navigate on the left-hand side menu to shipment management.

The screenshot displays the 'My Access Programs' interface for patient 240753 GATM-MAP. The left-hand side menu includes options like Home, Document Library, My Site, Patient Management, Patient Registration, Visit Registration, Shipment Management, and Reporting. The main content area is titled 'PATIENT DETAILS' and contains various fields for patient information, including Patient identifier (CAN0030014), Date registered (13-AUG-2018), Program Start Date, YOB (1978), Patient Group (aHUS), Status (Approved), Gender (Male), Height (140 cm), Weight (40 kg), and Reason for update. There are also fields for Username (GATMCAN1@DEMO.DEMO) and Password. Below the patient details is a 'COMMUNICATION' section with a table of questions and answers. The 'SHIPMENTS' section is highlighted with a red box and shows 'no data found' with a 'Request Shipment' button.

240753 GATM-MAP

MAP MENU

Home

Document Library

My Site

Patient Management

Patient Registration

Visit Registration

Shipment Management

Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email.

**ALEXION**

PATIENT DETAILS

Patient identifier CAN0030014 Date registered 13-AUG-2018

Secondary patient identifier

Program Start Date

YOB 1978

Patient Group aHUS

Status Approved

Gender Male

Height 140 cm

Weight 40 kg

Reason for update

Last resupply -

Next calculated resupply -

Approval Date 13-AUG-2018

Username GATMCAN1@DEMO.DEMO

Password

COMMUNICATION

Question	By	On	Answer	By	On
Please confirm XXXX	GATM, PXL	13-AUG-2018	Confirmed	Anderson, Mac	13-AUG-2018

CRF ITEMS

DOCUMENTS

VISITS

SHIPMENTS

no data found

Request Shipment

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

The content of existing orders can be accessed by clicking on the magnifying glass. Partially completed shipment requests which are not yet submitted by your site, can be resumed by clicking on the corresponding icon within the listing.

## 'How To' Manual for My Access Programs

Every patient supply request is planned for one-year supply. Please select the right quantity of kits for your patient based on the patient weight at time of visit for a six month period. Via the comment field you can include further notes to the shipment, for example to enter the calculated required dose. Please do not enter any patient specific contact or address details in My Access.

The screenshot displays the 'My Access Programs' web interface. At the top, there is a navigation bar with the PAREXEL logo, a user profile icon, and the text 'Welcome: GATM-PH1@DEMO.DEMO'. Below this, a breadcrumb trail reads 'Home > Shipment Management - Shipment Request / Receipt > Generate Shipment'. The main content area is titled '240753 GATM' and features a 'MAP MENU' on the left with options like 'Document Library', 'My Site', 'Patient Management', 'Shipment Management', and 'Reporting'. The central form is titled 'PATIENT INITIAL SHIPMENT REQUEST' and includes a 'Home' button. The form contains the following fields: 'Patient' (USA0172001), 'YOB' (2008), 'Patient Group' (PNH), 'Gender' (Male), 'Height' (180 cm equals 70.87 in), 'Weight' (73 kg equals 160.94 lbs), 'Product' (Soliris vial(s)), and 'Quantity of Kits' (1). A 'Shipment Comment' text area is also present. 'Back' and 'Continue' buttons are located at the top right of the form. The Alexion logo is visible at the bottom left of the form area. A footer at the bottom of the page states: 'Your use of the information on this site is subject to the Terms of Service and Privacy Policy of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015'.

At this point the Patient Information form and the Supply Agreement are required. At any time, you can find the corresponding document templates in your Document Library in the left-hand side menu.

At any case ensure to capture the patient's medical history and clinical status and provide as complete and up-to-date information as possible.

Please be advised that a valid, signed and up-to-date supply agreement must be uploaded in My Access Programs prior to initiate the approval shipment process.

# 'How To' Manual for My Access Programs

My Access Programs PAREXEL Welcome: GATMCAN1@DEMO.DEMO [Change Password](#) [Logout](#)

Home > Shipment Management - Shipment Request / Receipt > Generate Shipment

240753 GATM-MAP

MAP MENU Patient Initial Shipment Request > Required documents > Final Review > Confirmation with e-Signature

Home **REQUIRED DOCUMENTS**

Document Library *In order to review your request, we would like you to upload the patient intake form that was used during the patient's registration. In case you do not have it available please fill out a new appropriate patient intake form to capture the patient's medical history and clinical status. Please provide as complete and up-to-date information as possible.* [Back](#) [Cancel Shipment](#) [Continue](#)

My Site *Please be advised that a valid, signed and up-to-date supply agreement must be uploaded in My Access Programs prior to receiving access to treatment.*

Patient Management *As a reminder please make sure the patient visits are entered on a quarterly basis.*

Shipment Management

Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email.

Patient CAN0030014

Secondary patient identifier

YOB 1978

Patient Group aHUS

Gender Male

Quantity of Kits 6

Product Soliris

**UPLOAD REQUIRED DOCUMENTS**

The upload of required approval documents is mandatory. Please provide the documents to proceed.

Document Type -- Select --

Upload required documentation [Choose File](#) No file chosen [Upload required documentation](#)

**Mandatory Documents**

Category	Uploaded
GATM aHUS Patient Information Form	No
Supply Agreement for Temporary Use Canada	No

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

To complete the shipment request process, confirm the order statement and sign electronically.

My Access Programs PAREXEL Welcome: GATMCAN1@DEMO.DEMO [Change Password](#) [Logout](#)

Home > Shipment Management - Shipment Request / Receipt > Generate Shipment

240753 GATM-MAP

MAP MENU Patient Initial Shipment Request > Required documents > Final Review > Confirmation with e-Signature

Home **CONFIRMATION WITH E-SIGNATURE**

Document Library I hereby confirm that a valid, signed and up-to-date supply agreement has been uploaded in My Access Programs. [Back](#) [Cancel Shipment](#)

My Site

Patient Management

Shipment Management

Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email.

**ELECTRONIC SIGNATURE**

I have read and understood the above statement

Username

GATMCAN1@DEMO.DEMO

Password

[Sign](#)

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

After you have signed your request, you will receive a confirmation notification. The shipment and its content will be reviewed by PAREXEL. Once the shipment request is approved, the shipment will be handed over to the responsible PAREXEL distribution center and you will receive a corresponding notification. The system will list a planned delivery date based on the assumed lead time in your country.



# 'How To' Manual for My Access Programs

## 6.2. How to register a resupply shipment

Resupply shipment request follow the same process as initial. 300 days after the last shipment was approved you will receive a notification by the system that a new shipment is required. The corresponding open tasks would also be listed to allow you to quickly complete the request. You can alternatively navigate to the shipment request workflow as outlined in 7.1.

At time of first resupply for a patient in My Access Programs, the system will ask for the actual start date (only once). Please enter the treatment start date of the patient under the compassionate use setting. The system will not allow any dates prior of the initial patient supply triggered in My Access Programs, and of course no future date. This date can also be found outside of the resupply process in the patient details listed in the upper right corner as 'Program Start Date' as shown in section 6.2.

As part of the resupply workflow the system will ask you to confirm if a valid and up-to-date supply agreement is signed and available to be uploaded in the following. If you do not have one available please download the corresponding template from your Document Library in the left-hand side menu, fill it in (please do not amend the form) and have it signed by you and your institution with stamp on it.

The screenshot shows the 'My Access Programs' web interface. The top navigation bar includes 'My Access Programs', a home icon, the 'PAREXEL' logo, a user profile icon, and the text 'Welcome: GATMCAN1@DEMO.DEMO' with links for 'Change Password' and 'Logout'. The breadcrumb trail is 'Home > Shipment Management - Shipment Request / Receipt > Generate Shipment'. The main content area is titled '240753 GATM-MAP' and has a 'MAP MENU' with options: 'Resupply Shipment Request', 'Resupply Review', 'Required documents', 'Final Review', and 'Confirmation with e-Signature'. The 'Resupply Review' option is selected. On the left, there is a 'Document Library' menu with categories: 'My Site', 'Patient Management', 'Shipment Management', and 'Reporting'. The main content area is titled 'RESUPPLY REVIEW' and contains a reminder: 'As a reminder, please refer to and follow all local reporting requirements if an adverse event/serious adverse event occurs while a patient is on therapy. As any adverse events/serious adverse events are identified, we also ask that the attached Global Access To Medicine (GATM) Adverse Event (AE) Reporting Form be sent to AdverseEventReporting@alexion.com'. Below this is a 'Back' button, a 'Cancel Shipment' button, and a 'Continue' button. The patient details section includes: Patient: CAN0030006, Secondary patient identifier: YOB 2017, Patient Group: HPP CHILDREN - Perinatal / Infantile Onset (+6 months old), Gender: Female, Product: Strensiq, Quantity of Kits: 1, Days since last Shipment: 0, Actual start date: 15-AUG-2018, and Shipment Comment: 140ml / daily. Below the details is a 'STATUS UPDATE' section with a dropdown menu set to '- Select -' and a list item: '1. Please confirm a valid, signed and up-to-date supply agreement as well as an appropriate patient intake form are available to be uploaded in My Access Programs as they are necessary for the order review process.' The Alexion logo is visible in the bottom left of the content area. At the bottom of the page, there is a footer: 'Your use of the information on this site is subject to the Terms of Service and Privacy Policy of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015'.

Once you confirm the document is available you would be requested to upload it in the system.

My access will also ask for the patient information form to capture the patient's medical history and clinical status. Please provide as complete and up-to-date information as possible. You can always find the corresponding template in the Document Library.

# 'How To' Manual for My Access Programs

My Access Programs PAREXEL Welcome: GATMCAN1@DEMO.DEMO Change Password Logout

Home > Shipment Management - Shipment Request / Receipt > Generate Shipment

240753 GATM-MAP

MAP MENU Resupply Shipment Request > Resupply Review > Required documents > Final Review > Confirmation with e-Signature

Home REQUIRED DOCUMENTS

In order to review your request, please fill out the available appropriate patient intake form to capture the patient's medical history and clinical status. Please provide as complete and up-to-date information as possible. [Back](#) [Cancel Shipment](#) [Continue](#)

Document Library

My Site  Please be advised that a valid, signed and up-to-date supply agreement must be uploaded in My Access Programs prior to receiving access to treatment.

Patient Management  As a reminder please make sure the patient visits are entered on a quarterly basis.

Shipment Management

Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email:

Patient CAN0030006

Secondary patient identifier

YOB 2017

Patient Group HPP CHILDREN - Perinatal / Infantile Onset (<6 months old)

Gender Female

Quantity of Kits 1

Days since last Shipment 0

Actual start date 15-AUG-2018

Product Strensiq

Shipment Comment 140ml / daily

UPLOAD REQUIRED DOCUMENTS

The upload of required approval documents is mandatory. Please provide the documents to proceed.

Document Type -- Select --

Upload required documentation  No file chosen

Mandatory Documents

Category	Uploaded
GATM HPP Pediatric Patient Information Form	No
Supply Agreement for Temporary Use Canada	No

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

To complete the shipment request process, confirm the order statement and sign electronically.

My Access Programs PAREXEL Welcome: GATMCAN1@DEMO.DEMO Change Password Logout

Home > Shipment Management - Shipment Request / Receipt > Generate Shipment

240753 GATM-MAP

MAP MENU Patient Initial Shipment Request > Required documents > Final Review > Confirmation with e-Signature

Home CONFIRMATION WITH E-SIGNATURE

I hereby confirm that a valid, signed and up-to-date supply agreement has been uploaded in My Access Programs. [Back](#) [Cancel Shipment](#)

ELECTRONIC SIGNATURE

I have read and understood the above statement

Username

GATMCAN1@DEMO.DEMO

Password

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email:

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

## 7. HOW TO REPORT AN ADVERSE EVENT

Please refer to and follow all local reporting requirements if an adverse event/serious adverse event occurs while a patient is on therapy. As any adverse events/serious adverse events are identified, please complete the Global Access to Medicines (GATM) Adverse Event (AE) Reporting Form within 24 hours of awareness and send to the local Alexion mailbox. The corresponding local Alexion mailbox can be found on the last page of the safety form. You can find the Adverse Event (AE) Reporting Form in your left-hand side Main Menu, under the Document Library Section.

The screenshot shows the 'My Access Programs' web application interface. At the top, there is a navigation bar with 'My Access Programs', a home icon, the 'PAREXEL' logo, a help icon, and user information: 'Welcome: GATMCAH1@DEMO.DEMO', 'Change Password', and 'Logout'. Below the navigation bar, the main content area is titled '240753 GATM'. On the left, there is a 'MAP MENU' with several items: 'Home', 'Document Library' (highlighted with a red box), 'My Site', 'Patient Management', 'Shipment Management', and 'Reporting'. The main content area displays a 'WELCOME' message and several sections: 'On behalf of Alexion welcome to GATM...', 'In the document library area, you can find materials listed designed to further familiarize you, your staff, and your patient with the program.', 'Drug Supply Approval', 'Quarterly Follow-ups', and 'Adverse Events'. The 'Adverse Events' section contains the text: 'As a reminder, please refer to and follow all local reporting requirements if an adverse event/serious adverse event occurs while a patient is on therapy. As any adverse event/serious adverse event is identified, we also ask that the attached Global Access To Medicine (GATM) Adverse Event (AE) Reporting Form be sent to [AdverseEventReporting@alexion.com](mailto:AdverseEventReporting@alexion.com). You can find the Adverse Event (AE) Reporting Form in your Main Menu, under the Document Library Section.' The email address is also highlighted with a red box.

## 8. HOW TO REGISTER REQUIRED QUARTERLY FOLLOW UPS

Please be reminded that Alexion requires a quarterly visit entry to ensure a risk/benefit assessment is taking place for ongoing supply for your patient. For all your Approved patients please enter GATM My Access Programs and register a quarterly follow-up visit under the Patient Management section in your left-hand side of the main menu. You will be asked to complete a three-question survey that should only take a couple of minutes to complete.

**Entering follow ups on a timely manner are necessary to ensure continued access to treatment for your patients. Failure to register a quarterly follow up visit will result in stopped shipment.**

**Please note: after the 3<sup>rd</sup> missed follow-up visit registration your patient will be automatically discontinued.**

From your left side menu select 'Patient Registration' and 'Visit Registration'. Click the 'Add Visit' button and select the Patient Identifier to enter a follow-up.

# 'How To' Manual for My Access Programs

My Access Programs PAREXEL Welcome: GATMCAN1@DEMO DEMO [Change Password](#) [Logout](#)

Home

240753 GATM-MAP

**MAP MENU**

- Home
- Document Library
- My Site
- Patient Management
  - Patient Registration
  - Visit Registration
  - Shipment Management
  - Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email:

**WELCOME**

On behalf of Alexion welcome to GATM. A Global Access to Medicine-Managed Access Program that has been initiated to provide eligible patients outside the USA, access to Kanuma®, Soliris® and Strensiq®.

In the document library area, you can find materials listed designed to further familiarize you, your staff, and your patient with the provided treatment.

Drug Supply Approval  
In order to review your request, please fill out the available appropriate patient intake form to capture the patient's medical history and clinical status. Please provide as complete and up-to-date information as possible. Please be also advised that a valid, signed and up-to-date supply agreement must be uploaded in My Access prior to receiving access to treatment. Both templates are available under the Document Library section in the main Menu.

Quarterly Follow-ups  
A quarterly visit entry will be required to ensure a risk/benefit assessment is taking place for ongoing supply for each of your patients approved for access. You can register the patient follow up under Visit Registration in the Patient Management menu section. Keep in mind the system will notify you accordingly in case there was no action taken for a patient within the last 3 months.

Adverse Events  
As a reminder, please refer to and follow all local reporting requirements if an adverse event/serious adverse event occurs while a patient is on therapy. As any adverse events/serious adverse events are identified, we also ask that the attached Global Access To Medicine (GATM) Adverse Event (AE) Reporting Form be sent to [AdverseEventReporting@alexion.com](mailto:AdverseEventReporting@alexion.com).

**OPEN TASKS**

Task	Description	Open Since	Workflow	Additional Information
Complete Shipment Request	Complete the shipment request for Patient CAN0030014 Shipment 183327	15-AUG-2018	Shipment Request	-
Request Shipment	Request initial shipment for Patient CAN0030010	06-AUG-2018	Shipment Request	-
Complete Registration	Complete the registration for Patient CAN0030012	06-AUG-2018	Patient Registration	-
Complete Registration	Complete the registration for Patient CAN0030018	13-AUG-2018	Patient Registration	-
Complete Shipment Request	Complete the shipment request for Patient CAN0030010 Shipment 187125	06-AUG-2018	Shipment Request	-
Complete Registration	Complete the registration for Patient CAN0030017	13-AUG-2018	Patient Registration	-
Complete Registration	Complete the registration for Patient CAN0030020	15-AUG-2018	Patient Registration	-
Request Shipment	Request initial shipment for Patient CAN0030014	13-AUG-2018	Shipment Request	-
Complete Shipment Request	Complete the shipment request for Patient CAN0030010 Shipment 187082	06-AUG-2018	Shipment Request	-

**MY PATIENTS**

[Register new patient](#)

Patient	YOB	Gender	Patient Group	Patient Status	Registration Status	Approval Status	Initial Supply	Resupply	Queries	Last Step	Next Step
CAN0030001	2015	Female	aHUS	Rejected			-	-	-	Patient ineligible (19-JUL-2018)	-
CAN0030002	2015	Female	LAL-D	Rejected			-	-	-	Patient ineligible (19-JUL-2018)	-

You can select the visit name of your choice, but we would advise you to start from the 1<sup>st</sup> follow up for consistency. Please enter the information as outlined. Once data entry has been completed, please use the 'Save' button in the upper right corner.

My Access Programs PAREXEL Welcome: GATM-PH1@DEMO DEMO [Change Password](#) [Logout](#)

Home > Patient Management - Visit Registration > Edit Visit

240753 GATM

**MAP MENU**

- Home
- Document Library
- My Site
- Patient Management
  - Patient Registration
  - Visit Registration
  - Shipment Management
  - Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email:

**EDIT VISIT**

Patient Identifier: USA0172001 [Back](#) [Save](#)

Visit Name: 1st follow-up

Visit Date: 31-Jul-2019

**VISIT QUESTIONS**

Question	Answer
1. Does the patient meet the program described criteria to continue the therapy?	* - Select -
2. Does the potential benefit of continued use outweigh the potential risks of use?	* - Select -
3. I acknowledge I have an obligation to report all adverse events within the 24 hours of awareness according to the applicable Alexion policies/procedures and local regulatory requirements.	* - Select -

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

# 'How To' Manual for My Access Programs

Within the patient case you have access to all previously entered follow-ups. In addition, you have the option to register for your patient additional visits or amend existing ones by clicking the edit button.

The screenshot displays the 'My Access Programs' interface for patient 240753 GATM-MAP. The page is divided into a left sidebar with navigation options (Home, Document Library, My Site, Patient Management, Shipment Management, Reporting) and a main content area titled 'PATIENT DETAILS'. The patient details form includes fields for Patient Identifier (CAN0030006), Date registered (30-JUL-2018), Secondary patient identifier, Program Start Date, YOB (2017), Patient Group (HPP CHILDREN - Perinatal / Infantile Onset (<6 months old)), Last resupply (15-AUG-2018), Status (Approved), Next calculated resupply (16-AUG-2018), Gender (Female), Approval Date (30-JUL-2018), Height (20 cm), and Weight (100 kg). There is a 'Reason for update' text area and a 'Save' button. Below the details are sections for CRF ITEMS, DOCUMENTS, VISITS, and SHIPMENTS. The VISITS section contains a table with one entry: '1st follow-up' on '15-AUG-2018'. An 'Add Visit' button is located to the right of the table. A red box highlights the VISITS section and the 'Add Visit' button. The footer contains a disclaimer: 'Your use of the information on this site is subject to the Terms of Service and Privacy Policy of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015'.

My Access Programs PAREXEL Welcome: GATMCAN1@DEMO.DEMO [Change Password](#) [Logout](#)

Home > Patient Management - Patient Registration > CAN0030006

### 240753 GATM-MAP

#### MAP MENU

- Home
- Document Library
- My Site
- Patient Management
- Shipment Management
- Reporting

If you have questions, which cannot be answered by the corresponding user guide, please contact your local monitor or Customer Care Helpdesk directly via email:

#### PATIENT DETAILS

Patient Identifier: CAN0030006 Date registered: 30-JUL-2018 [Back](#) [Save](#)

Secondary patient identifier:

YOB: 2017

Program Start Date:

Patient Group: HPP CHILDREN - Perinatal / Infantile Onset (<6 months old) Last resupply: 15-AUG-2018

Status: Approved Next calculated resupply: 16-AUG-2018

Gender: Female Approval Date: 30-JUL-2018

Height: 20 cm

Weight: 100 kg

Reason for update:

Username: GATMCAN1@DEMO.DEMO

Password:

#### CRF ITEMS

#### DOCUMENTS

#### VISITS

Edit	Visit Name	Visit Date	
	1st follow-up	15-AUG-2018	<a href="#">Add Visit</a>

#### SHIPMENTS

Your use of the information on this site is subject to the [Terms of Service](#) and [Privacy Policy](#) of PAREXEL. This site is published by PAREXEL who is solely responsible for its content. © PAREXEL 2015

## **9. HOW TO ACCESS AND REVIEW YOUR DATA**

The reporting and download pages provide an aggregate of all site-specific reports available in My Access Programs. Click on each page on the left of your screen to view the associated reports. The reports include a cumulative listing of data specific to your site and high-level summaries of patient specific information, Kanuma, Strensiq or Soliris orders, etc. Within the cumulative reports, you can click on the magnifying glasses to view additional details. The “Actions” button allows you to filter information and add/remove columns for a customized report. You can save or download a copy of any report by clicking “Actions” Below are a few examples of reports you can run in My Access Programs.

### **9.1. Site Report**

This report provides a high-level summary of your site contact information and metrics. The metrics include the number of patients approved at your site and the number of Kanuma/Strensiq/Soliris shipment requests at your site. Your Contact and / Address details can be changed at any time on the Contact / Address Management page under My Site options.

### **9.2. Patient Report**

This report list provides a summary of the patients that have been entered the program at your site. The cumulative report will identify the number of patients that have been approved at your site, the number of patients that are active in the GATM program, the number of patients that have discontinued the program, etc. The high-level reports provide summaries of individual patients with details such as registration dates, number of orders placed and next expected drug supply.

### **9.3. Shipments Report**

This report provides a summary of all of shipments placed by your site. The cumulative report will identify patient number, shipment number, shipment type (initial or resupply), and shipment status. The high-level reports provide summaries of individual shipments with details such as shipment request date and kits requested. It is the treating physician’s responsibility to maintain oversight over patient compliance and routinely check My Access to ensure patients are receiving shipments in a timely manner based on the resupply timeline in the protocol.

## 10. FREQUENTLY ASKED QUESTIONS

- I forgot my password.
  - If you forgot your password, please use the link ‘Forgot password?’ and enter the email address. A new, one-time use password will be sent to you.
- I have not received my registration emails.
  - Please check your SPAM folder as the emails might have been stored here.
  - If not in SPAM folder, please contact the main helpdesk at [cls-support@parexel.com](mailto:cls-support@parexel.com).
- I want to change my password.
  - In the header line, click on “Change Password”. In the popup window, provide your current password and the new password of your choice.
- How do I find new programs?
  - Once you have registered in My Access Programs and have logged in, you need to look for programs you are interested in. To do so, click on the “Search for new program” icon and enter a search term to find programs open for registration in your country. You can register to each of the programs directly from the search results.
- I cannot request a shipment.
  - In order to request a shipment, your patients need to be approved by Alexion. Contact your assigned CSM for assistance.
- I have received a message inside the application – what now?
  - All messages will be displayed on the Home Page inside the specific program. Via the green “Resume” icon, the application will link you to the case directly and you can work on the question received. The message will disappear as soon as you answered the question.
- I would like to add my site personnel so they can support me.
  - You can register your site personnel as site users via ‘Site User Management’ in each program. You will need the name and email address and assign them the function they should perform. A site user can support several programs at the same time.
- What are open tasks?
  - Open tasks are meant to help you keep track of all actions that are required by you / the site users in the application. They will only appear if there are any open action items. By clicking on the green ‘Resume’ icon, you will be linked to the case directly and can act on it.

## **11. WHEN TO CONTACT US**

### **11.1. When to contact PAREXEL Clinical Site Manager**

- Clarification of steps of how to request drug re-supply
- Please write to [GATM\\_MyAccessSupport@parexel.com](mailto:GATM_MyAccessSupport@parexel.com)
- I cannot find my program.
- User does not receive notifications.
- I want to update demographics for already registered patients.
- I want to update the provided answers for a registered patient
- I need to have a document deleted.
- Move patient to another site.
- Questions related to requested shipments
- A shipment needs to be marked as cancelled

### **11.2. When to contact Alexion Local Medical Affairs Manager.**

- Medical related protocol questions
- Questions regarding IRB/EC payments
- Questions related to approved shipments

### **11.3. When to contact Technical Support**

- I cannot find my program.
- I cannot login in My Access.
- I receive an error while performing an activity in the platform



## 'How To' Manual for My Access Programs

### 12. APPENDIX

Patient Status Pending	Shipment request has been initiated by the treating physician, but registration process is not yet complete
Patient Status Stopped Treatment	Patient has been discontinued
Patient Status Registered	Patient registration has been completed by the treating physician and is waiting for review
Patient Status Not Approved	Patient has been reviewed and rejected to enter GATM
Patient Status Approved	Patient has been approved for treatment
Patient Overdue for Resupply	The registration of the expected on a yearly basis supply request has been missed.
Patient Overdue for Follow Up	The registration of the expected follow up visit has been missed.
Order Status Processed	Shipment request has been completed by the treating physician and is waiting for review
Order Status Setup	Shipment request has been initiated by the treating physician, but request process is not yet complete
Order Status Not approved	Shipment request has been rejected
Order Status Approved	Shipment request has been approved