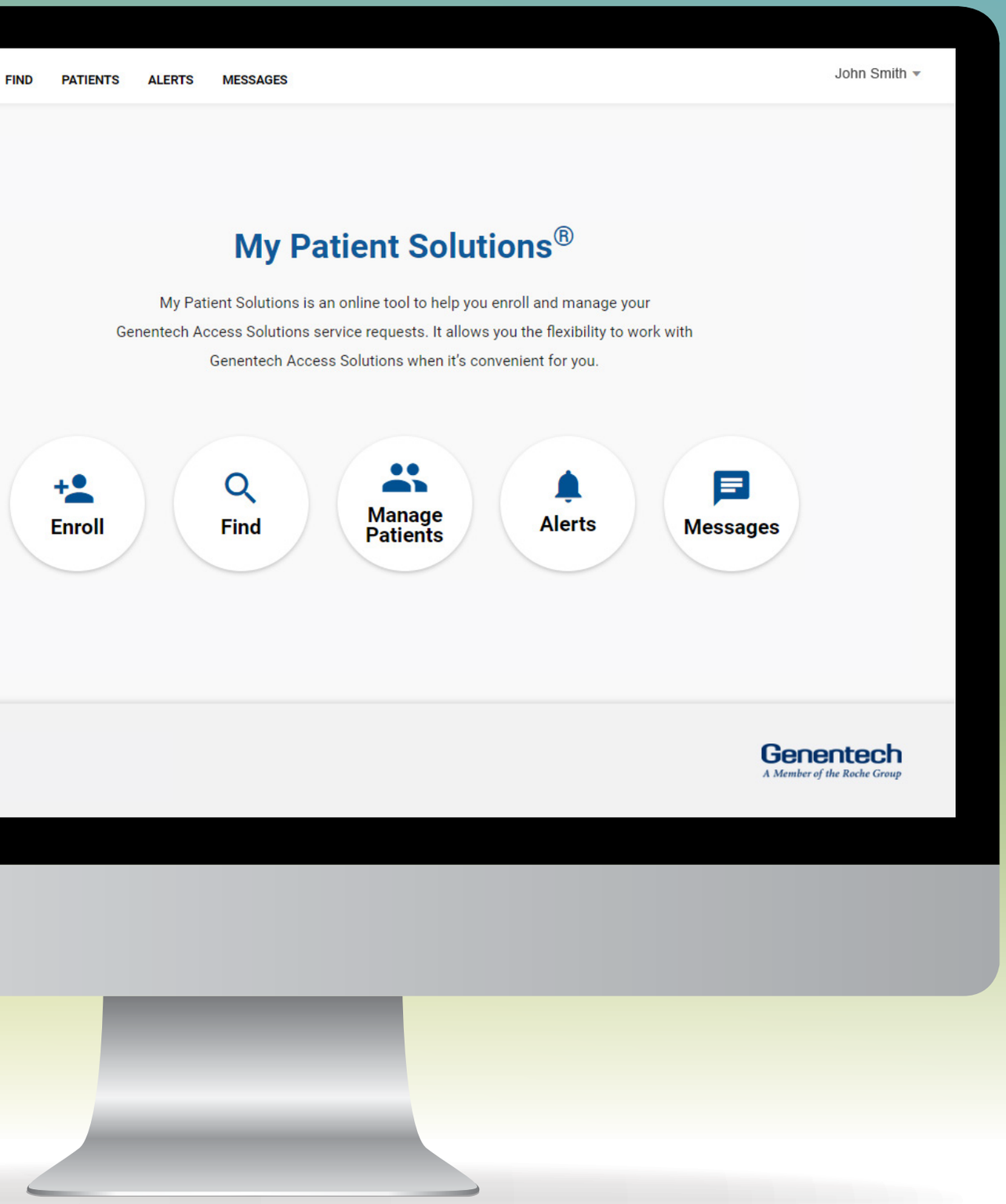


UPDATED
July 2021

My Patient Solutions® for Health Care Practices

USER GUIDE

- About My Patient Solutions
- Account Setup
- Steps for Use
- Additional Information

Genentech
A Member of the Roche Group
Access Solutions

About My Patient Solutions® for Health Care Practices

My Patient Solutions is an online tool to help you enroll patients in Genentech Access Solutions and the Genentech Patient Foundation and manage your service requests.

With My Patient Solutions, you can:

- Message your Genentech Access Solutions or Genentech Patient Foundation Specialist
- Follow up on prior authorizations (PAs) or appeals and download the PA form (if available)
- View Benefits Investigation (BI) Reports
- View co-pay assistance referral information and outcomes*
- See which service requests require action
- Enroll and re-enroll patients in Genentech Access Solutions or the Genentech Patient Foundation
  - Send your patients a link to the paperless Patient Consent Form
- View Genentech Patient Foundation eligibility and coordinate shipments
- Request benefits reverification/recertification†
- Export a report of your customized and/or filtered patient lists

Additional features for practices that prescribe OCREVUS® (ocrelizumab)

- Manage infusion dates
- View treatment coordination milestones

If you have questions about My Patient Solutions:

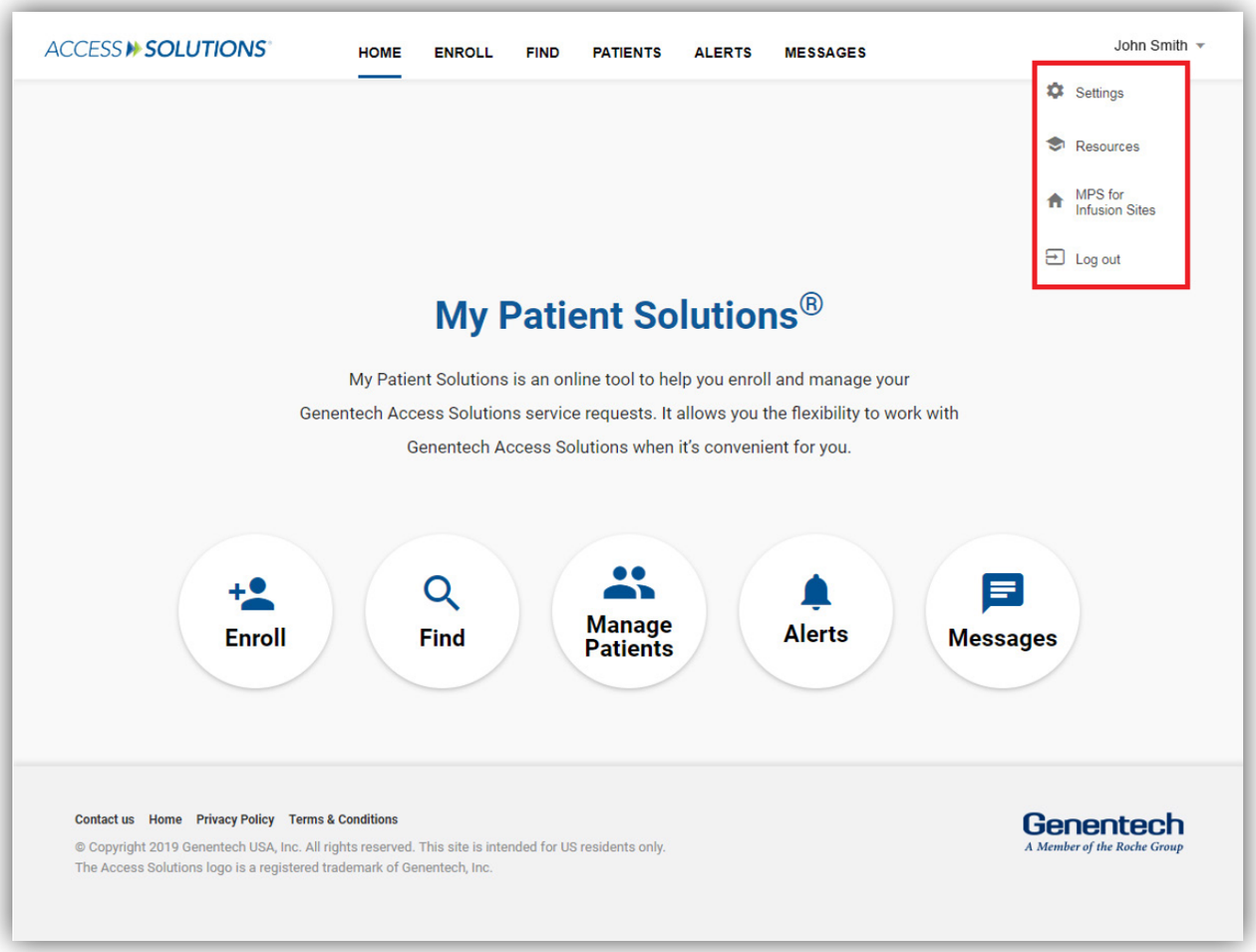
- Contact your Genentech representative
- Call Genentech Access Solutions at **(866) 4ACCESS**/(866) 422-2377

*You may also view enrollment dates for patients enrolled in certain programs.
†This feature is available for certain brands only.

Update User and Practice Settings

Once you have activated your account and logged in, you can add or deactivate users, practice locations and/or prescribers if you have been designated as a practice administrator. Consider designating at least 2 users as administrators.

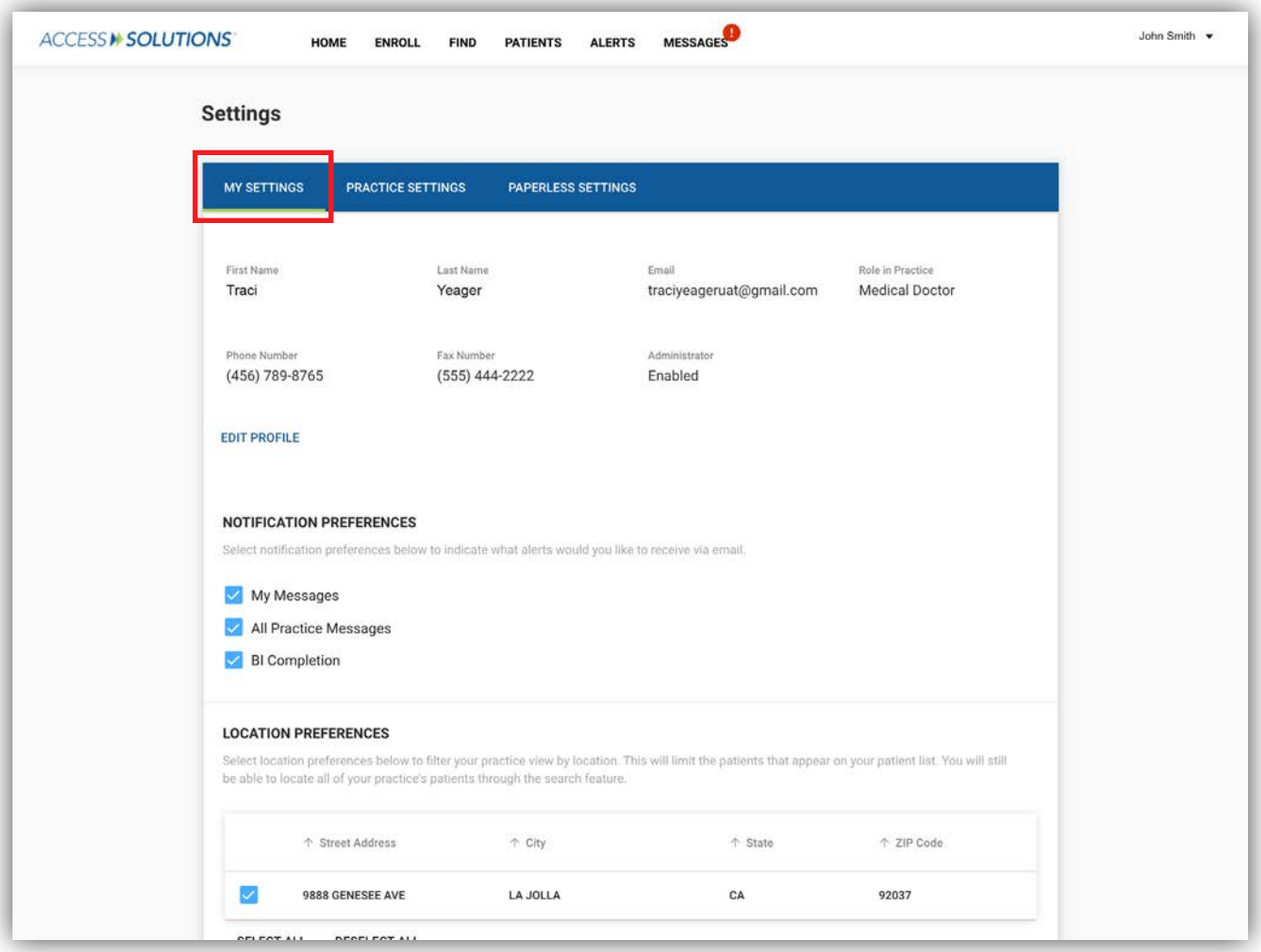
Manage your settings



- Select your username at the top right corner to open the dropdown menu
- Select SETTINGS

Update User and Practice Settings (cont)

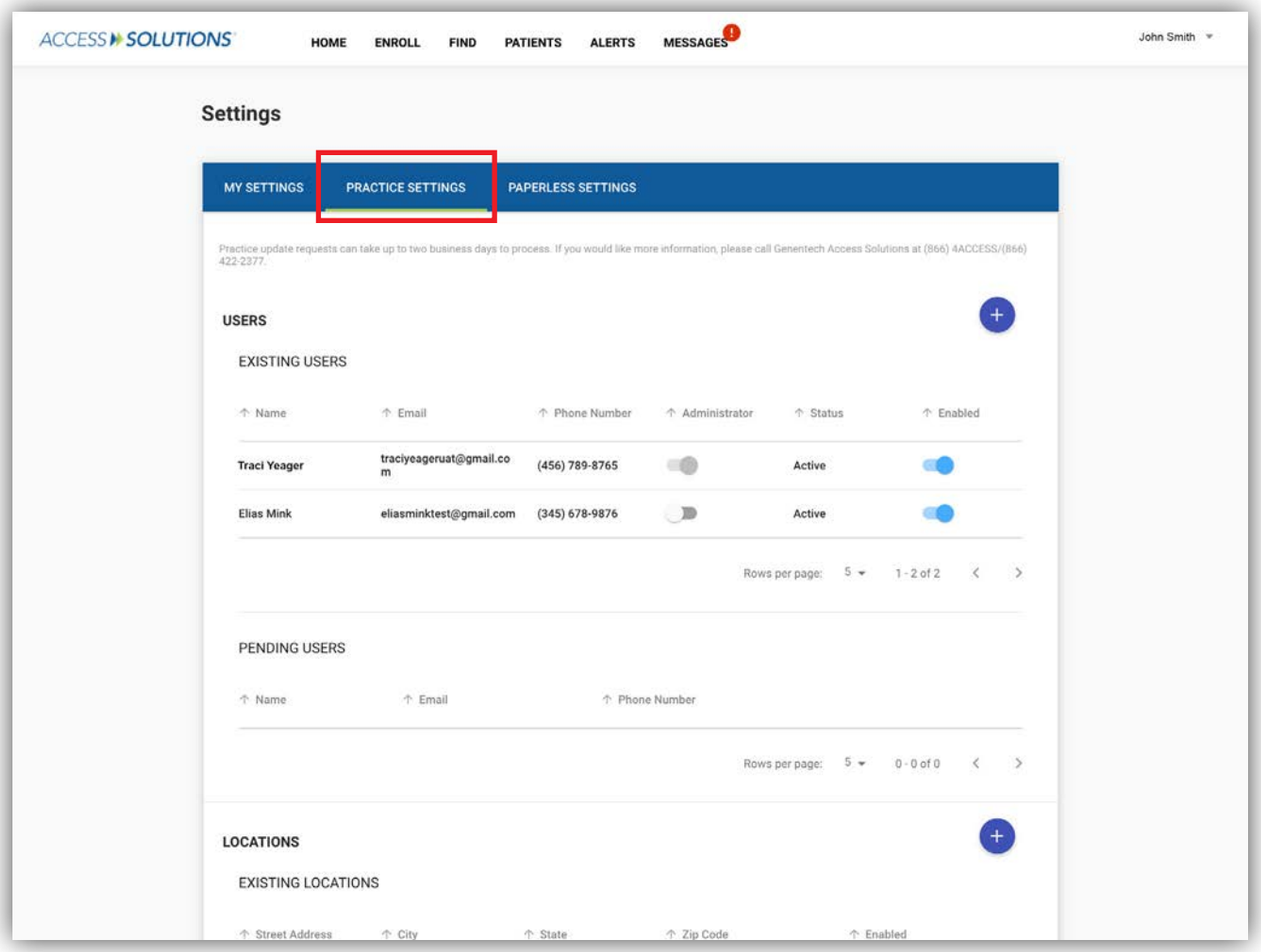
Manage your settings (cont)



- Go to MY SETTINGS to manage your:
  - Location preferences
  - Email preferences for the messaging feature (individual and practice)
  - Email preferences confirming the completion of benefits investigations (BIs)

Update User and Practice Settings (cont)

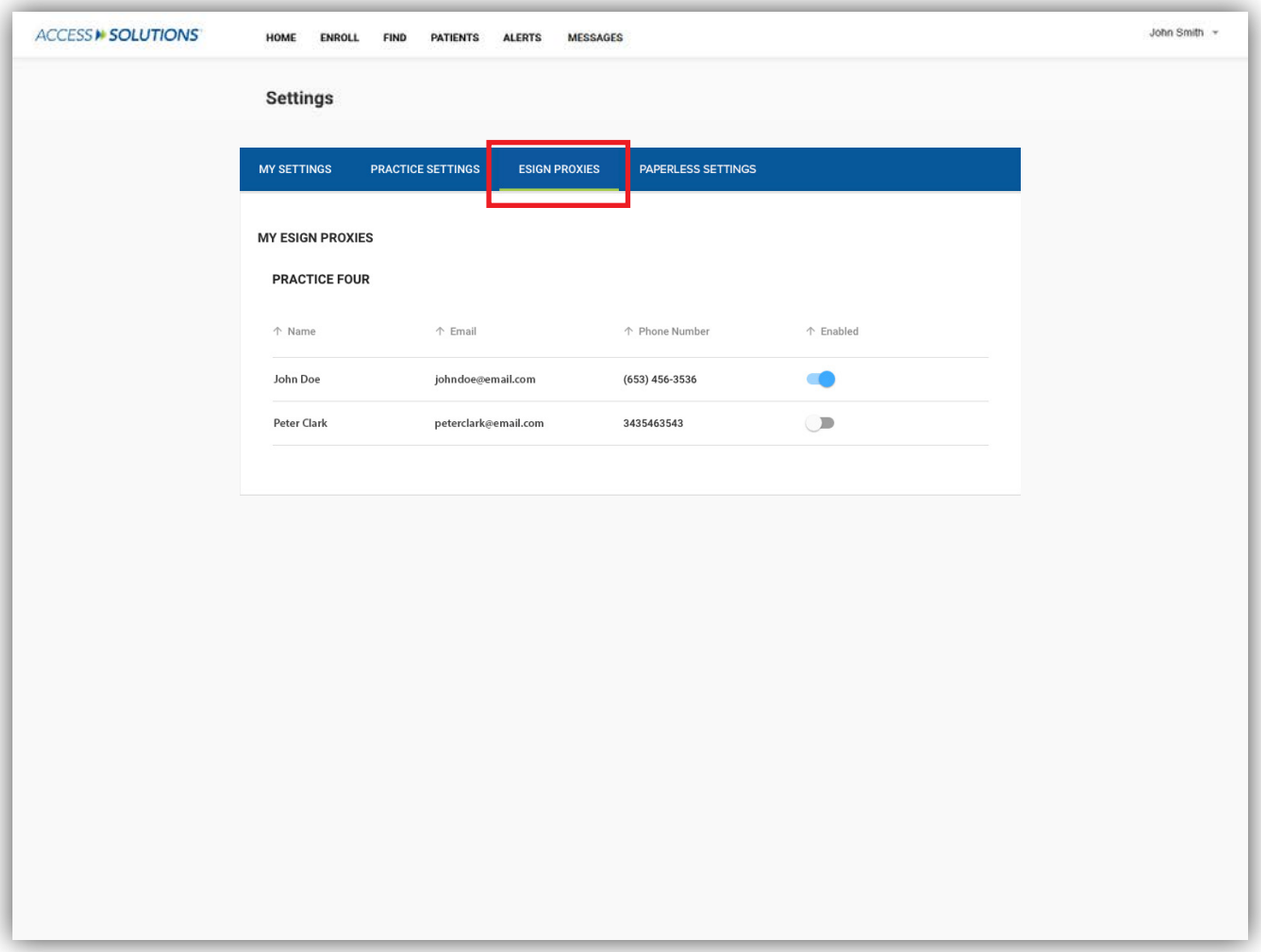
View, add or deactivate users, practice locations and/or prescribers (administrators only)



- Go to the PRACTICE SETTINGS tab:
  - — Here you can view or add users, practice locations and/or prescribers as well as invite prescribers to sign up for eSignature
  - — You can also deactivate existing users, practice locations and/or prescribers to protect patient health information

Update User and Practice Settings (cont)

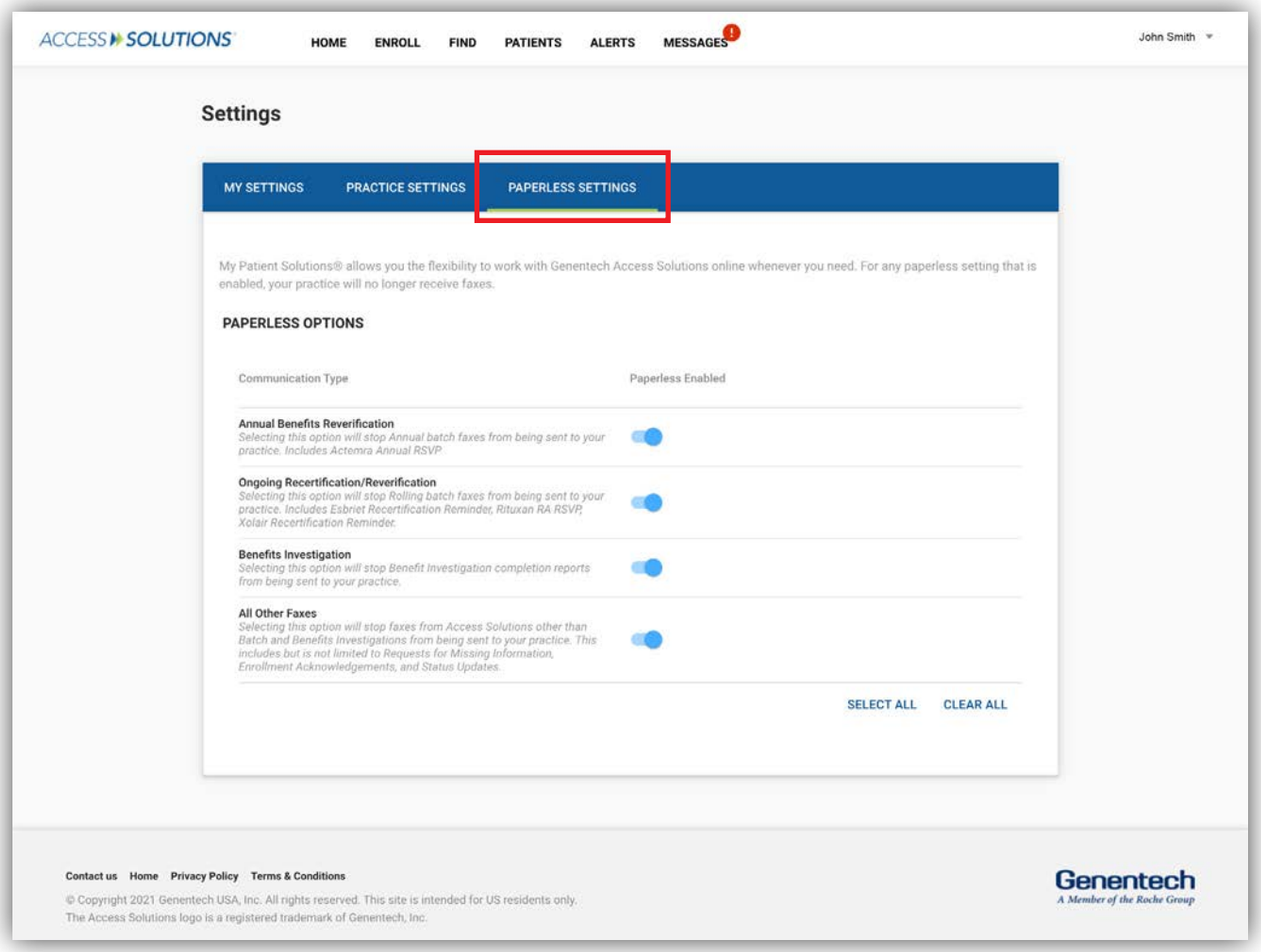
Manage proxies



- Go to ESIGN PROXIES to view, enable or disable proxies:
  - — You must enroll in eSignature before you can designate proxies
  - — See Set Up eSignature for more information

Update User and Practice Settings (cont)

Paperless settings



- Go to PAPERLESS SETTINGS
- Select PAPERLESS ENABLED for each program for which you do **not** wish to receive faxes

Update User and Practice Settings (cont)

Important points to remember about updating settings

- All practice locations added during practice registration are active by default
- Locations must be the physician's office address (it cannot be the pharmacy or billing address)
- When adding a new prescriber:
  - — Please have the prescriber's NPI number and state license number available
  - — Check the box to invite the prescriber to sign up for eSignature
- Any changes made by an administrator apply to all users
- To permanently remove users, practice locations and/or prescribers, you must contact Genentech Access Solutions at **(866) 4ACCESS**/(866) 422-2377
- The ESIGN PROXIES tab will only appear for users who are prescribers
- Hovering over a physician's name in SETTINGS will display that physician's proxies

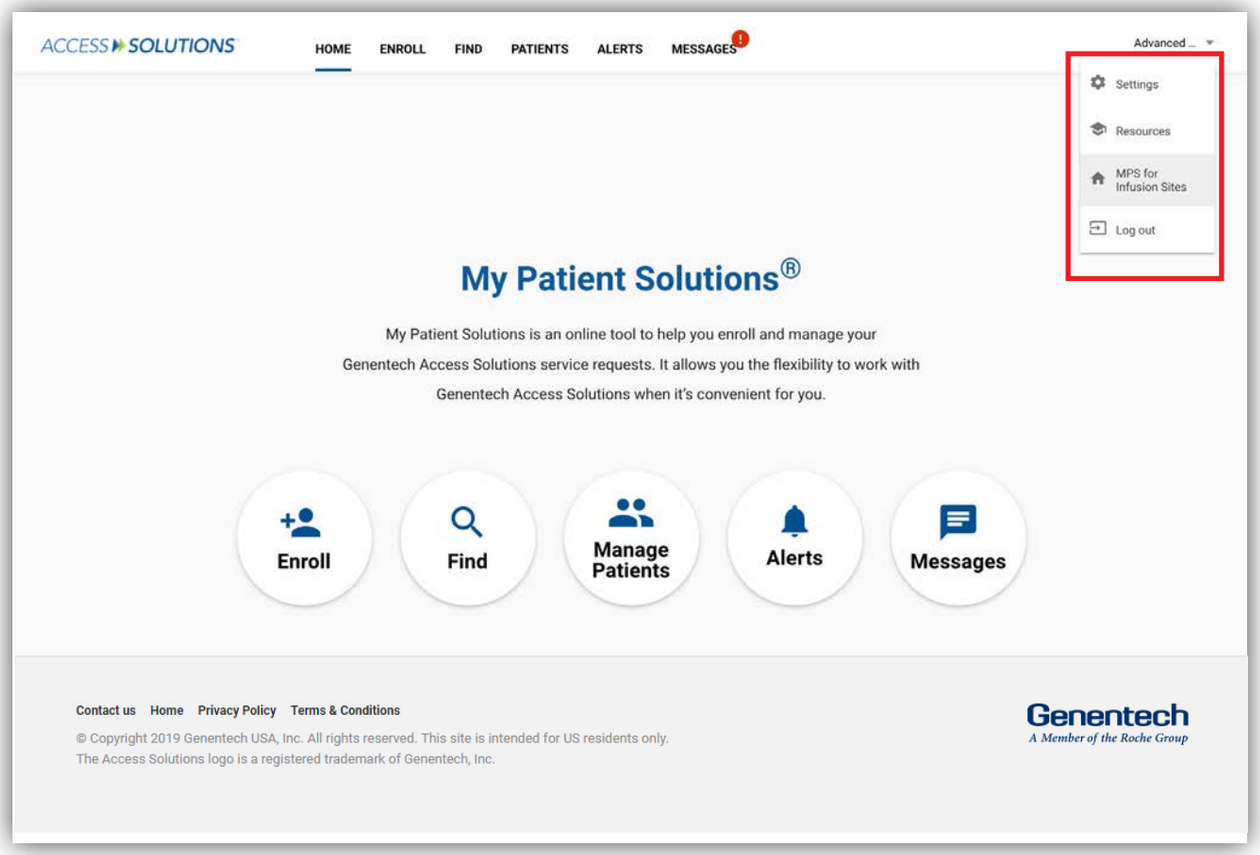
NPI=National Provider Identifier.

For OCREVUS® (ocrelizumab) only

Link to My Patient Solutions® for Infusion Sites

If you prescribe and infuse OCREVUS, you can register for both My Patient Solutions for Health Care Practices and My Patient Solutions for Infusion Sites and navigate between them. You will not need to enter your login information again.

Navigate to My Patient Solutions for Infusion Sites

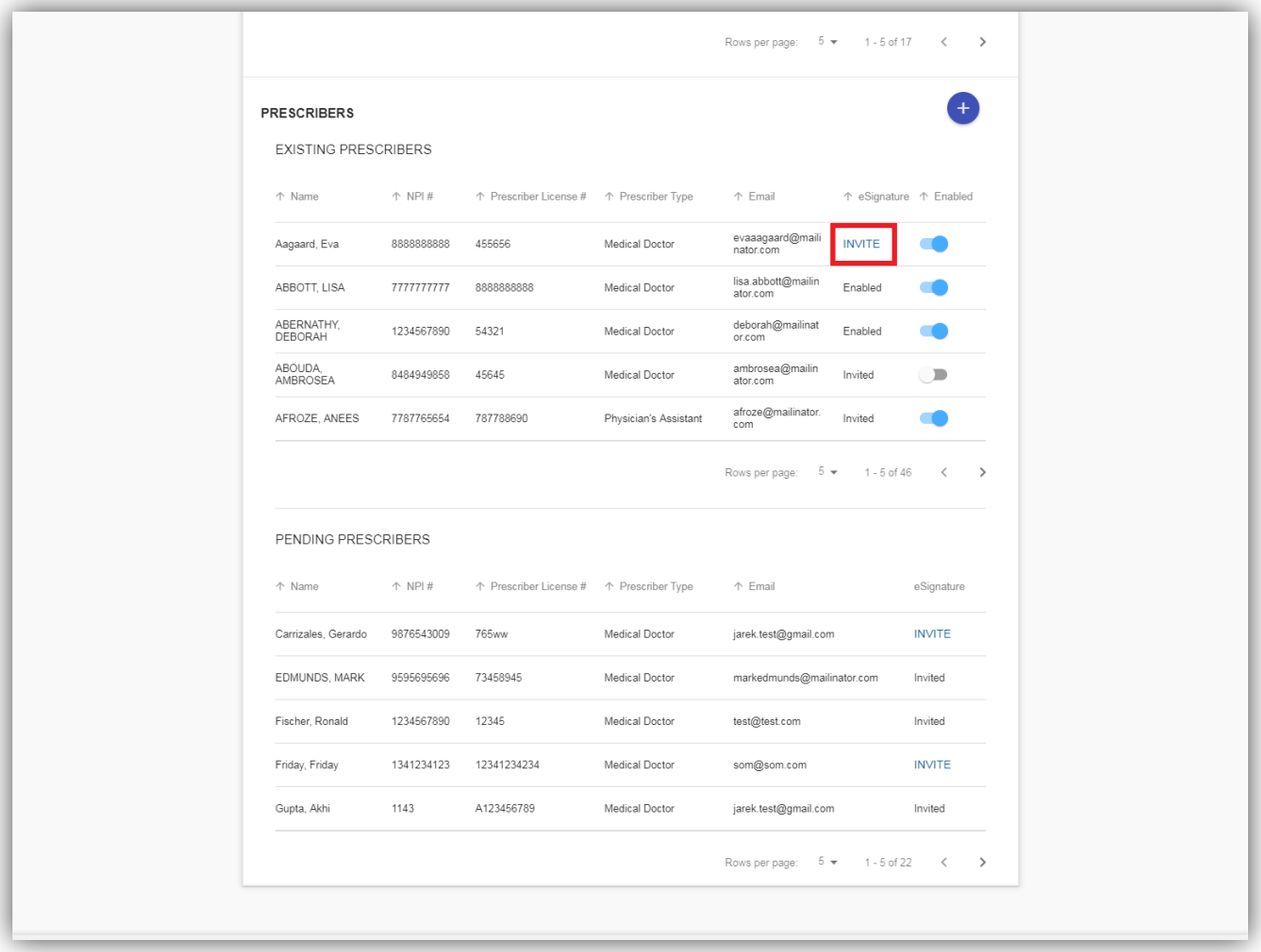


- Select your name in the top right corner from the landing page
- Select MPS FOR INFUSION SITES from the dropdown menu

Set Up eSignature

eSignature allows for a completely paperless enrollment process. Prescribers who have enabled eSignature can designate appropriate members of their office staff to sign the Prescriber Service Form on their behalf. My Patient Solutions® for Health Care Practices eSignature enrollment is only valid for this system. Administrators can invite current or pending prescribers to set up eSignature.

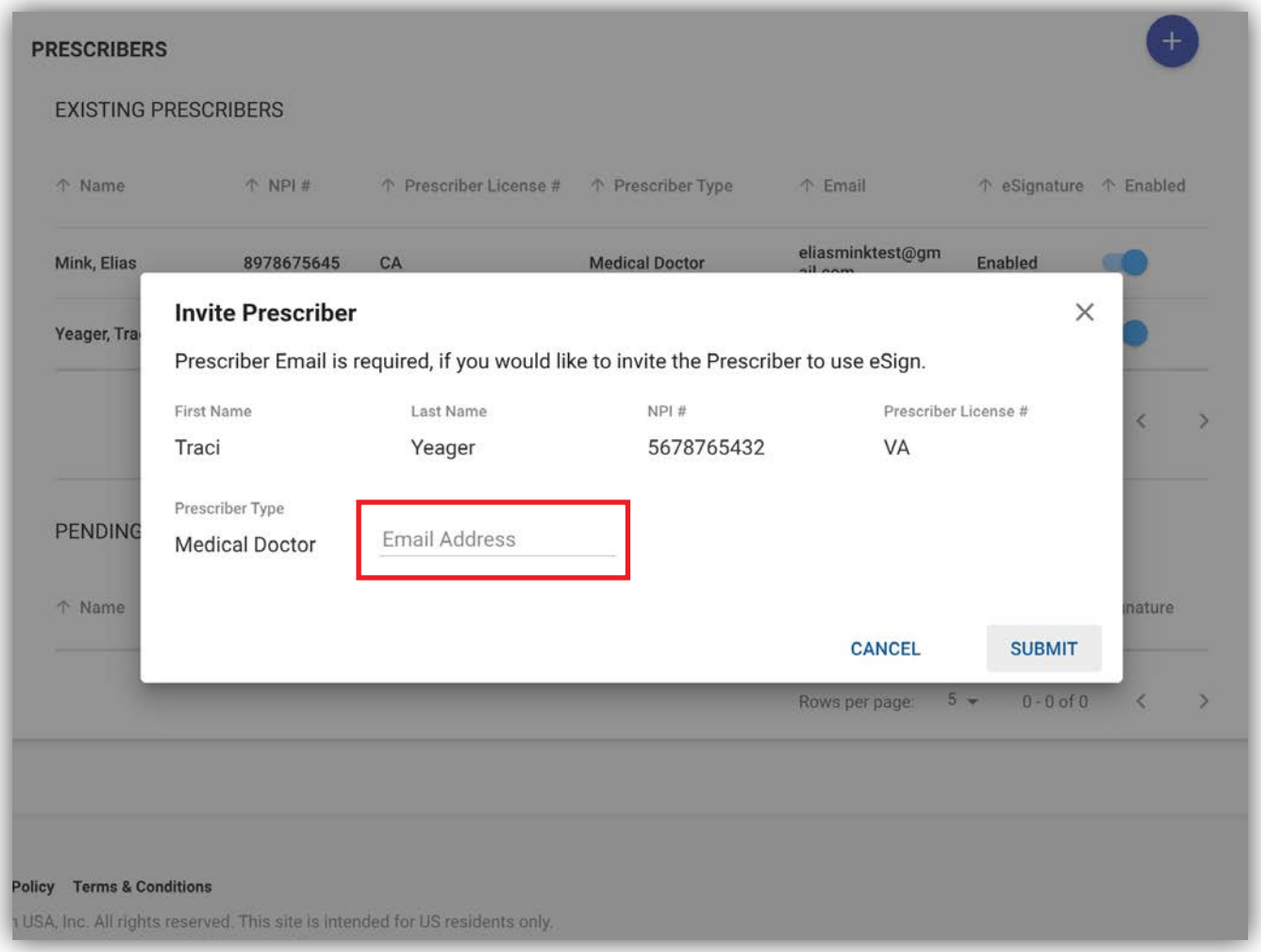
Invite a prescriber to use eSignature



- Scroll down to the PRESCRIBERS section within PRACTICE SETTINGS
- Select INVITE next to his or her name
  - — Prescribers must be My Patient Solutions users to sign up for eSignature

Set Up eSignature (cont)

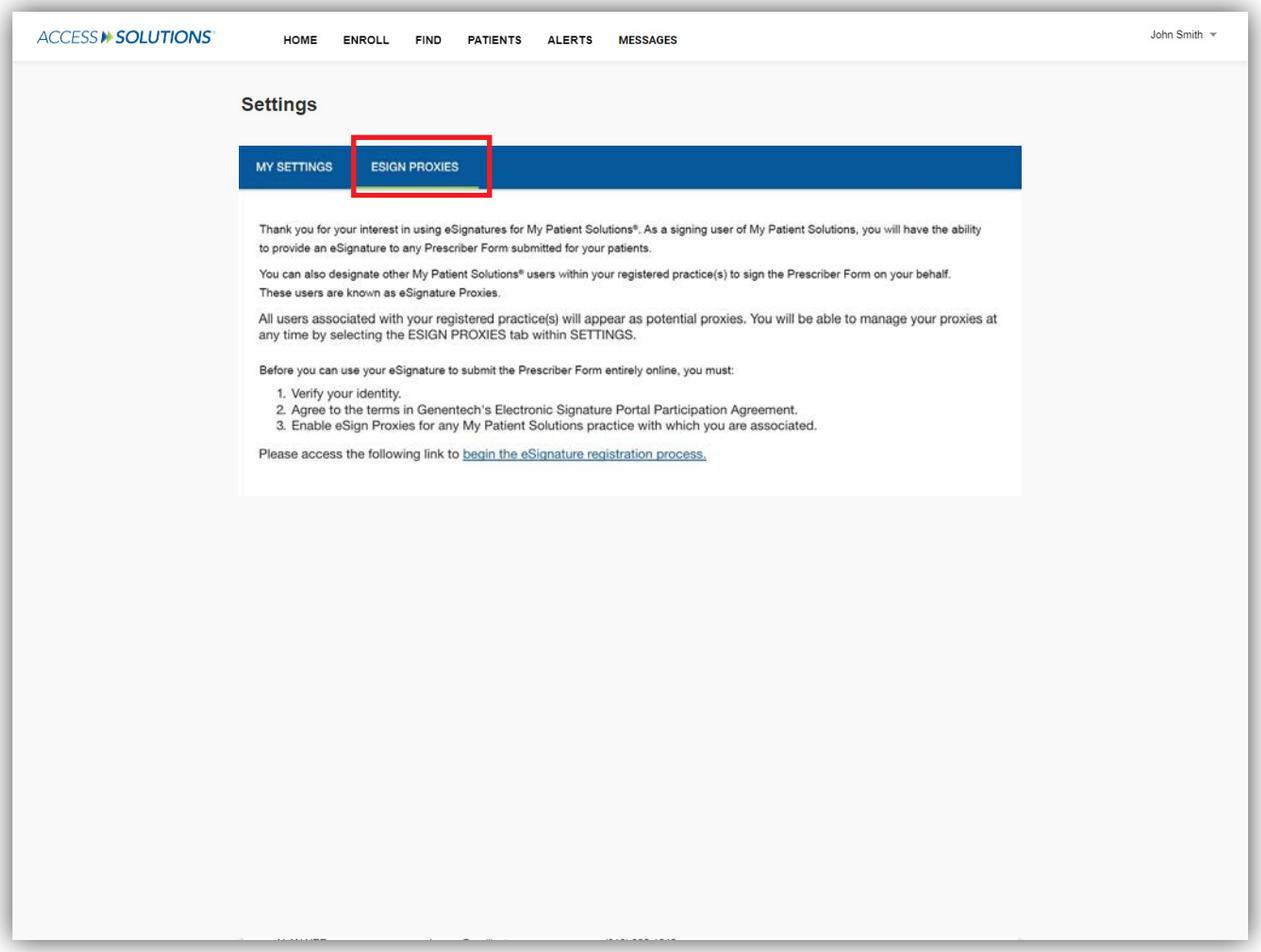
Invite a prescriber to use eSignature (cont)



- Fill in the prescriber's email address in the pop-up window
  - This email address must match the email connected to the prescriber's My Patient Solutions® account
- Prescribers receive the same email all users receive when activating an account
  - Follow the link in the activation email and activate your account

Set Up eSignature (cont)

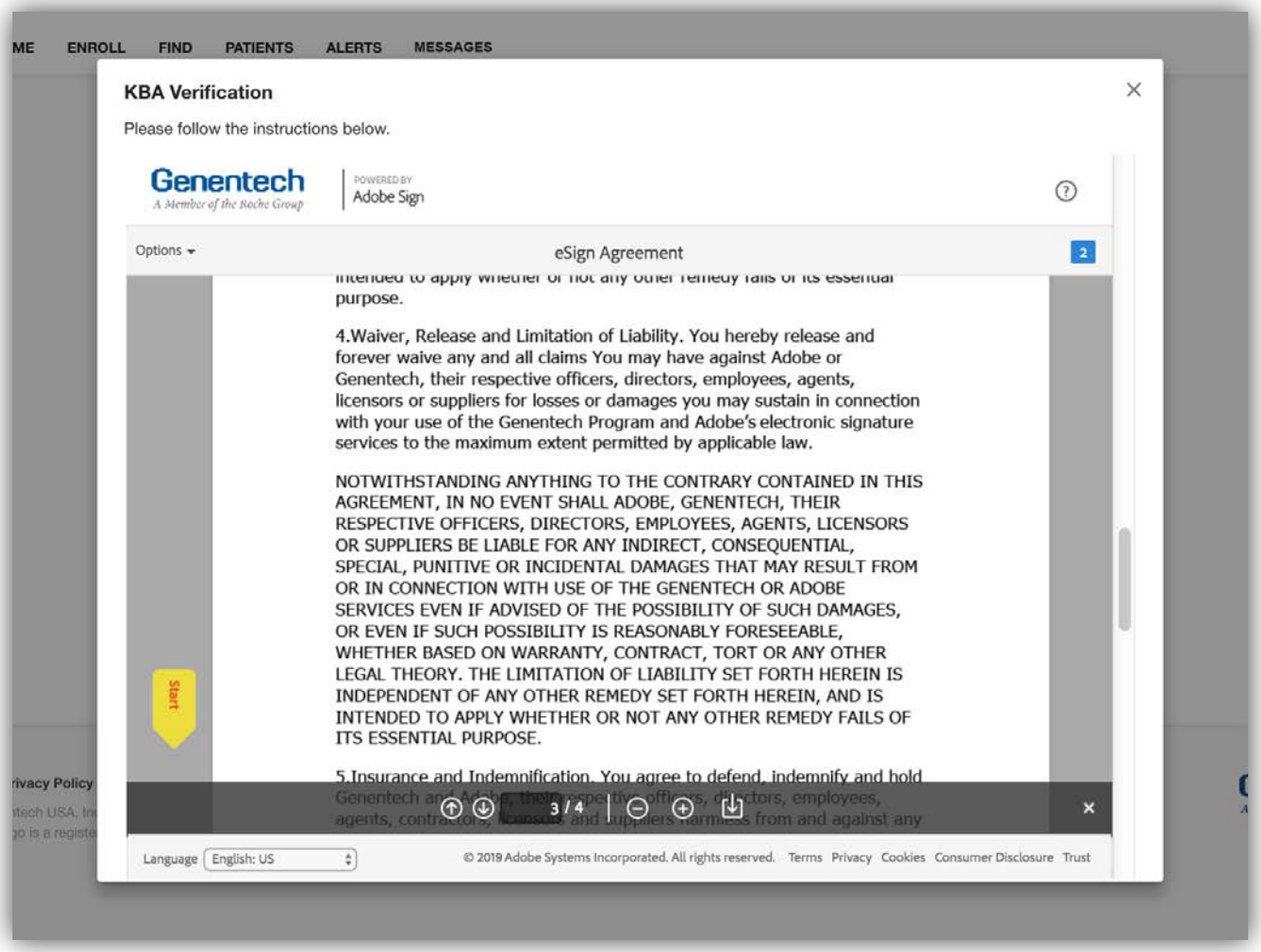
Sign up for eSignature (prescribers only)



The first time you log in after activating your account, you will be automatically redirected to the ESIGN PROXIES tab within SETTINGS.

Set Up eSignature (cont)

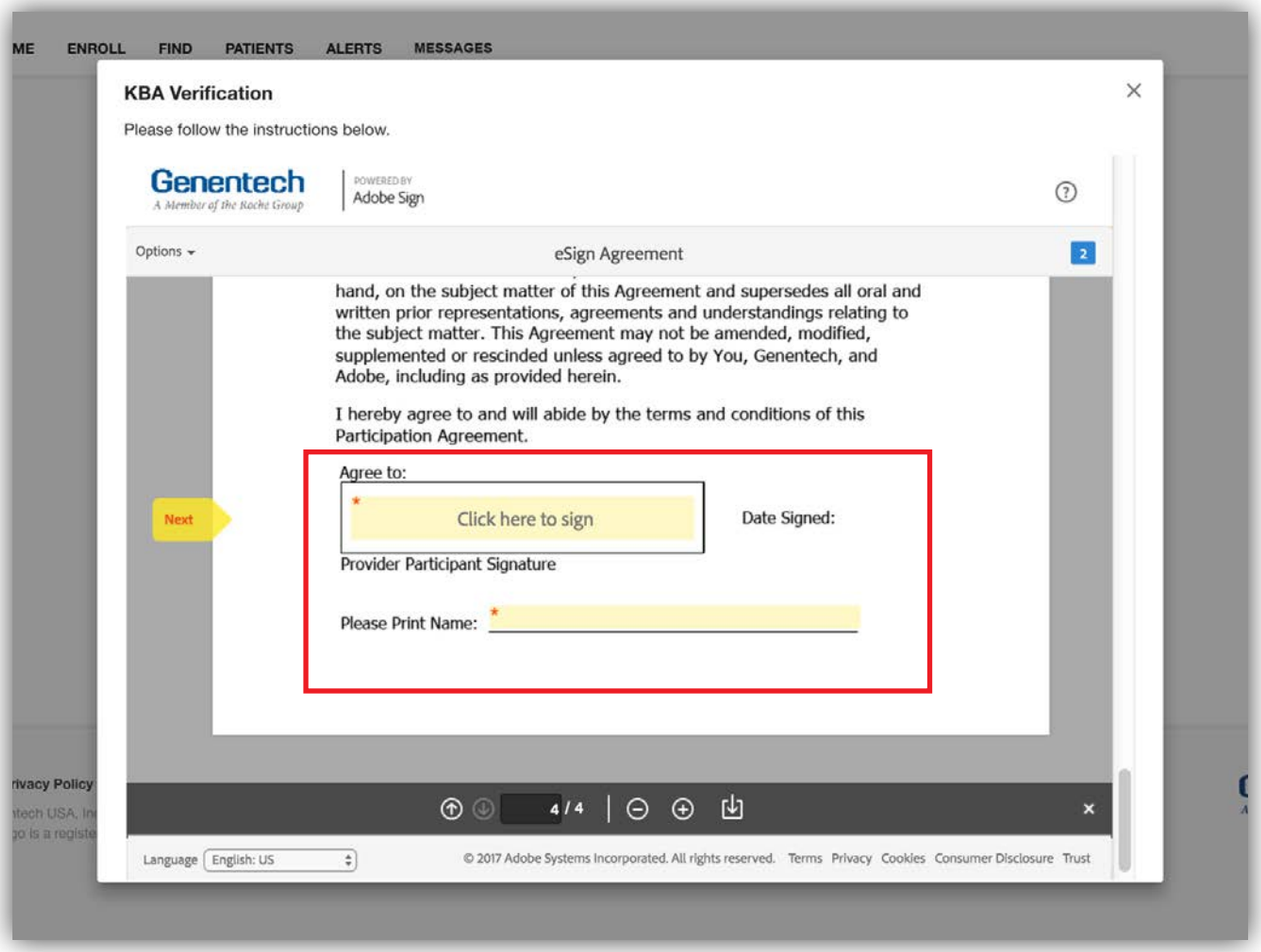
Sign up for eSignature (prescribers only) (cont)



Agree to the terms and conditions in the ELECTRONIC SIGNATURE PORTAL PARTICIPATION AGREEMENT to continue.

Set Up eSignature (cont)

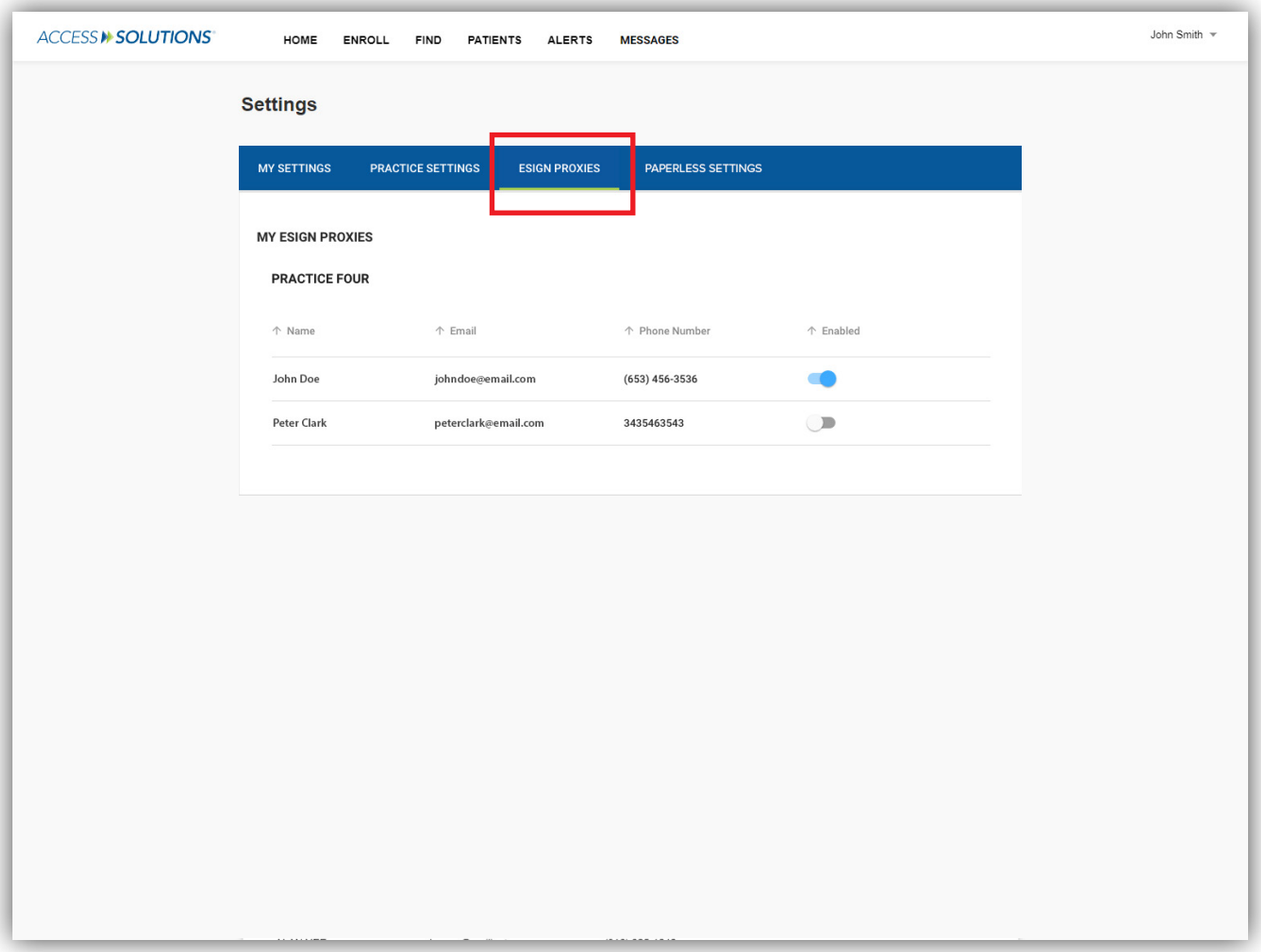
Sign up for eSignature (prescribers only) (cont)



- Verify your eSignature contains no typographical errors before continuing:
  - Confirm that the spelling of the name on each eSignature is an exact match to the name as it is spelled when the prescriber sets up this feature
  - Any deviations or misspellings will cause the eSignature to be invalid and the submission to remain incomplete

Set Up eSignature (cont)

Manage your proxies (prescribers only)



Go to ESIGN PROXIES under SETTINGS to view and enable/disable proxies for all practice locations.

Set Up eSignature (cont)

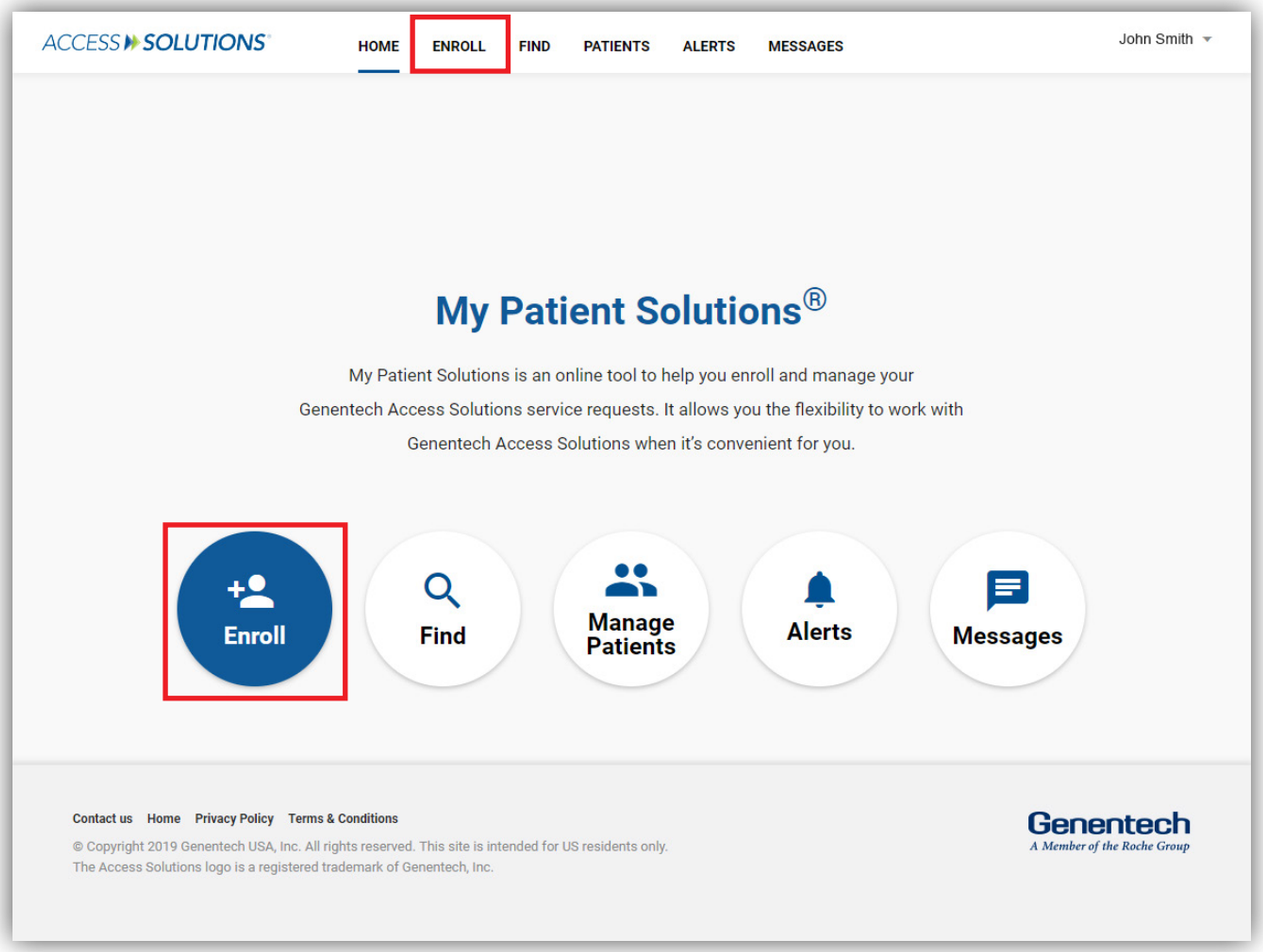
Important points to remember about eSignature

- Prescribers setting up a new eSignature must be both approved prescribers and My Patient Solutions® for Health Care Practices users
- Prescribers can manage proxies across multiple practices
- Administrators may invite pending prescribers. However, prescribers will not be able to sign up for eSignature until they have been confirmed as prescribers in the system and have activated their My Patient Solutions accounts
- After the eSignature has been set up, all subsequent visits to the ESIGN PROXIES screen will allow the prescriber to manage his or her proxies

Enroll Patients

My Patient Solutions® for Health Care Practices allows for a simple and completely paperless enrollment process. By completing the form fields in My Patient Solutions, you are completing an online version of the Prescriber Service Form or the Prescriber Foundation Form. The dynamic fields of these forms display only the information required for your specific service request.

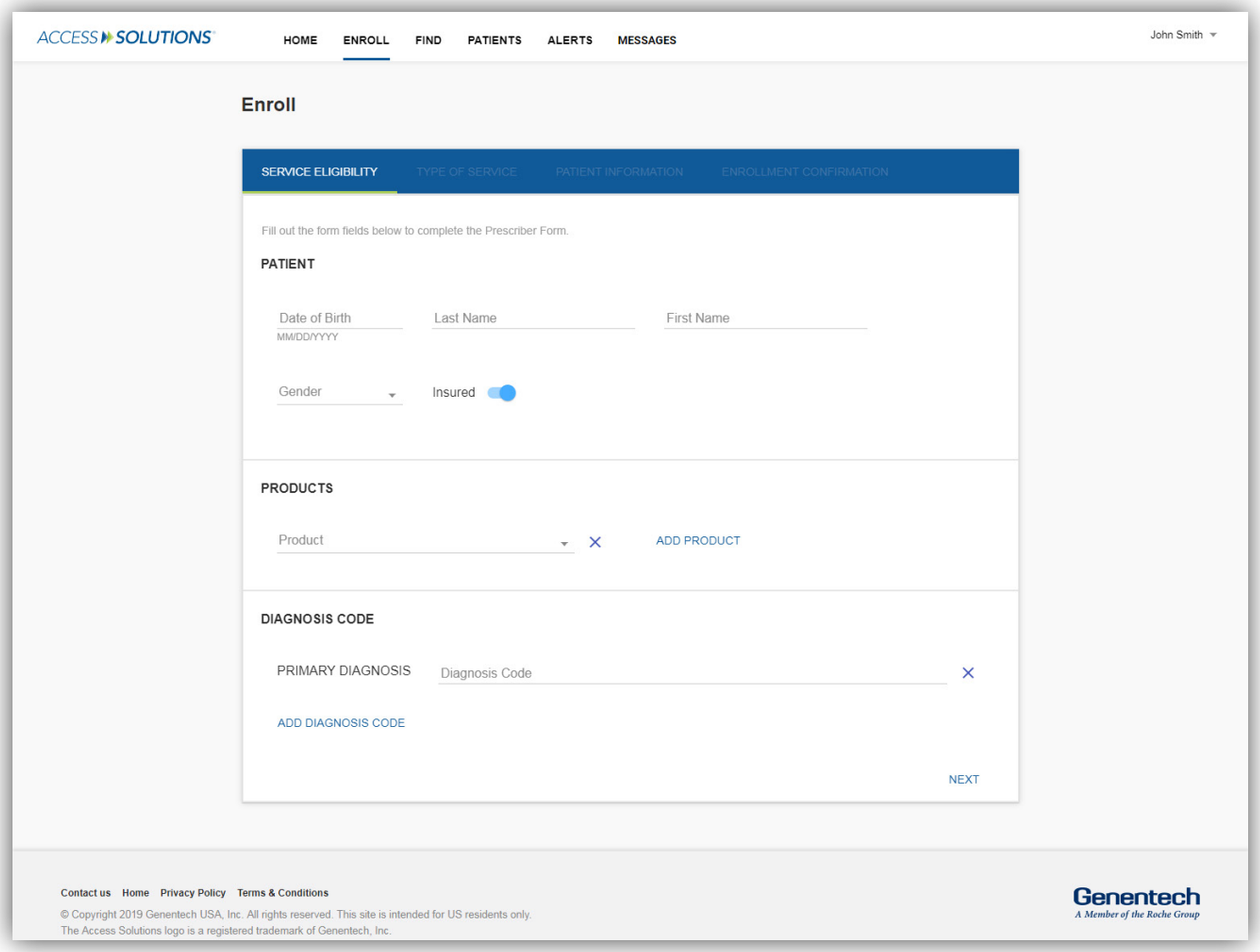
Begin enrollment process



Select ENROLL from the center of the screen or from the top navigation bar.

Enroll Patients (cont)

Enter patient information, insurance status and diagnosis code(s)

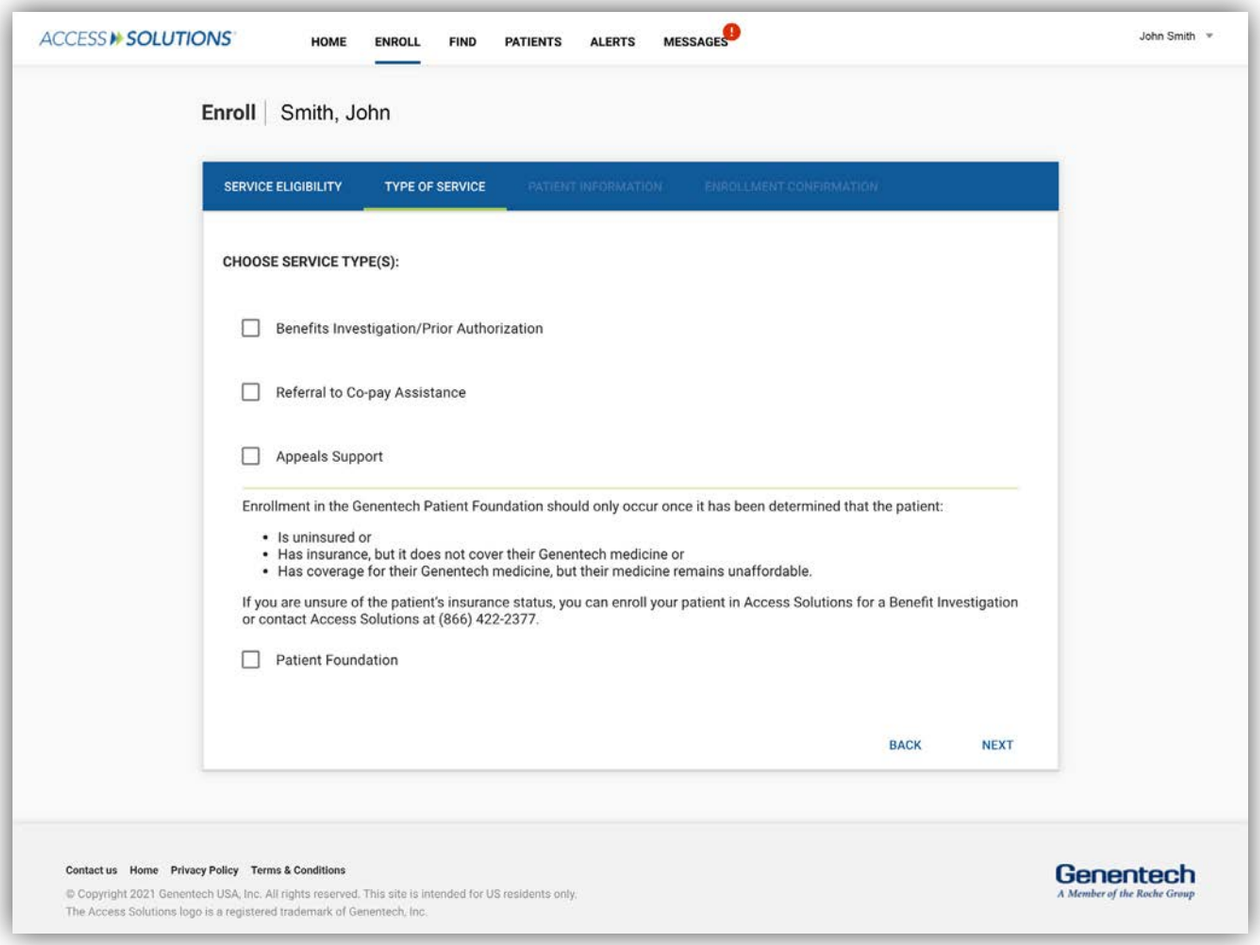


- Complete the patient, product and diagnosis code information
- Identify whether the patient is insured or uninsured
- Add up to 3 products and 3 diagnosis codes by selecting ADD PRODUCT and/or ADD DIAGNOSIS CODE
  - The DIAGNOSIS CODE field will autocomplete when you begin typing a code
- This information is universal to both forms

Note: Both the Prescriber Service Form and the Prescriber Foundation Form will be labeled “Prescriber Form” at the top of the page.

Enroll Patients (cont)

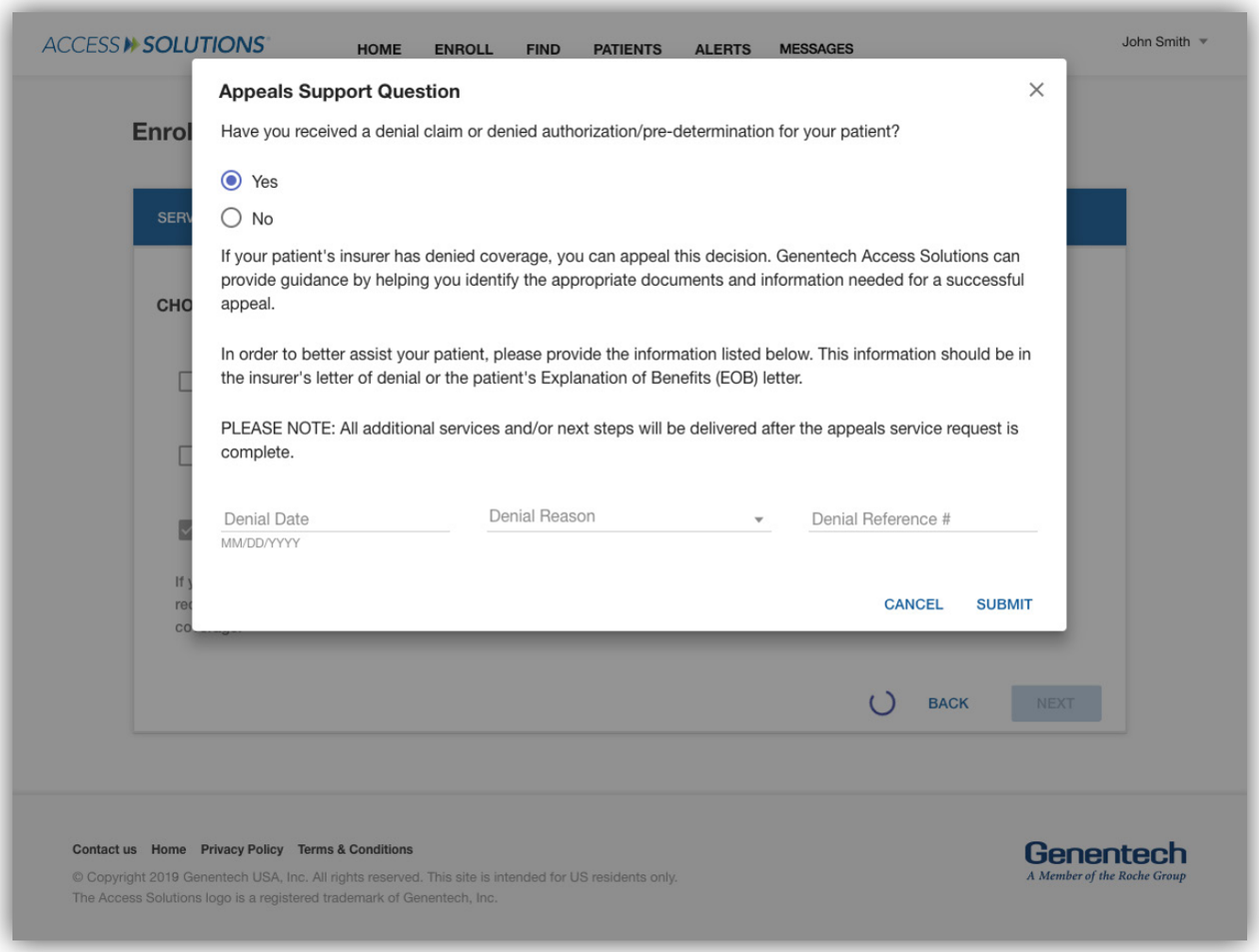
Complete the Prescriber Service Form or Prescriber Foundation Form



- Choose the Service Type(s) you are requesting for your patient
- Depending on which service(s) you choose, you will be taken to complete either the Prescriber Service Form or the Prescriber Foundation Form:
  - If you request coverage and reimbursement support or financial assistance, you will be taken to the Prescriber Service Form
  - If your patient is uninsured and/or you are requesting assistance from the Genentech Patient Foundation, you will be taken to the Prescriber Foundation Form

Enroll Patients (cont)

Complete the Prescriber Service Form or Prescriber Foundation Form (cont)

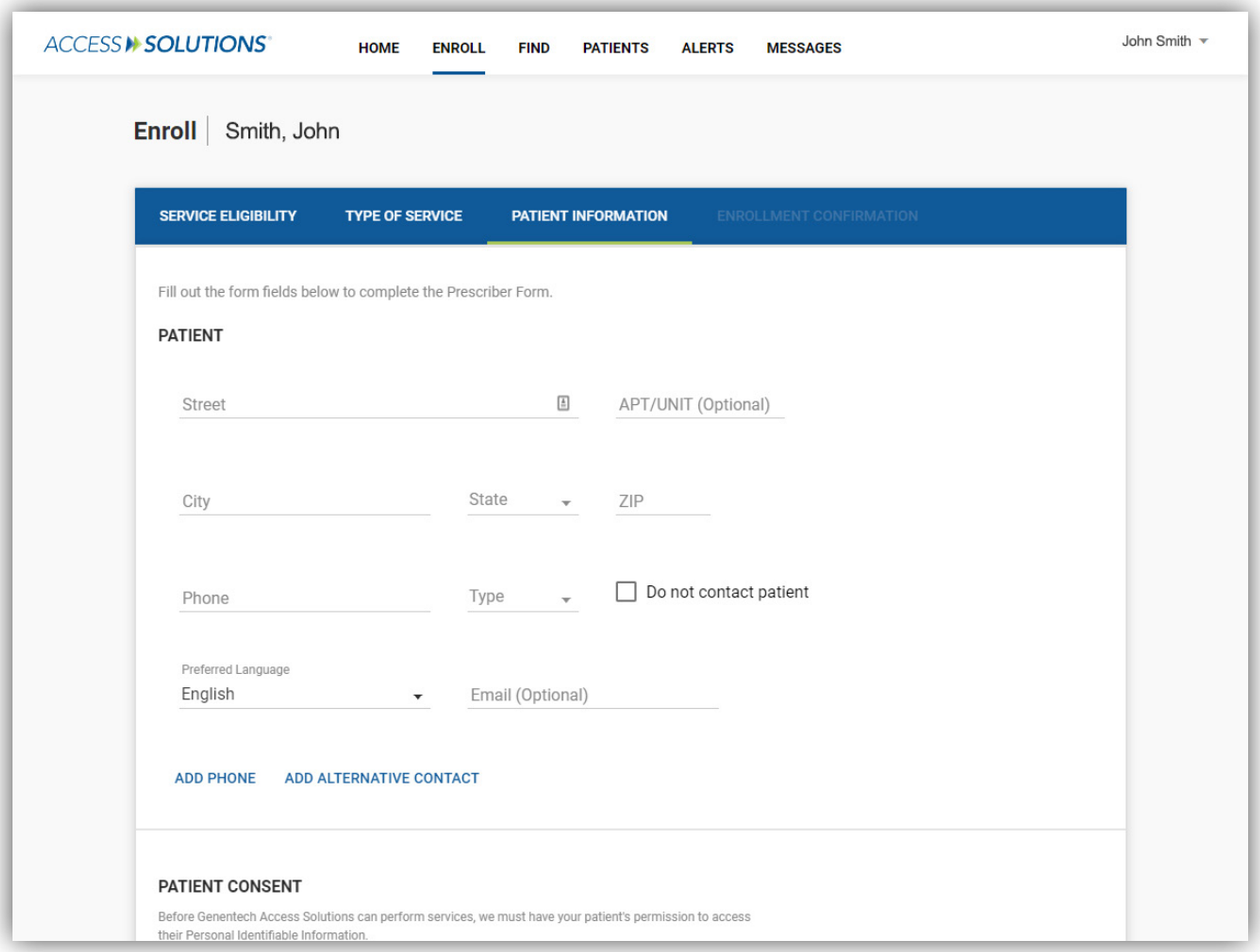


If you select APPEALS SUPPORT:

- Confirm if you have received a denial claim or denial authorization/predetermination for your patient:
  - If you select YES, you will be asked for the denial date, reason and a denial reference number before continuing to the next screen
  - If you select NO, then SUBMIT, you will be taken to the final page of the form

Enroll Patients (cont)

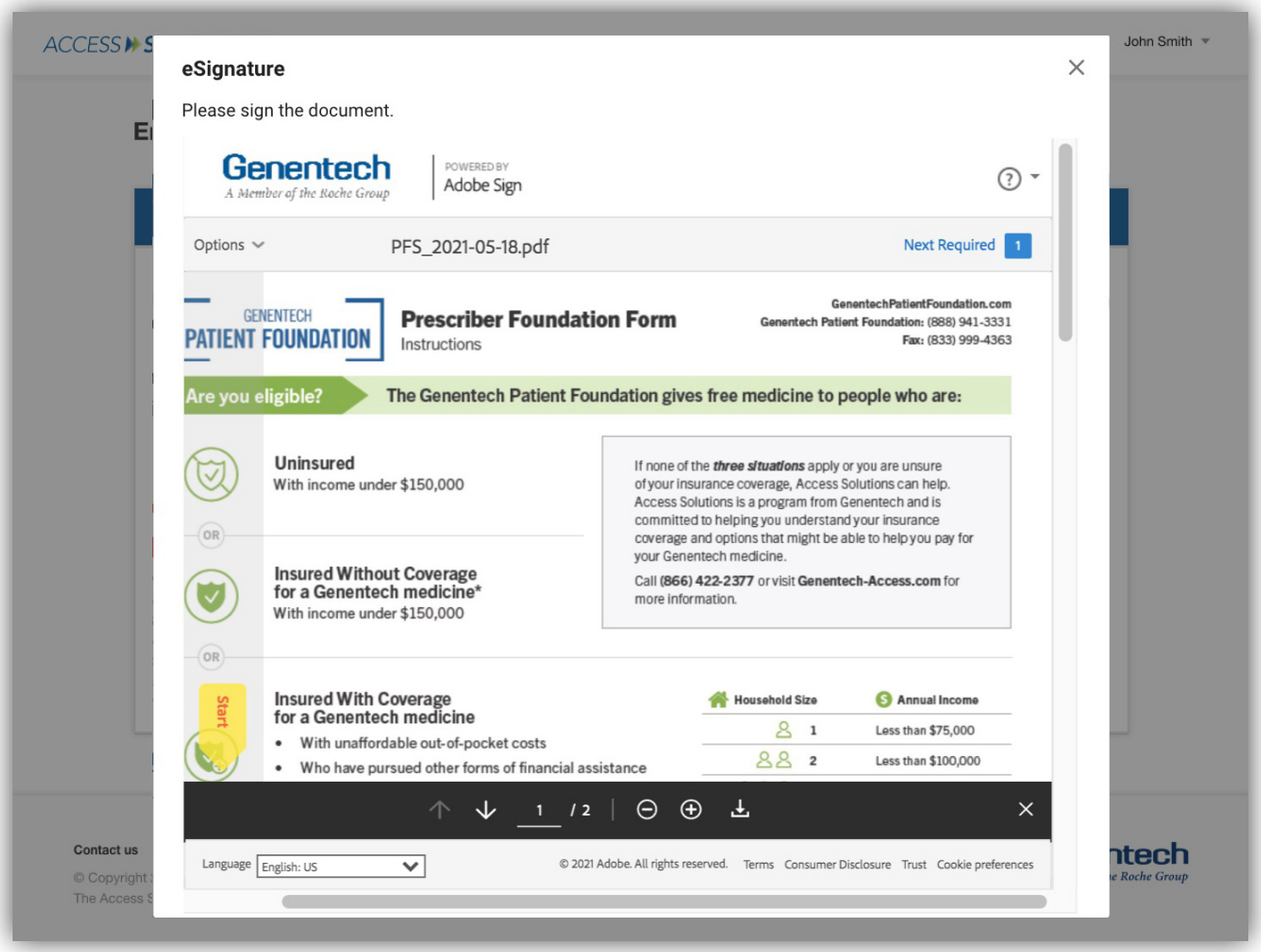
Complete the Prescriber Service Form or Prescriber Foundation Form (cont)



- Complete the final page of the form, which may include additional patient, insurance and provider information
- You can also upload a Patient Consent Form at this stage, as well as provide specific information for your service request(s)

Enroll Patients (cont)

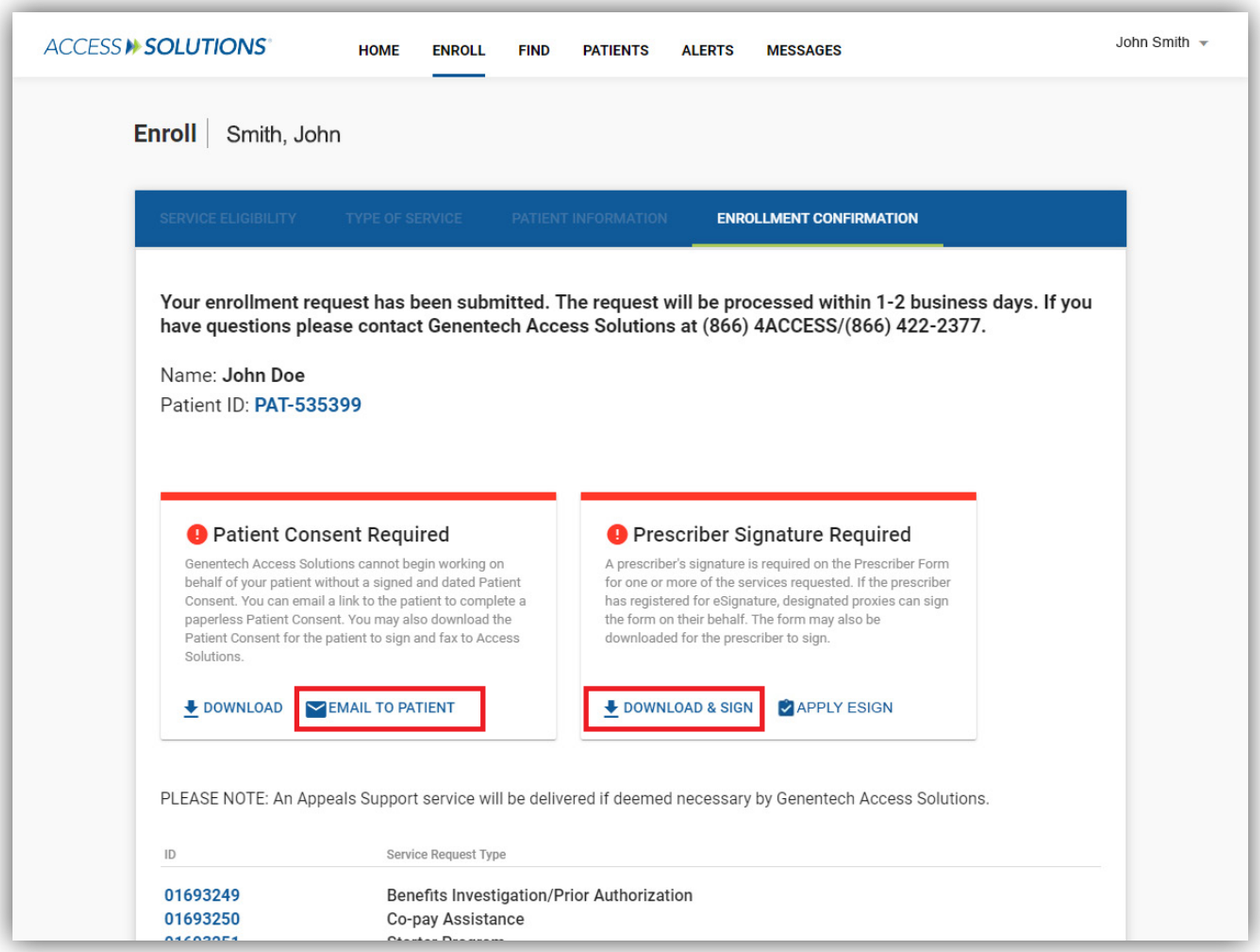
Submit the form using eSignature



- The Prescriber Service Form may require a signature to complete submission
- The Prescriber Foundation Form always requires a prescriber signature
- To use eSignatures:
  - Select APPLY ESIGN (prescribers and proxies only)
  - You will be prompted to apply your eSignature to the form

Enroll Patients (cont)

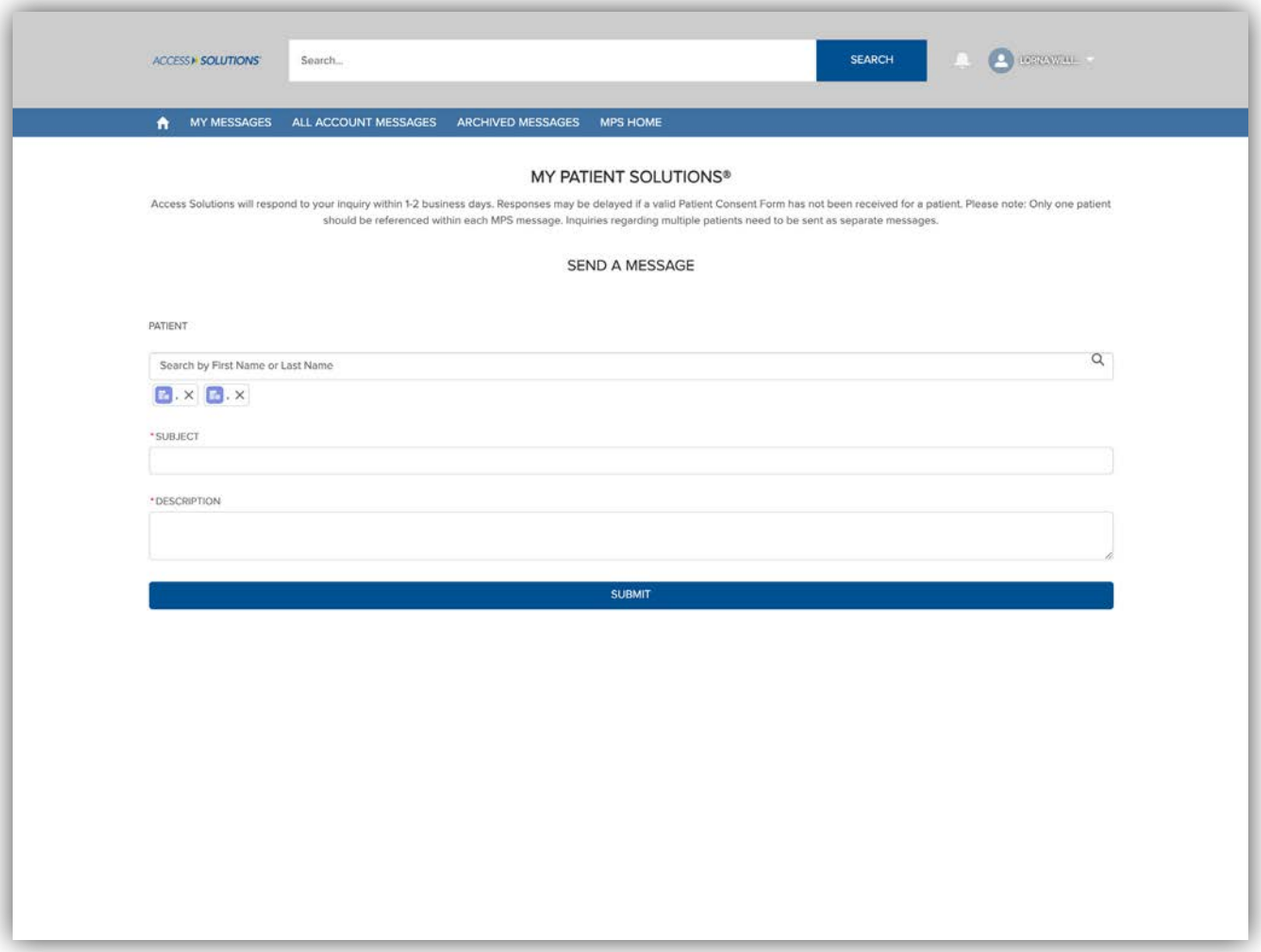
Submit the form without using eSignature



- Depending on the services requested, the Prescriber Service Form may require a prescriber signature
- The Prescriber Foundation Form always requires a signature
- If you do not use eSignature, you can:
  - Download and print the form, then have the prescriber sign it
  - Either fax the form to Genentech Access Solutions/the Genentech Patient Foundation or upload it to My Patient Solutions® for Health Care Practices via the SERVICE REQUEST DETAILS screen
- From this screen you can also send the patient a link to the paperless Patient Consent Form to complete enrollment

Enroll Patients (cont)

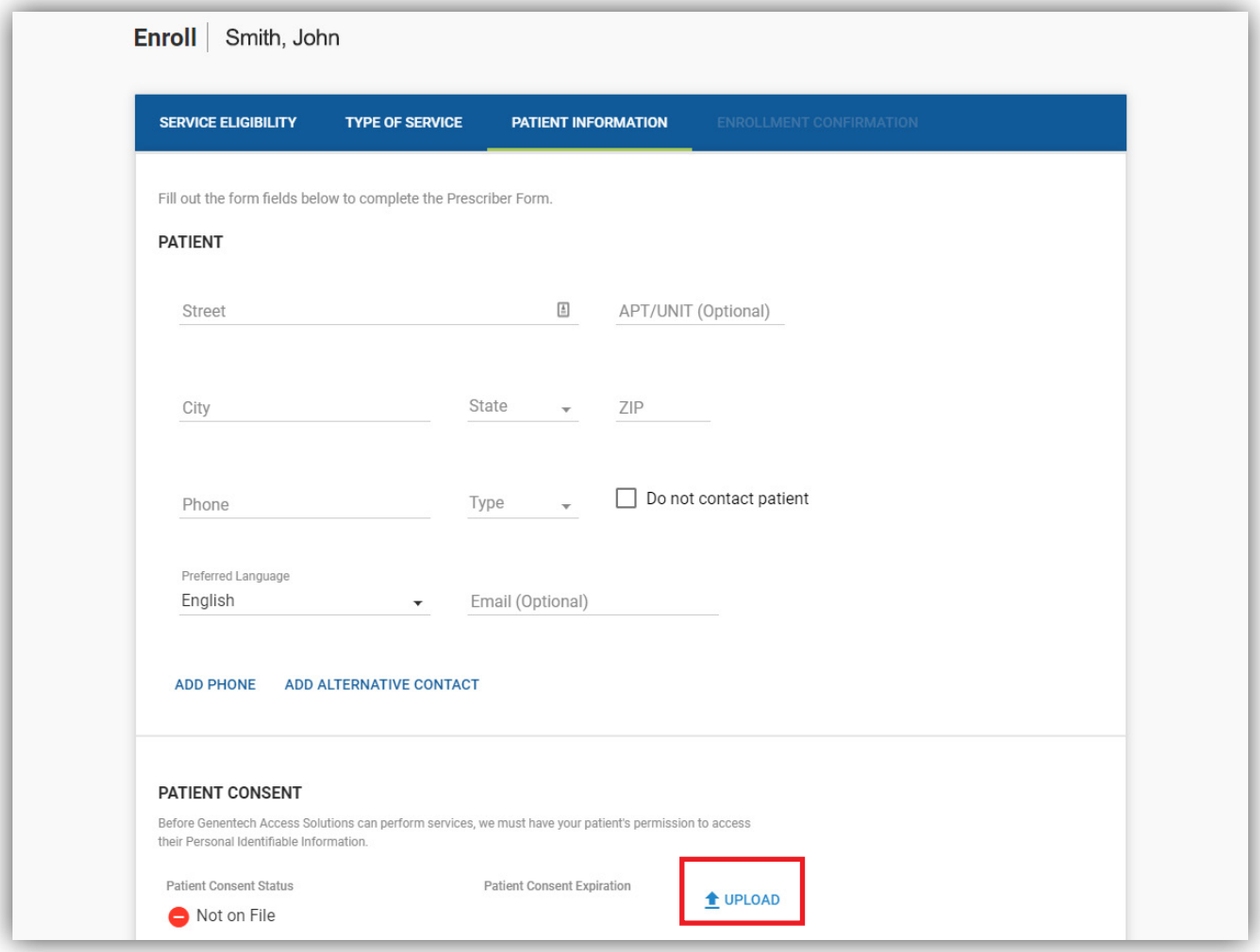
Correct information (if needed) using the messaging feature



- Use the messaging feature to correct information on the Prescriber Service Form, Prescriber Foundation Form or Patient Consent Form, if needed
- See Message Your Genentech Access Solutions Specialist for more information

Enroll Patients (cont)

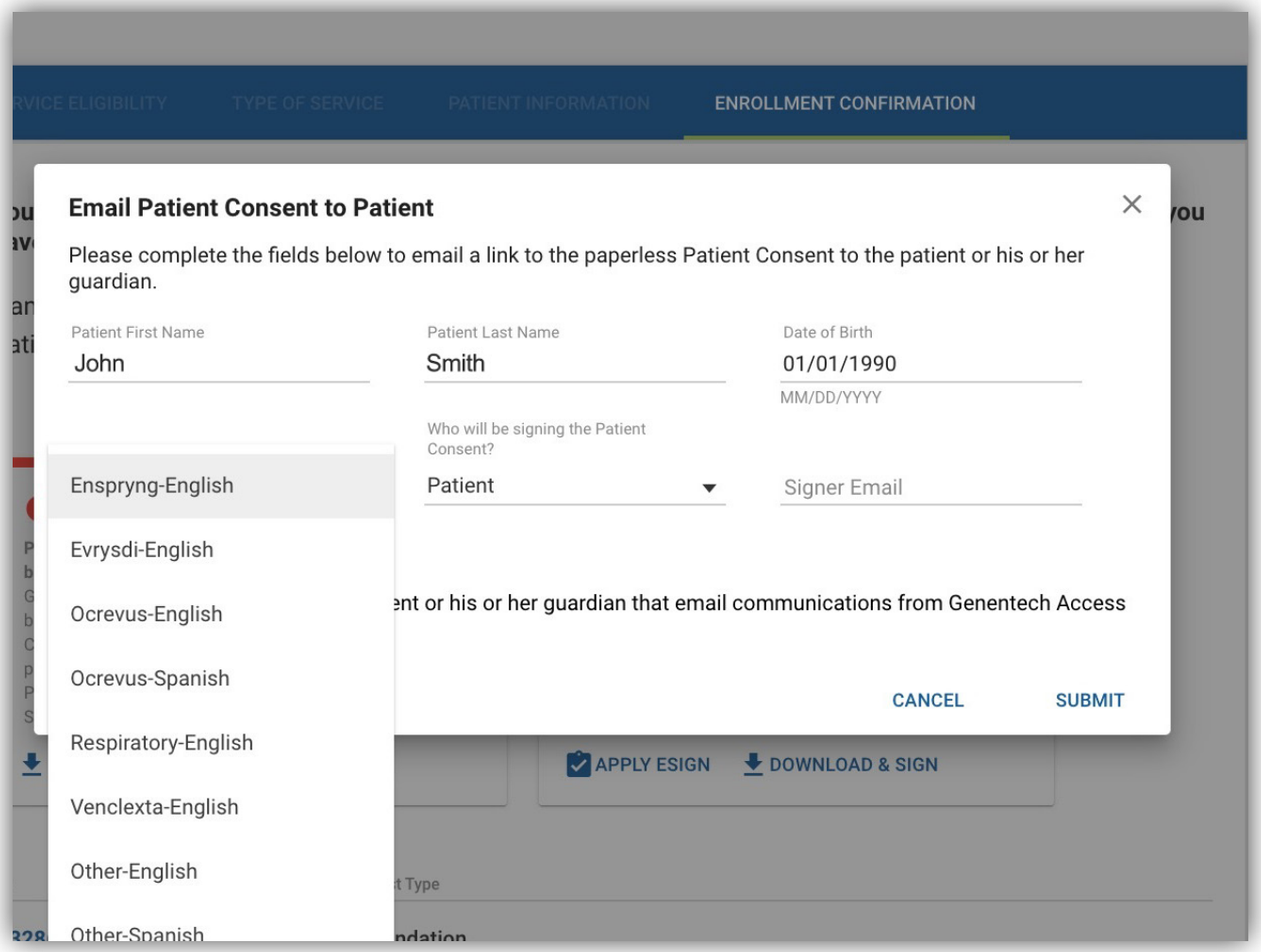
Upload the Patient Consent Form to My Patient Solutions® for Health Care Practices



- Upload a scanned copy of the completed Patient Consent Form
  - This can be done from the PATIENT INFORMATION or ENROLLMENT CONFIRMATION screen

Enroll Patients (cont)

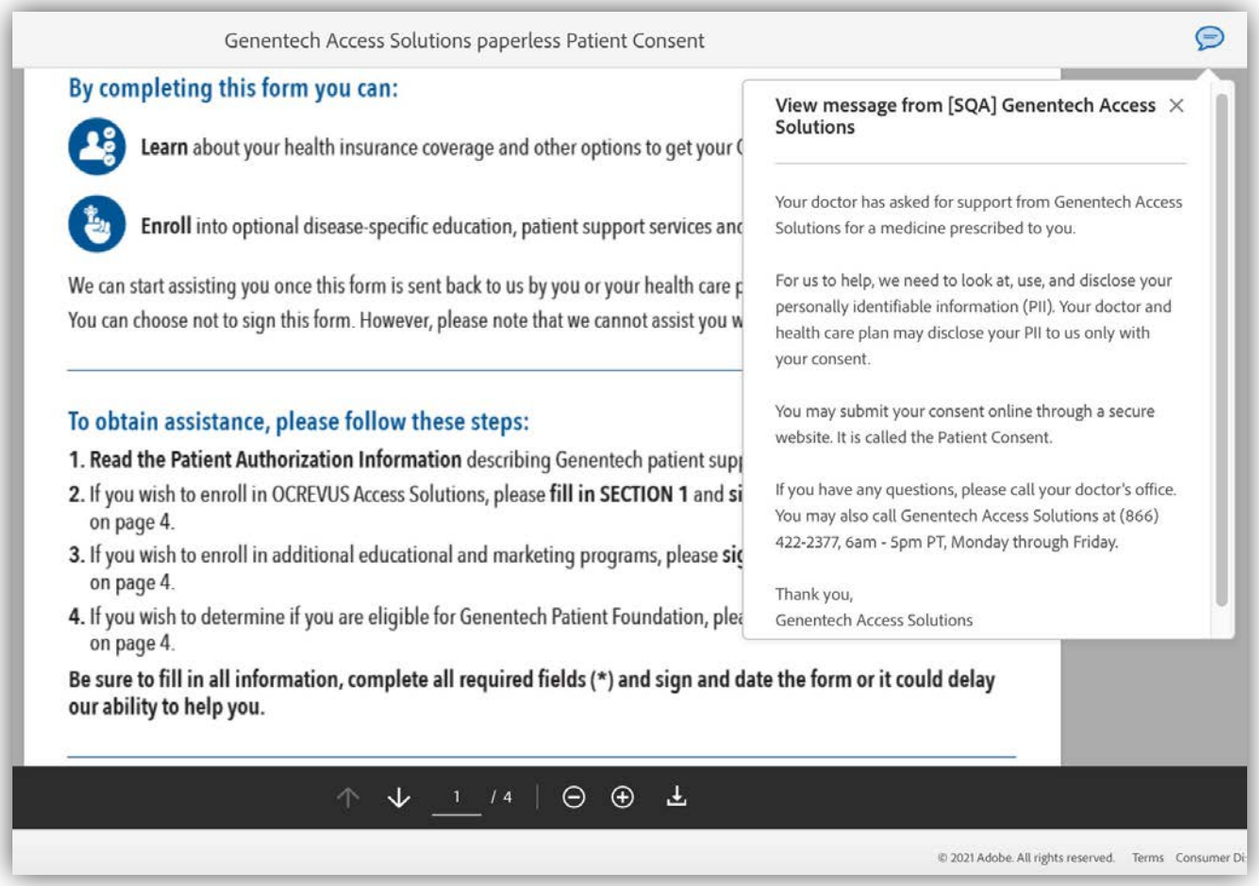
Send a link to the paperless Patient Consent Form



- Select EMAIL TO PATIENT from the ENROLLMENT CONFIRMATION SCREEN to send your patient a link to the paperless Patient Consent Form
  - This link may also be sent from the Patient List (under the ACTIONS dropdown menu) or within the patient's profile

Enroll Patients (cont)

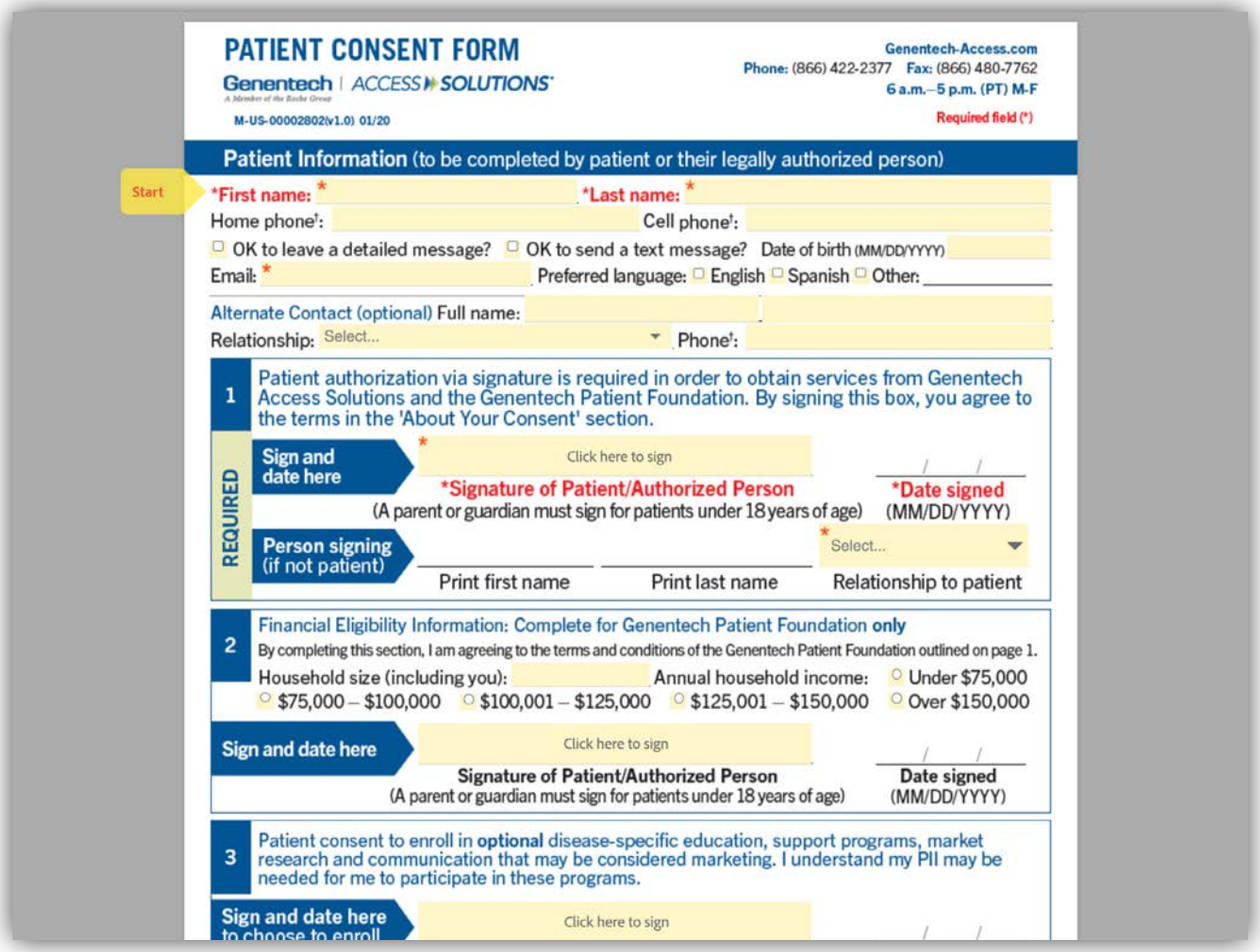
Send a link to the paperless Patient Consent Form (cont)



- Patients select the link in the email and are taken directly to the paperless Patient Consent Form to complete enrollment:
  - Patients can also access the paperless Patient Consent Form directly at Genentech-Access.com/PatientConsent
  - Certain brands have different forms. Any brand-specific Patient Consent Form can be found at Forms and Documents on Genentech-Access.com

Enroll Patients (cont)

Access the paperless Patient Consent Form



- Patients complete the paperless Patient Consent Form
- Patients may use their finger (on mobile devices) or a mouse (on desktop devices) to sign the paperless Patient Consent Form

Enroll Patients (cont)

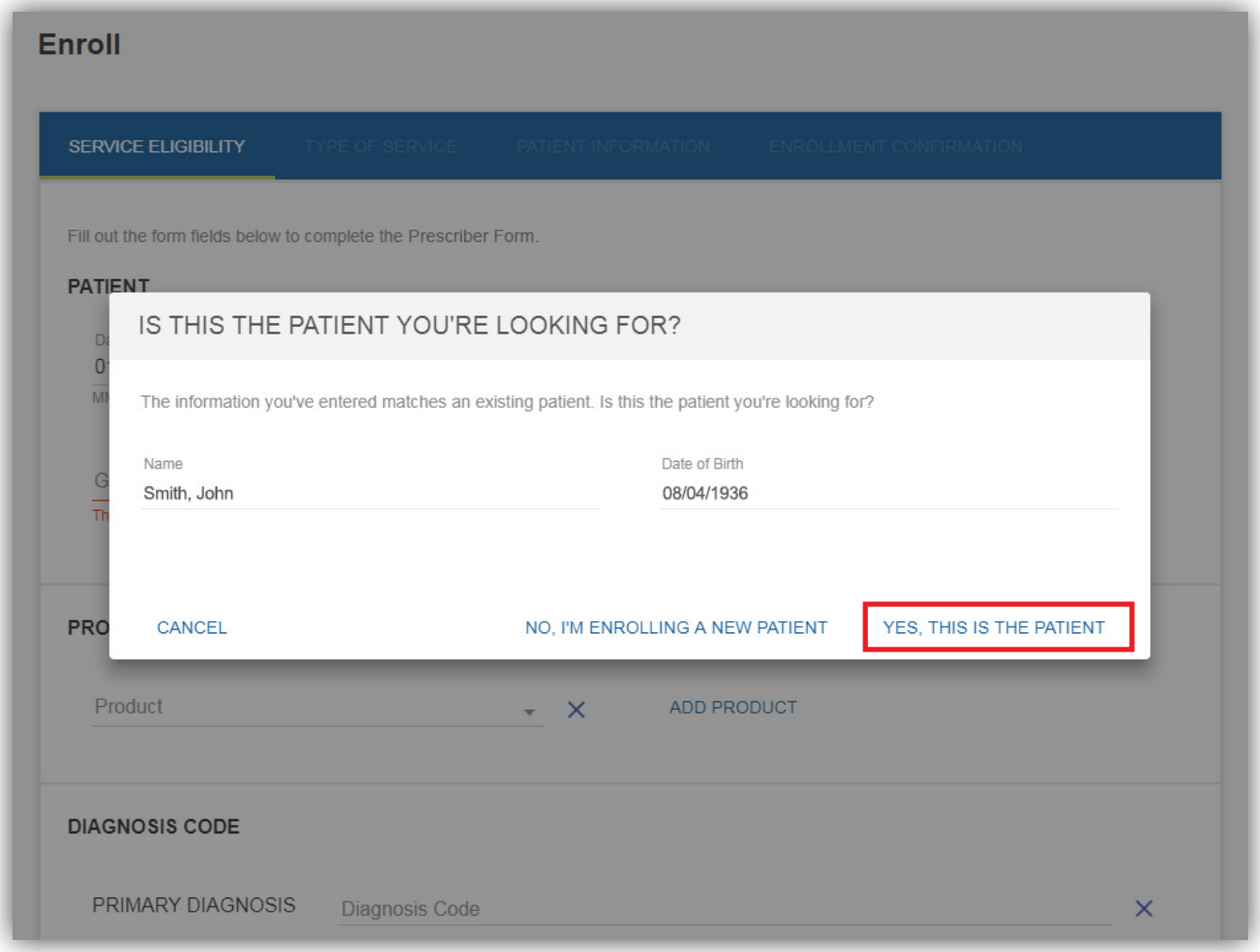
Important points to remember about patient enrollment

- My Patient Solutions® for Health Care Practices notifies you if any required fields on the Prescriber Service Form have not been completed; the paperless Patient Consent Form has similar functionality
- If the prescriber does not have an eSignature activated, you will be prompted to download the Prescriber Service Form and then upload a scanned copy of the signed form within the NEXT STEPS section of the service request
- If a signature is not required, the Prescriber Service Form submission is complete
- You can also submit the completed form:
  - Via Quick Enroll by selecting E-Submit in Forms and Documents at Genentech-Access.com
  - By downloading and faxing the form
- If your office does not have scanning capabilities, the signed paper Patient Consent Form can be sent to Genentech Access Solutions via fax or text message
- To ensure patients receive the form in their message inbox, please advise them to add **echosign@echosign.com** to their address book or safe list

Re-enroll Patients

Re-enrolling your patients is easy with My Patient Solutions® for Health Care Practices. There are 3 ways to re-enroll patients.

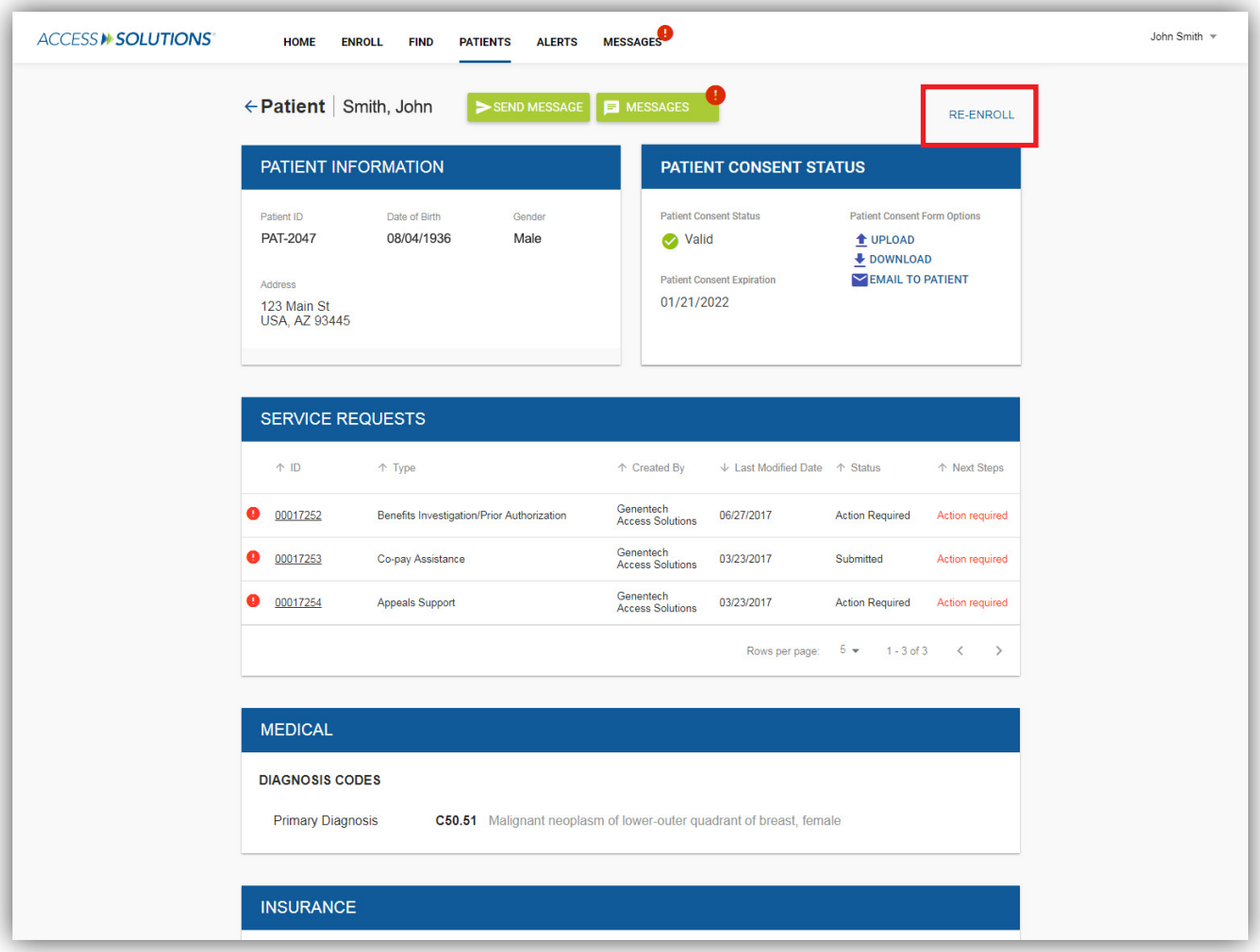
Via the enrollment screen



- Begin typing in the patient's details
  - — My Patient Solutions will alert you if the information matches an existing patient
- Select YES, THIS IS THE PATIENT to continue

Re-enroll Patients (cont)

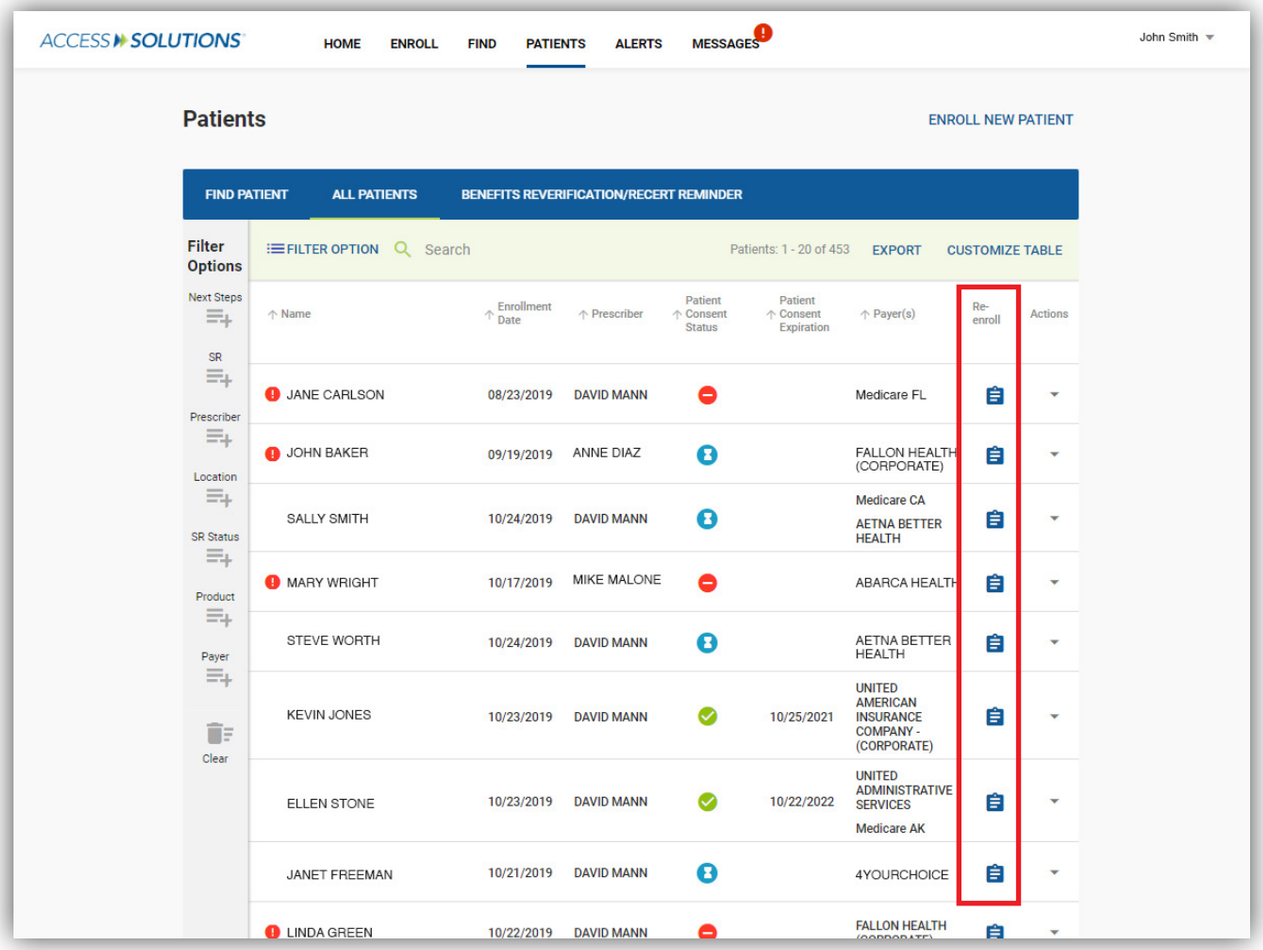
Via the patient profile screen



Select RE-ENROLL at the top right corner of the patient profile.

Re-enroll Patients (cont)

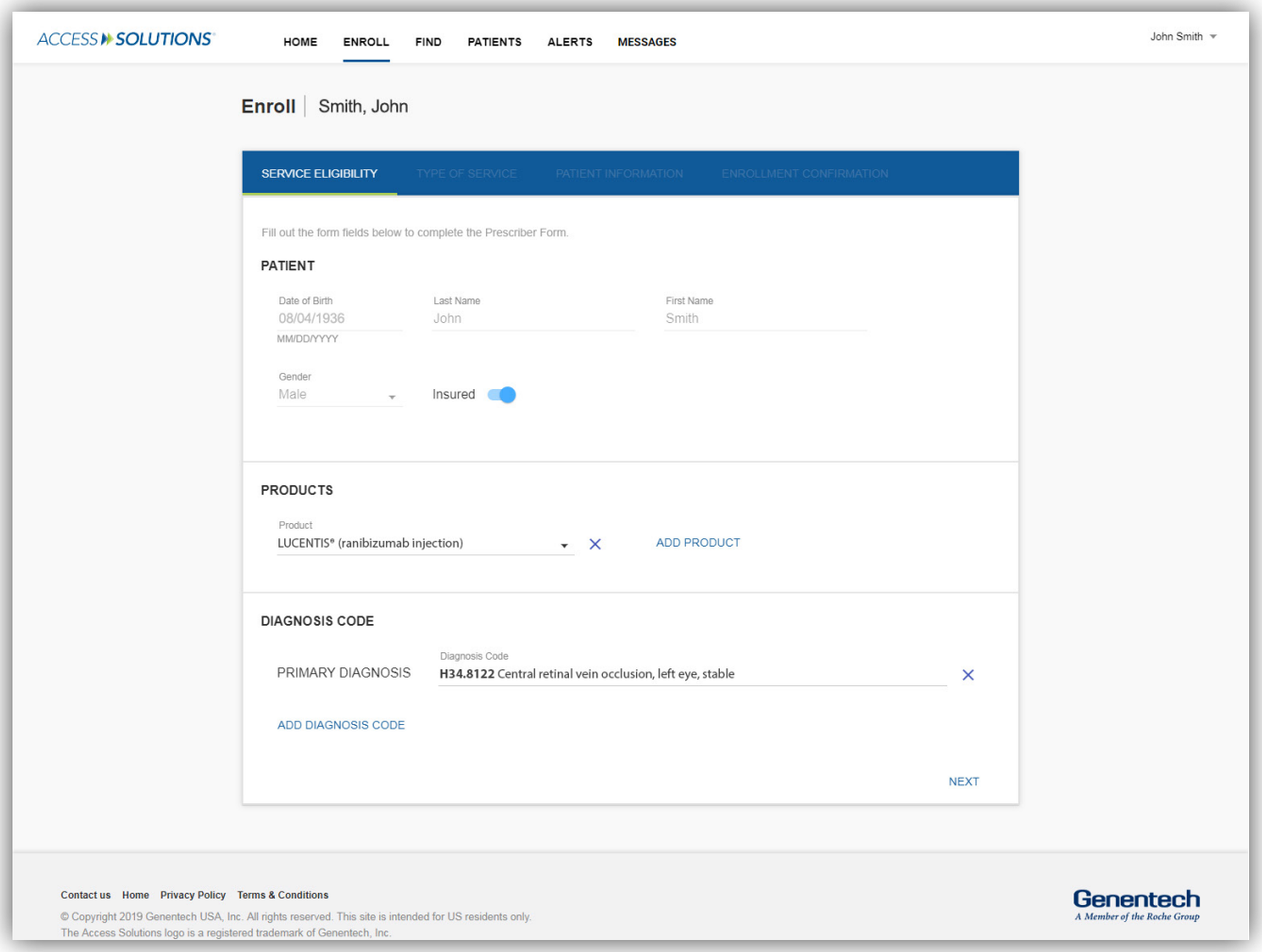
Directly from the patient list



Select the icon under RE-ENROLL for the appropriate patient.

Re-enroll Patients (cont)

Directly from the patient list (cont)

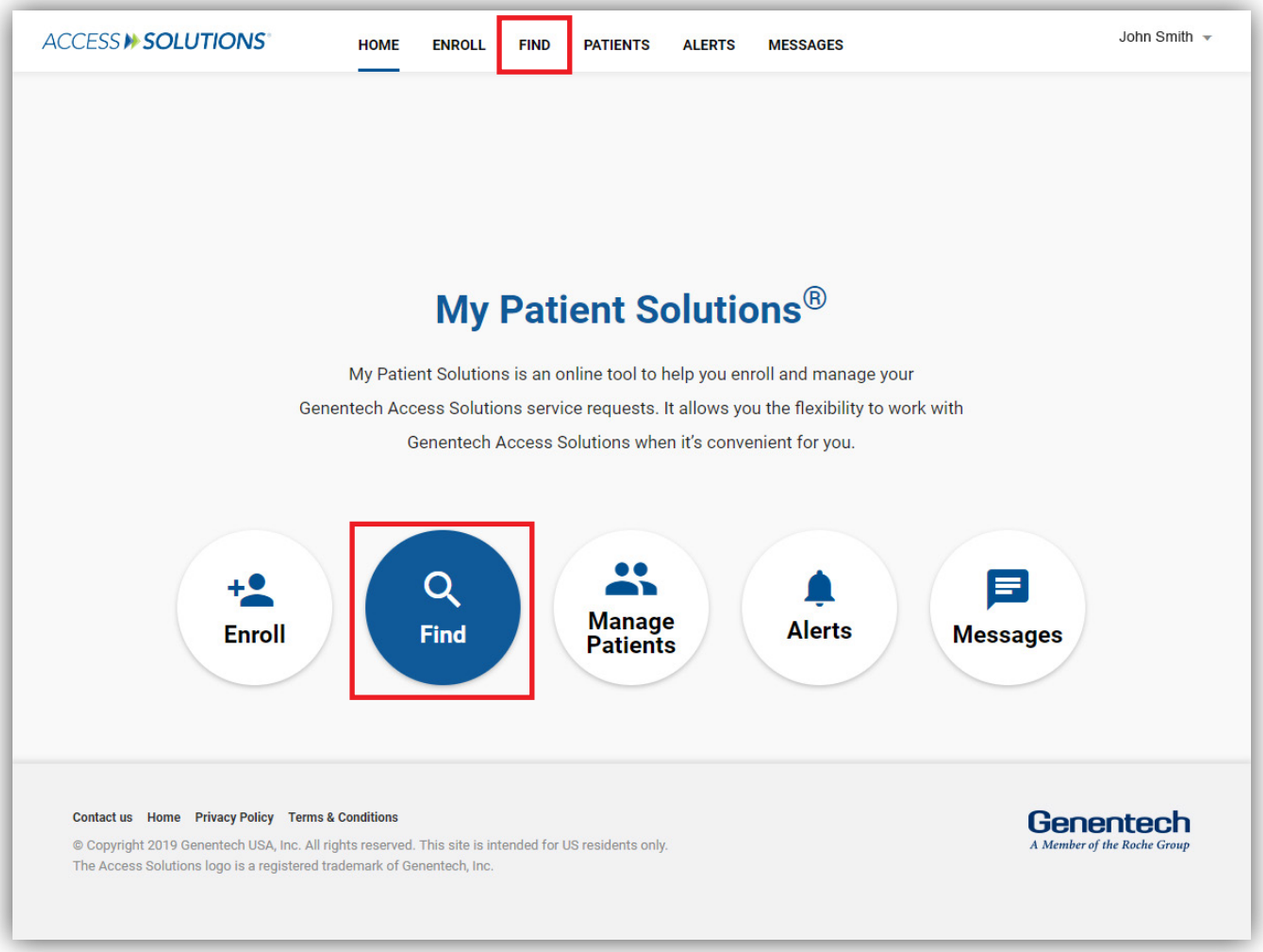


- Review the information in the prepopulated enrollment form
- Reselect the type(s) of services you are requesting and submit the form

Your Patient List

Your patients who have been enrolled in Genentech Access Solutions and/or the Genentech Patient Foundation within the past 18 months are populated in the patient list. Here you can access several useful features, including searching for specific patients, uploading Patient Consent Forms, re-enrolling patients and seeing which patients require further action (designated with a ! icon).

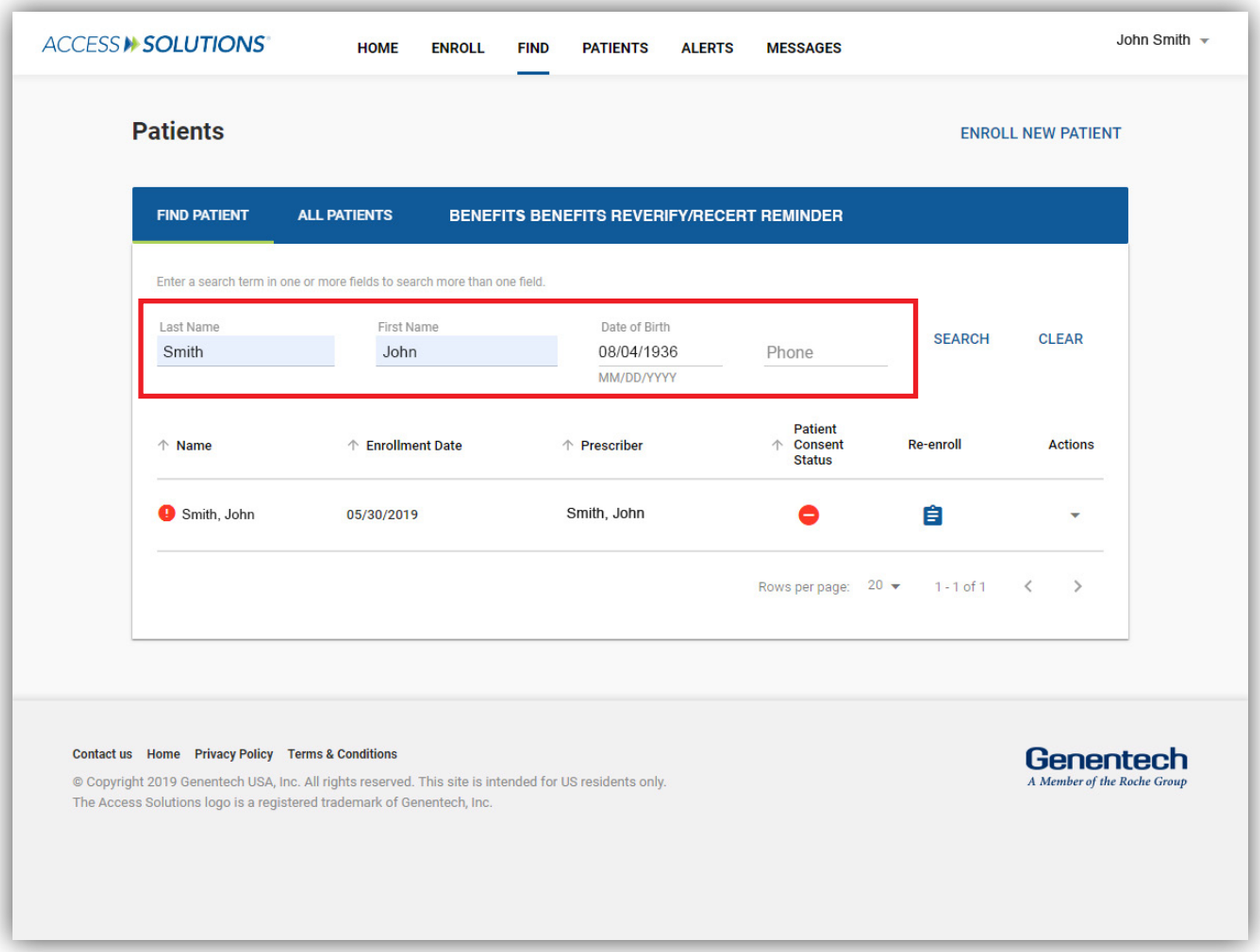
Search for patients



- Select FIND from the center of the screen or from the top navigation bar
  - This takes you to the FIND PATIENT tab of the Patients section

Your Patient List (cont)

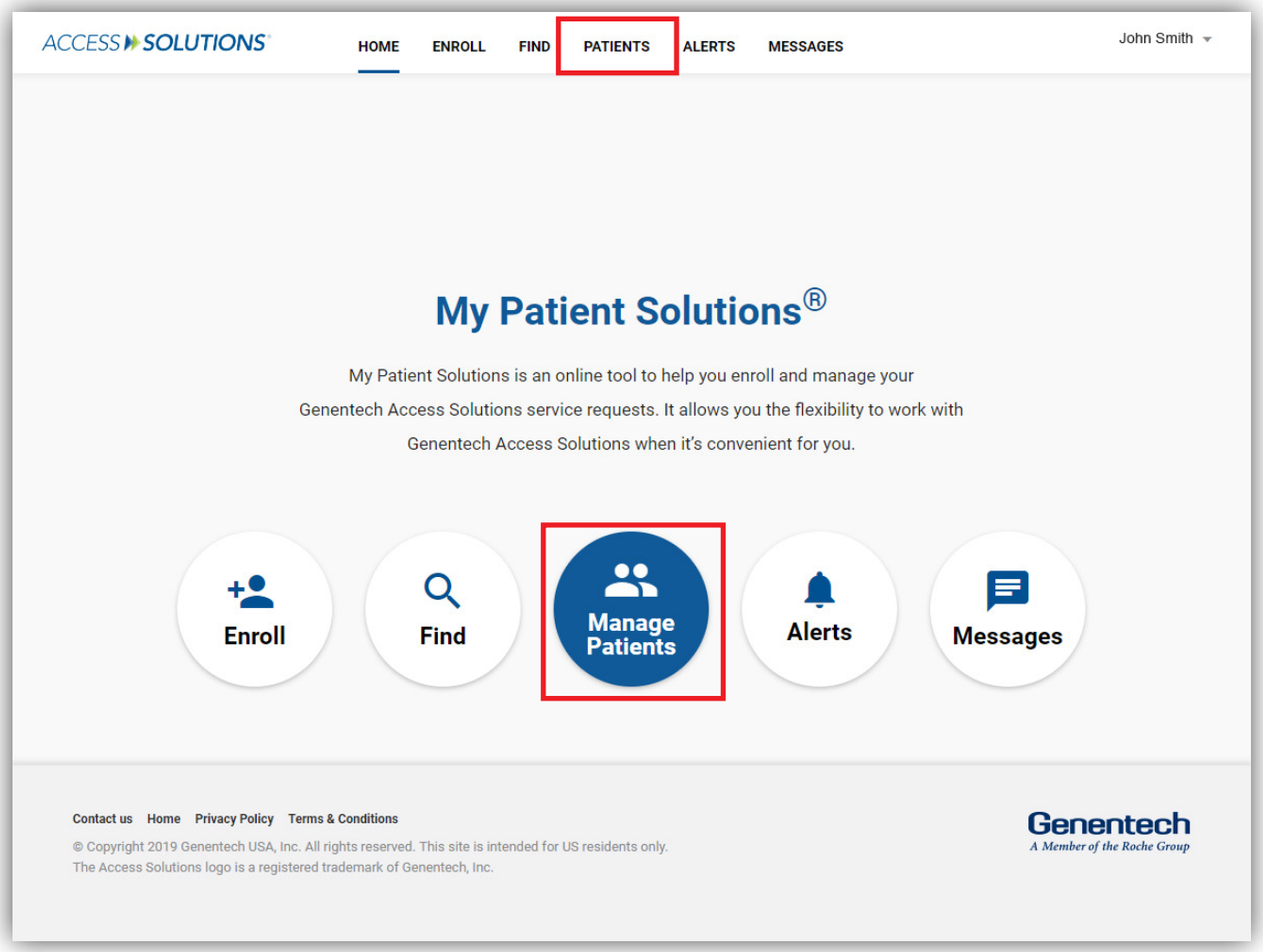
Search for patients (cont)



- Search for a patient by his or her first name, last name, date of birth or phone number:
  - Only 1 of these search criteria is required
  - The results will be returned below the search fields

Your Patient List (cont)

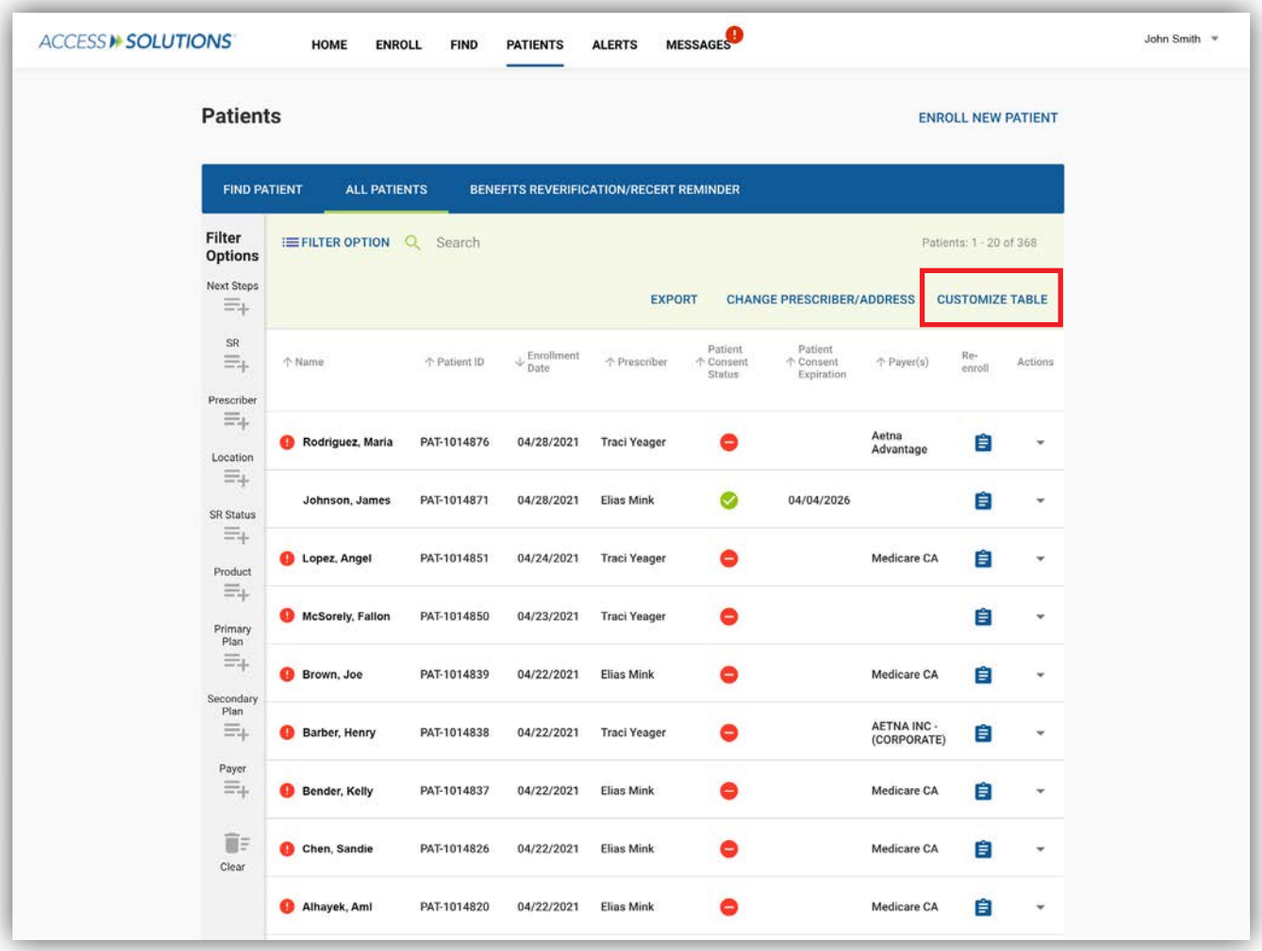
Access your patient list



- Select MANAGE PATIENTS from the center of the screen or PATIENTS from the top navigation bar
  - — This takes you directly to the ALL PATIENTS tab of your patient list

Your Patient List (cont)

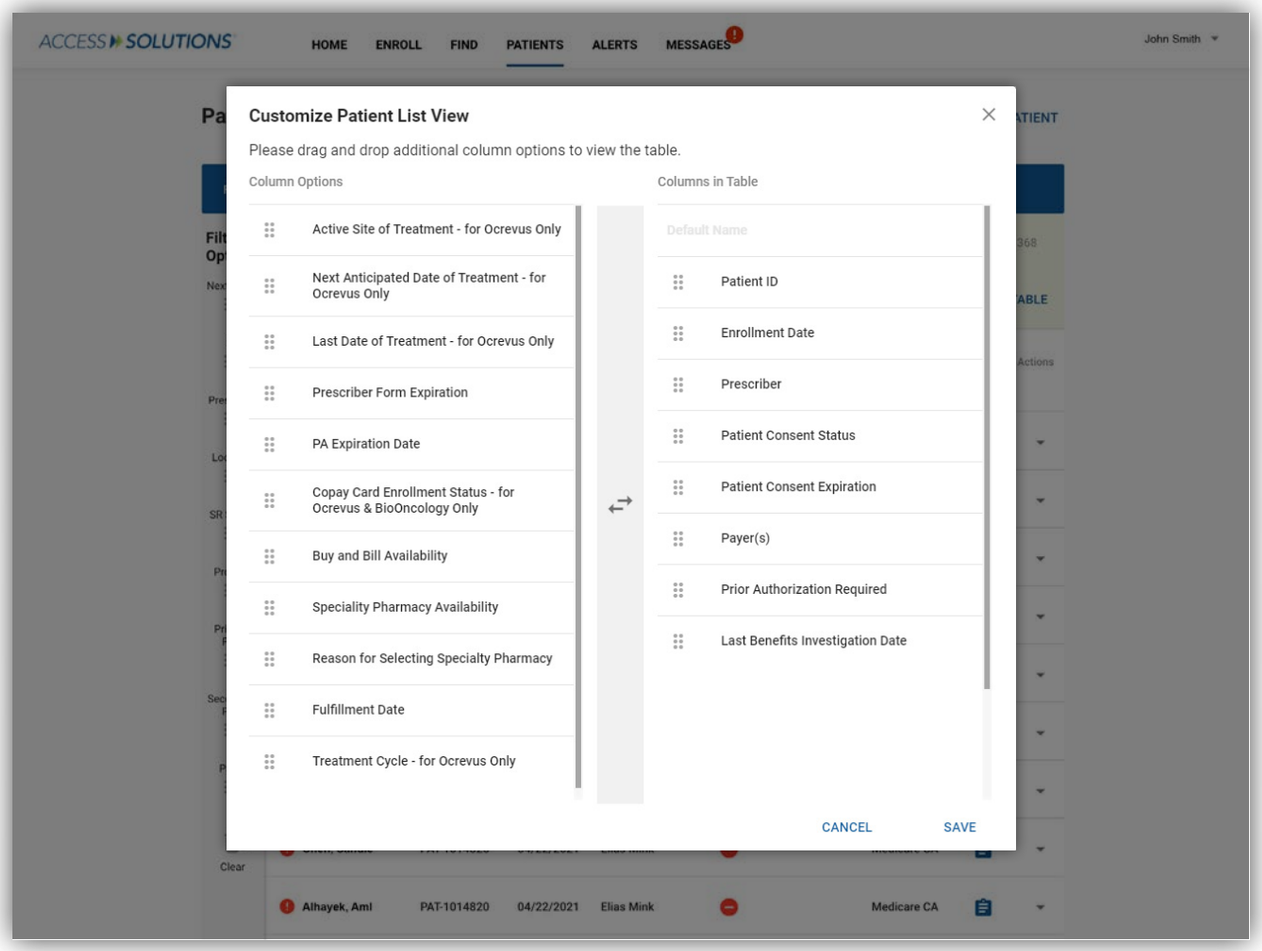
Customize your patient list



- Select the CUSTOMIZE TABLE link
  - An overlay will appear that allows you to select which columns will be displayed in your patient list

Your Patient List (cont)

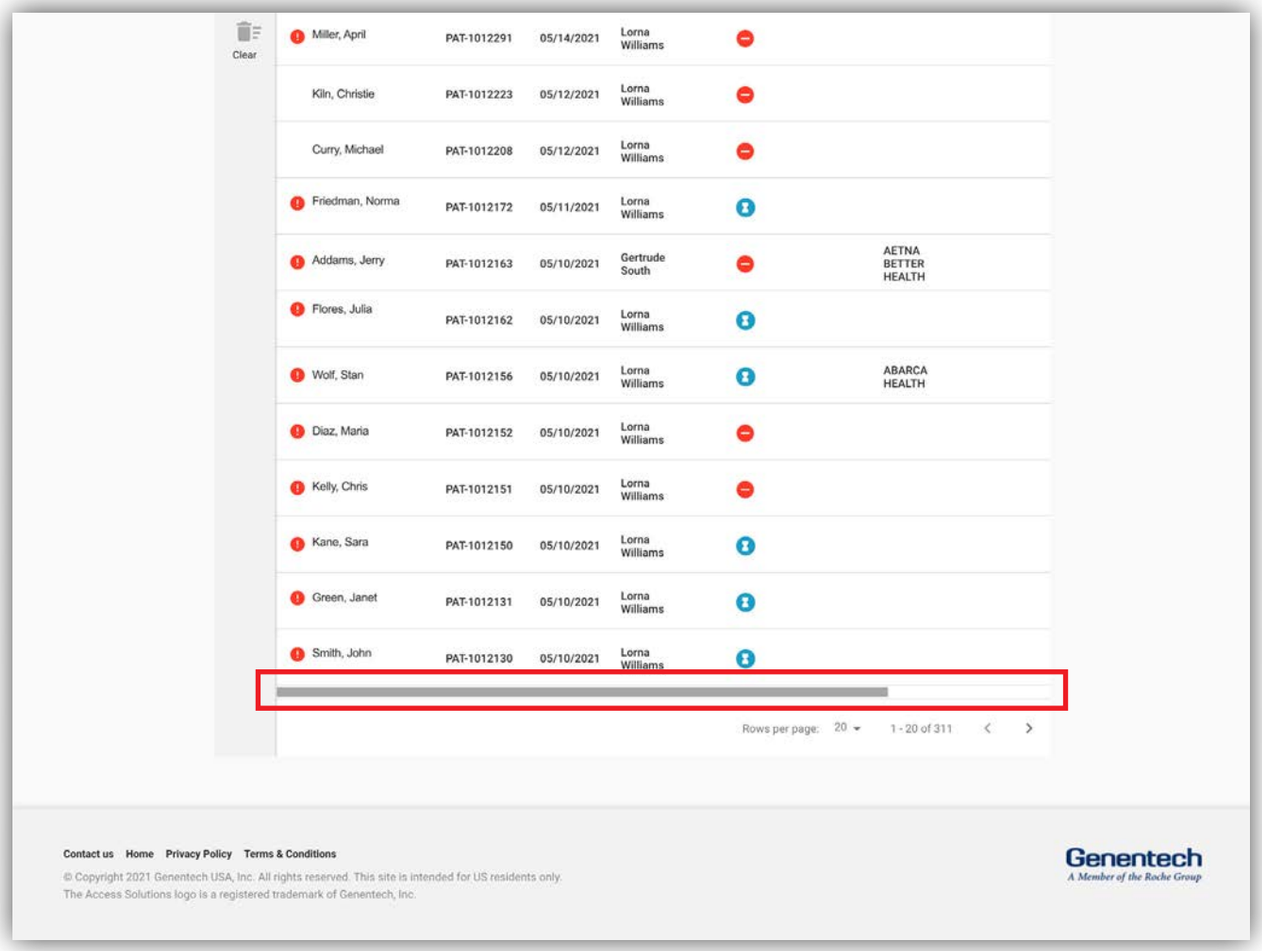
Customize your patient list (cont)



- Drag and drop column options into your list
  - — You can reorder columns as you see fit
- Save your preferences
- Some columns are available for certain brands only (and are indicated as such)

Your Patient List (cont)

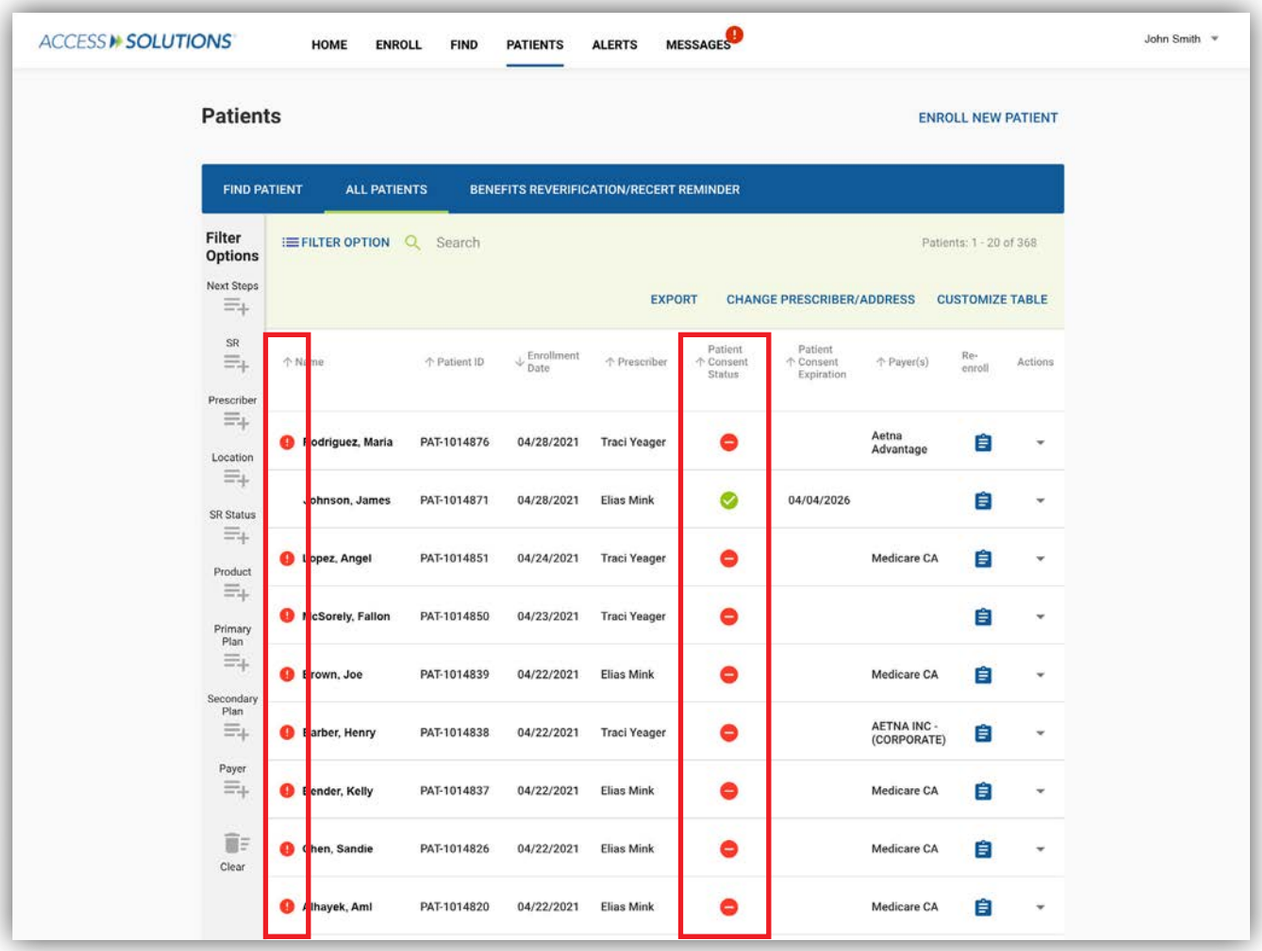
Customize your patient list (cont)



Use the horizontal scroll bar at the bottom of the page to view additional columns if the number of columns you selected exceeds the space allowed on the screen.

Your Patient List (cont)

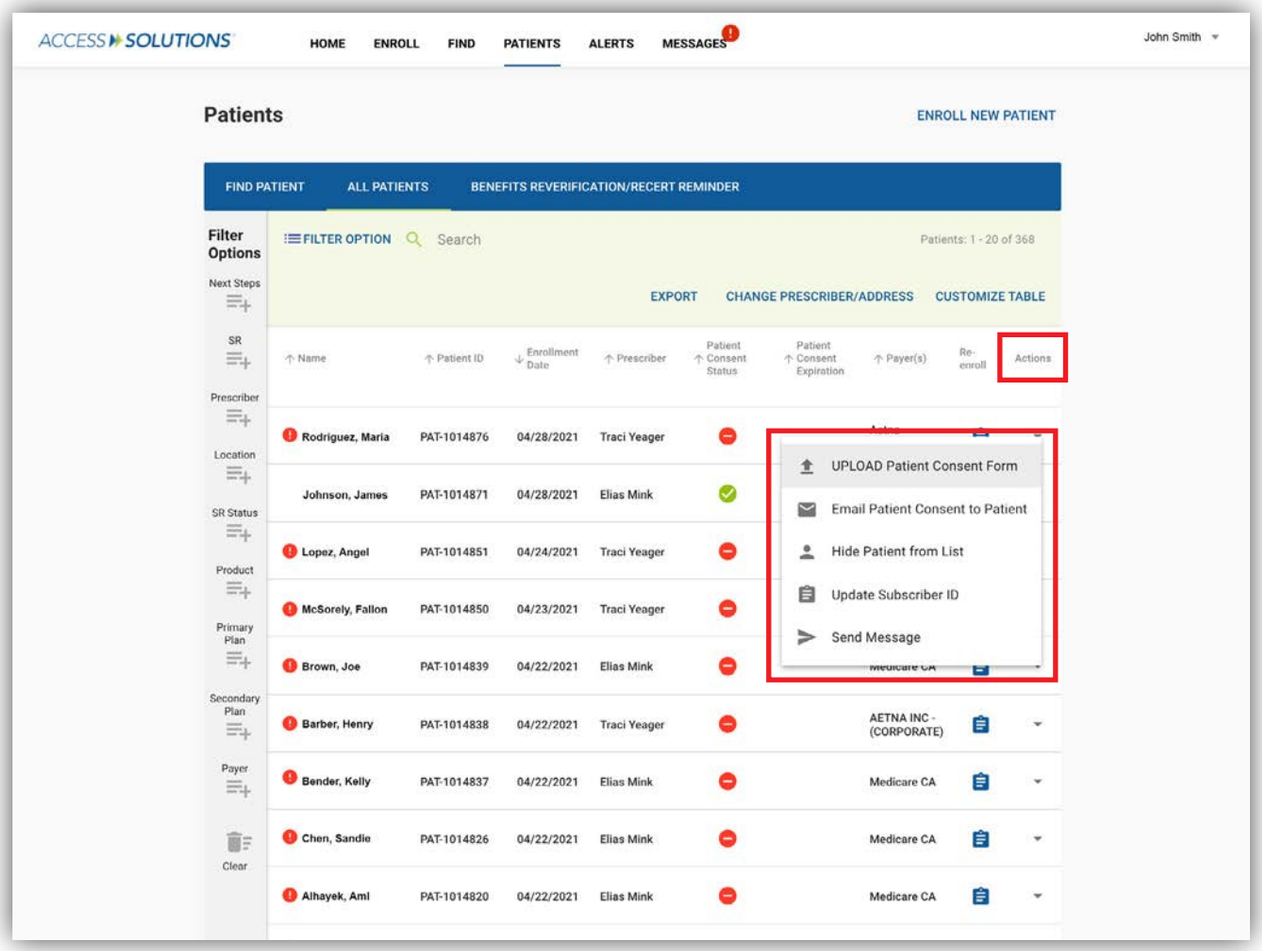
View your patient list



- Determine if an action needs to be taken (shown by the ! icon)
- Confirm if the patient has a valid Patient Consent Form on file (shown by the ✓ and − icons; the ⧗ icon means the Patient Consent Form is pending and the ! icon means the form is incomplete)
  - You can hover over each icon for more information or view a legend here

Your Patient List (cont)

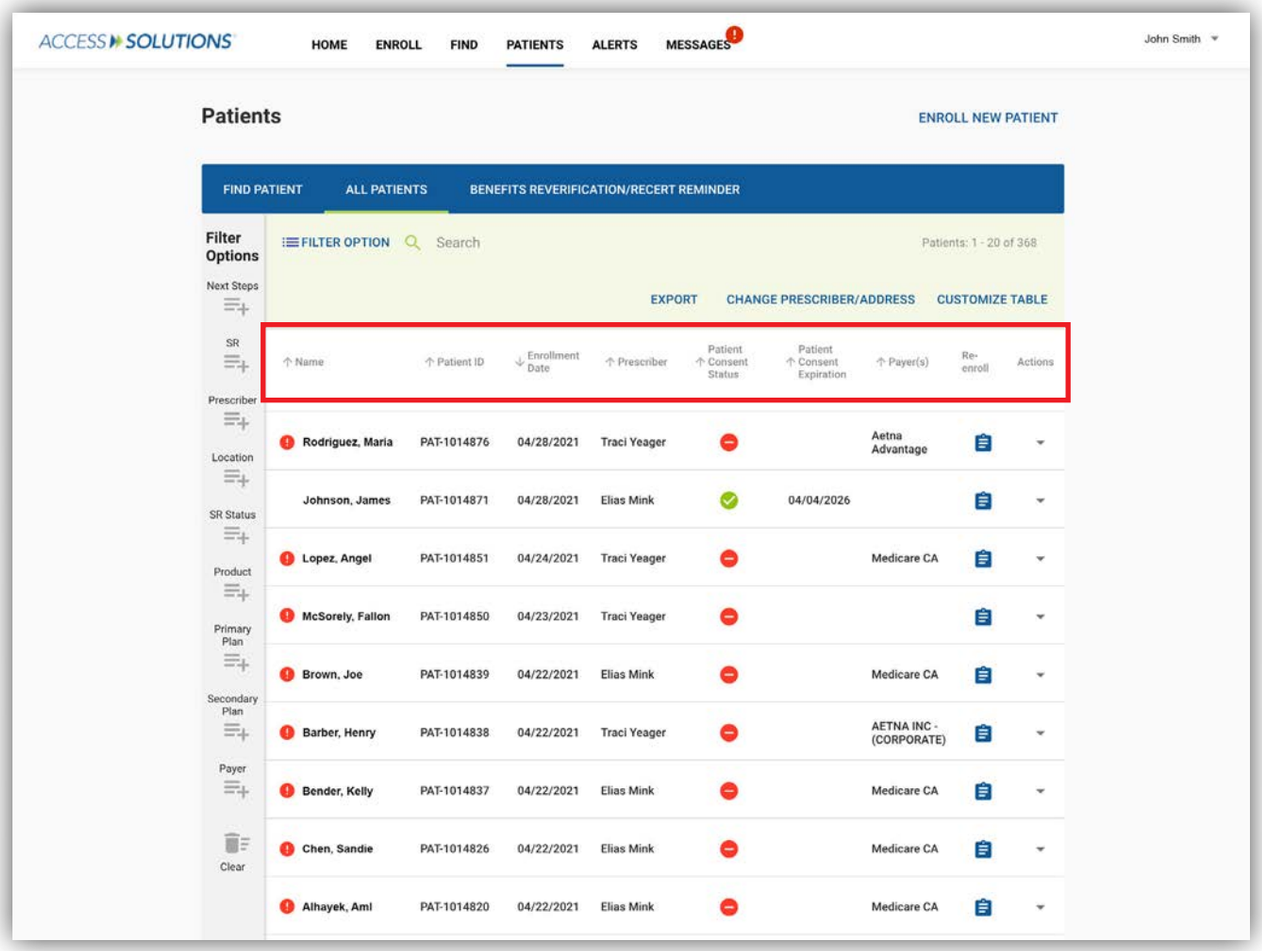
View your patient list (cont)



- Use the ACTIONS dropdown menu to:
  - — Upload a scanned copy of the Patient Consent Form
  - — Email the patient a link to the paperless Patient Consent Form
  - — Hide the patient from your patient list
  - — Update the Subscriber ID for a patient's insurance
  - — Send a message to your Genentech Access Solutions or Genentech Patient Foundation Specialist

Your Patient List (cont)

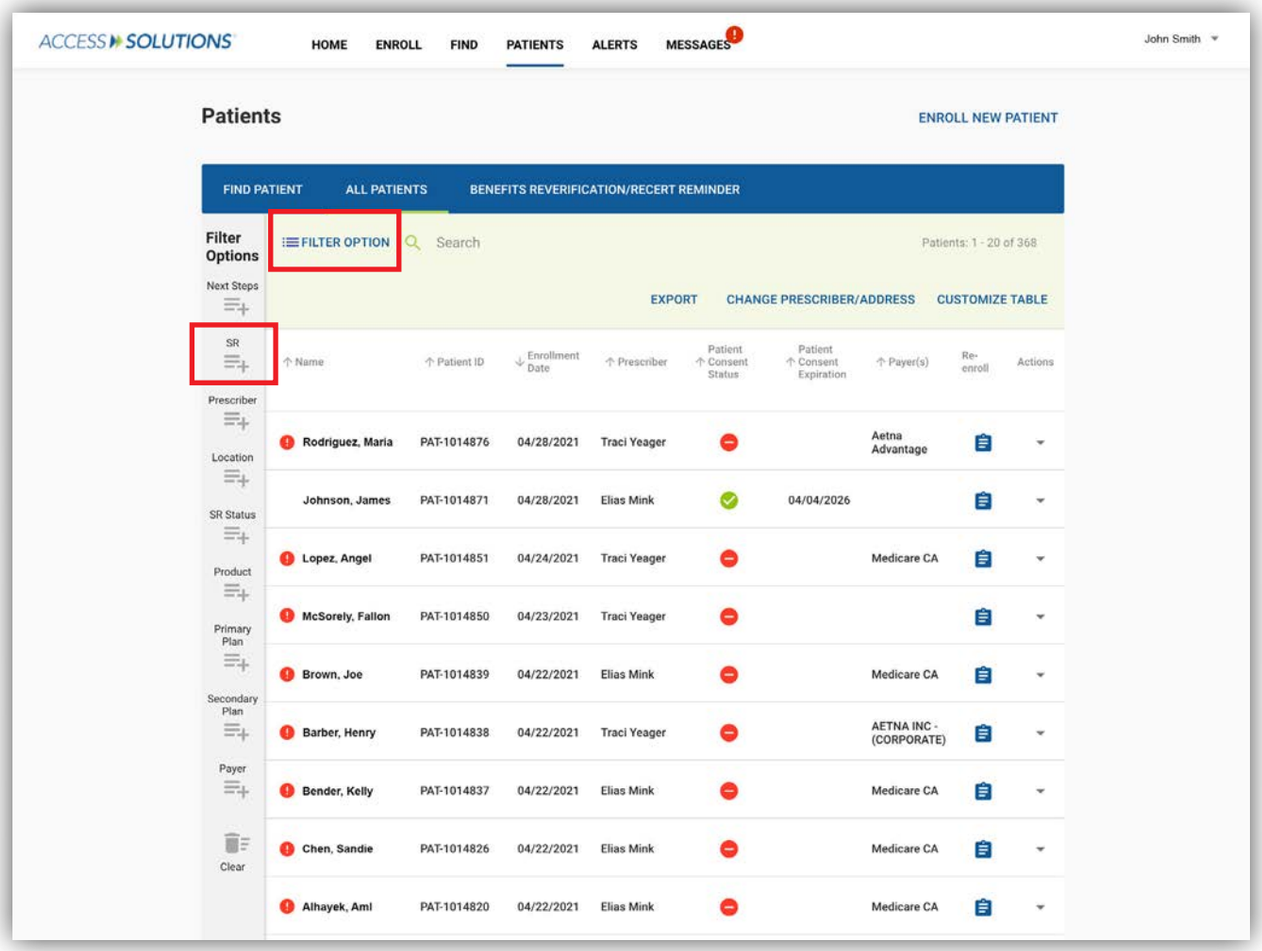
Sort your patient list



- Sort your patient list by any of the columns you selected that have an ↑ or ↓ icon next to the column name
- Select the column header to sort by that column

Your Patient List (cont)

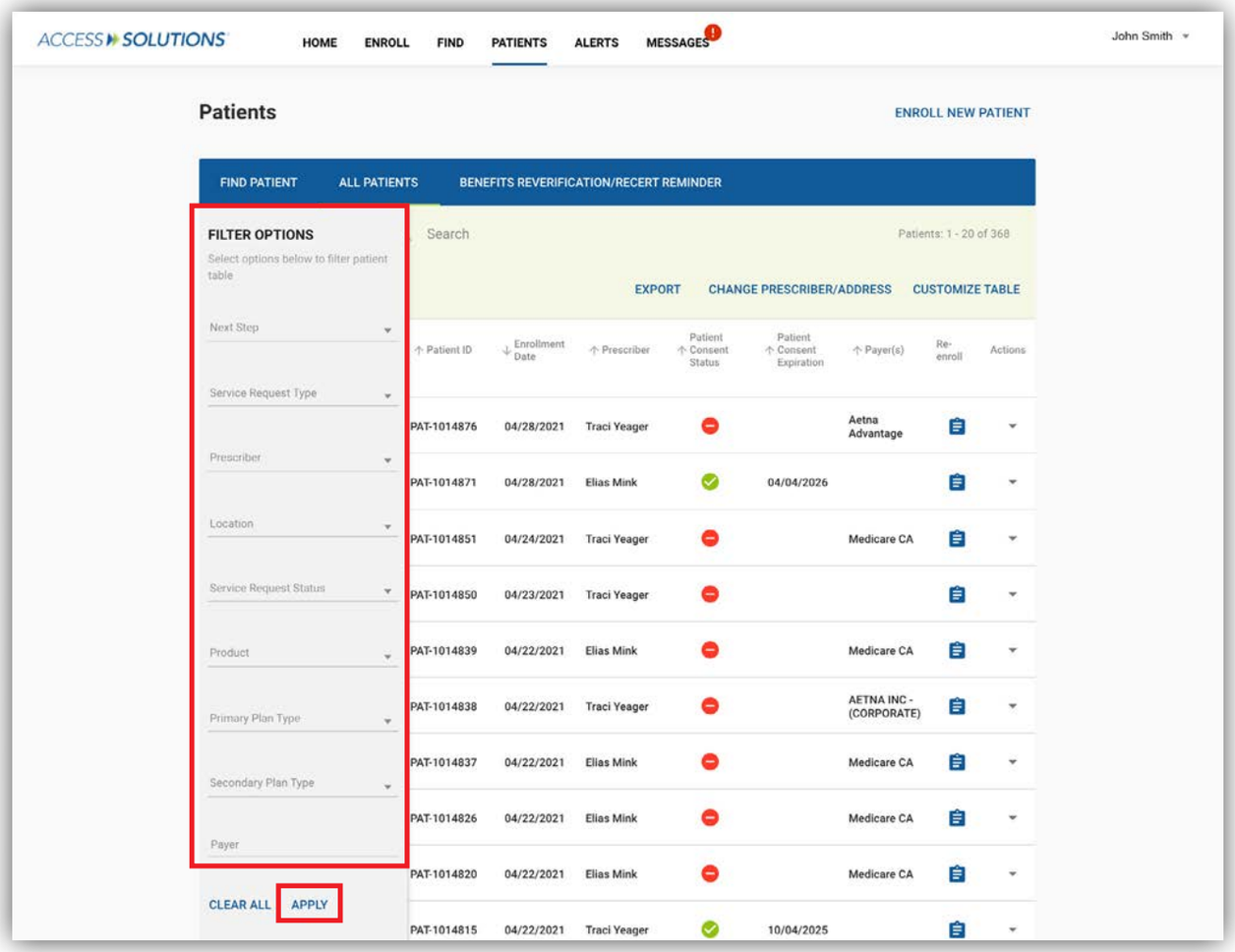
Filter your patient list



To expand the filtering options, select a filtering category or FILTER OPTION at the top of the screen next to the search bar.

Your Patient List (cont)

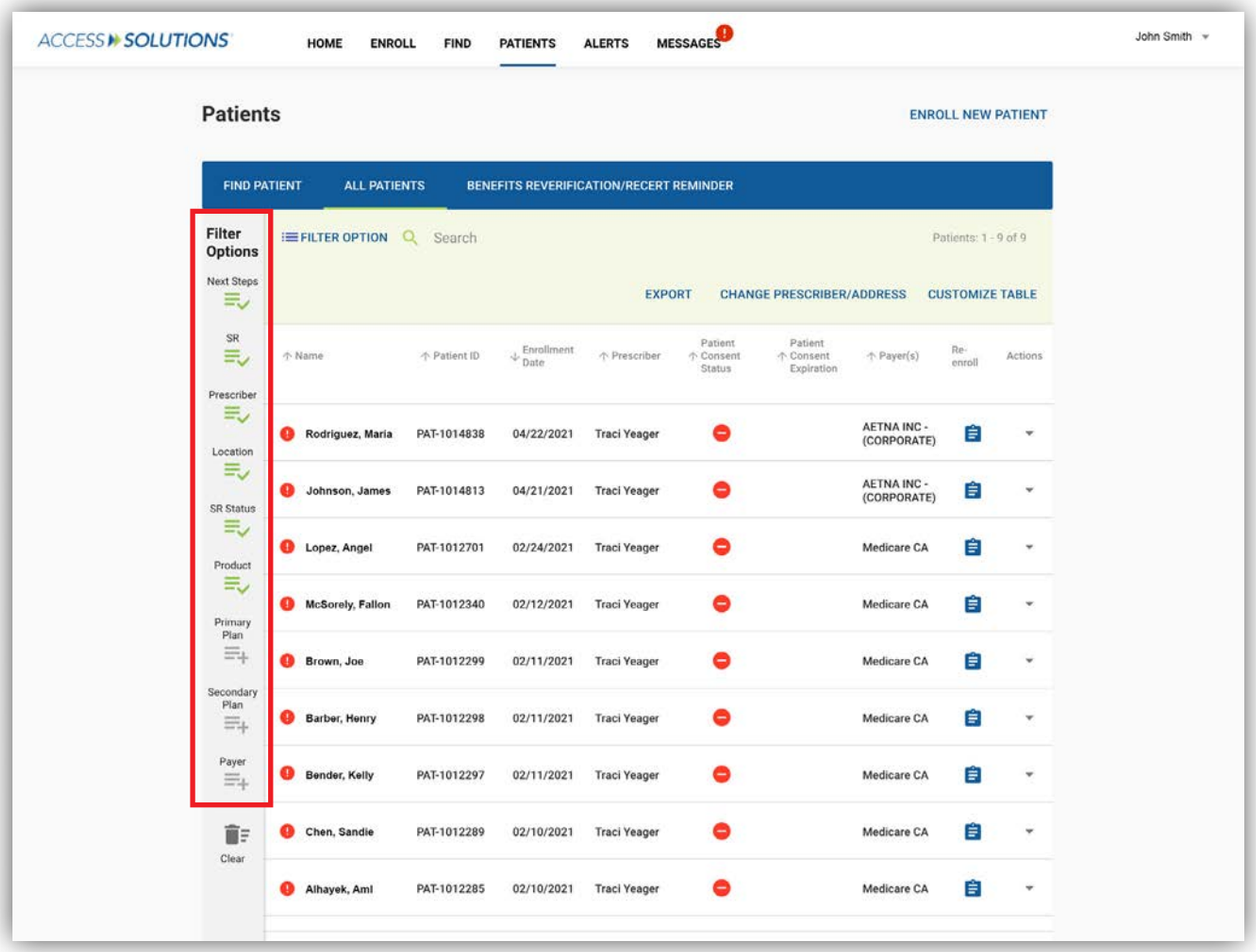
Filter your patient list (cont)



- Filter your patient list by:
  - Next step
  - Service request type
  - Prescriber
  - Location
  - Service request status
  - Product
  - Primary plan type
  - Secondary plan type
  - Payer
- Apply the filters you have selected

Your Patient List (cont)

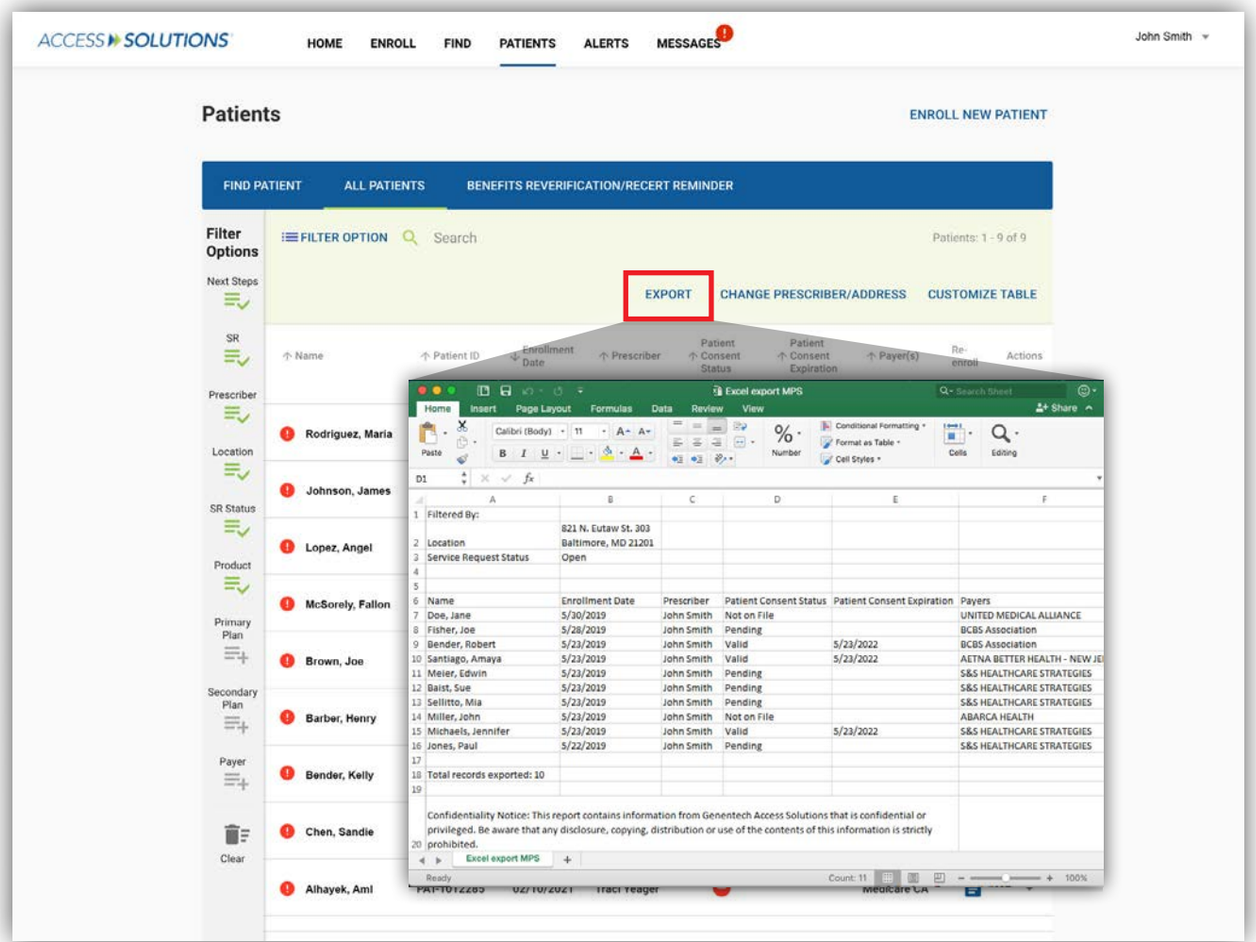
Filter your patient list (cont)



- Active filters will be shown with a green check mark to the left of the screen
- Reset your filters by selecting CLEAR

Your Patient List (cont)

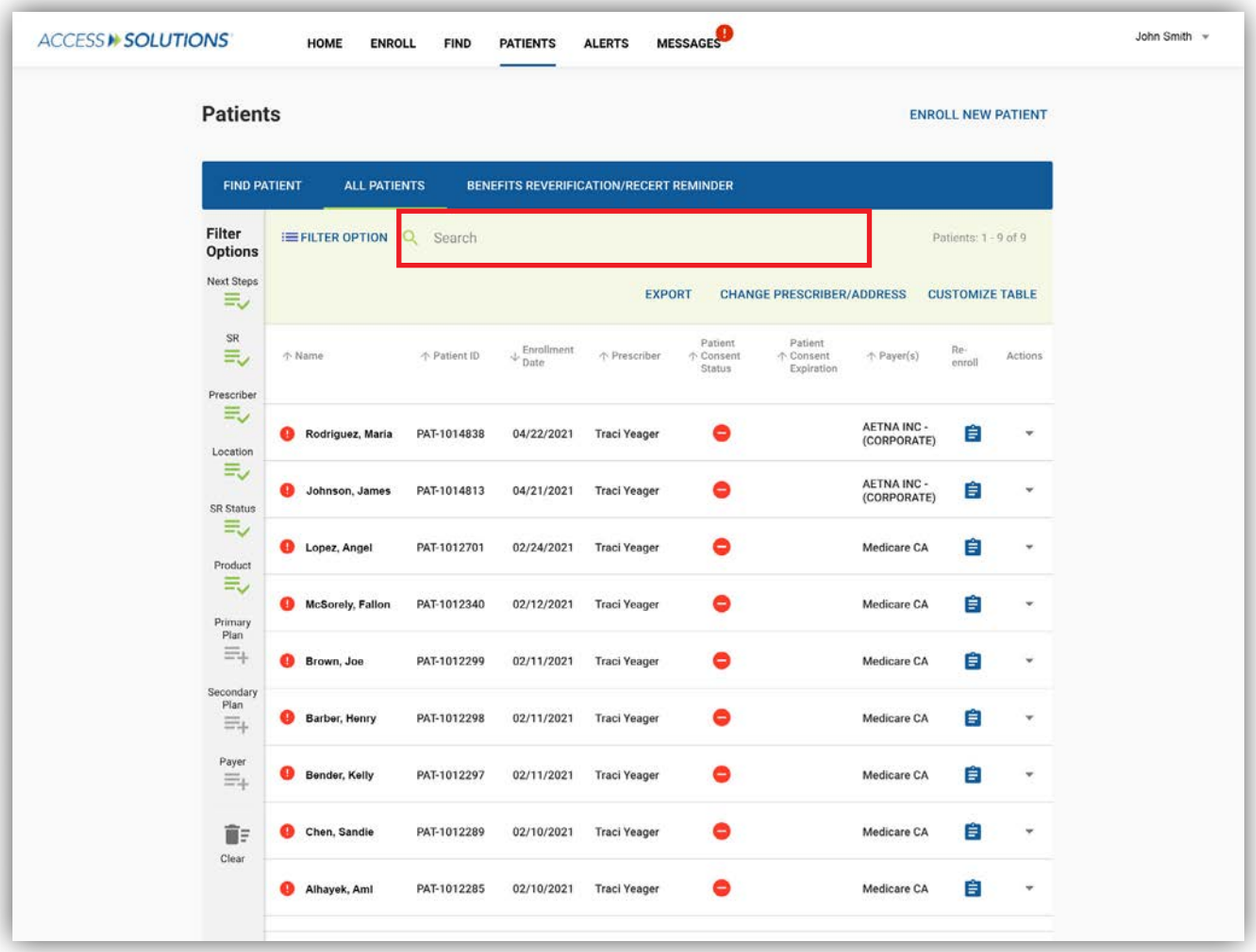
Export a report of your patient list



- Select the EXPORT button from the patient list
- An Excel® file will be created, containing your filtered and sorted list
  - The exported file will show information for all the columns you selected when customizing your patient list

Your Patient List (cont)

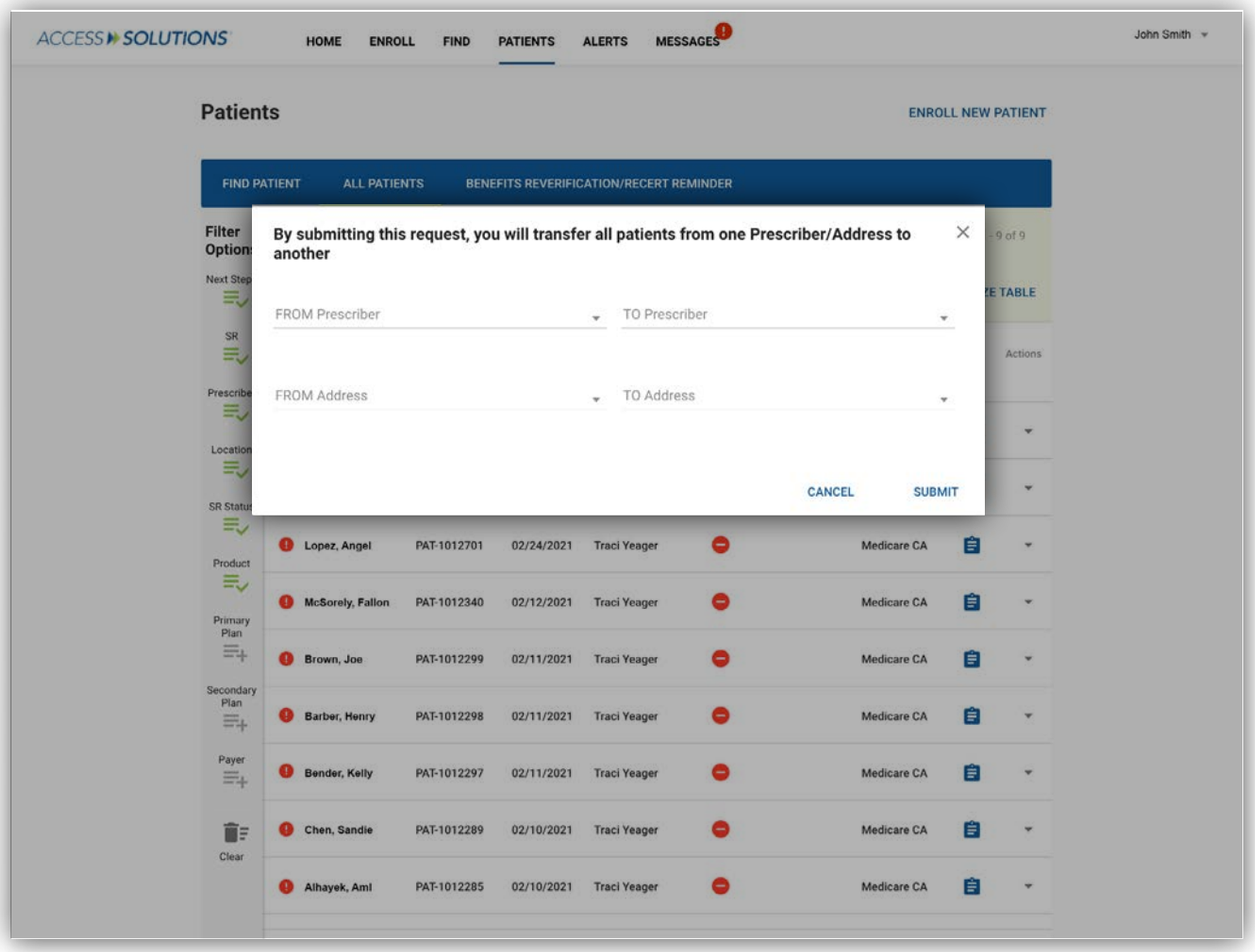
Search for a specific patient in the patient list



- Type the patient's first **or** last name in the green SEARCH bar at the top of the list
  - If you cannot find a specific patient in your patient list, check your location settings

Your Patient List (cont)

Change prescriber/address



- Select CHANGE PRESCRIBER/ADDRESS from the top of the page
- Update the prescriber information
  - Submitting this request will update prescriber information for all patients [in a filtered list]

Your Patient List (cont)

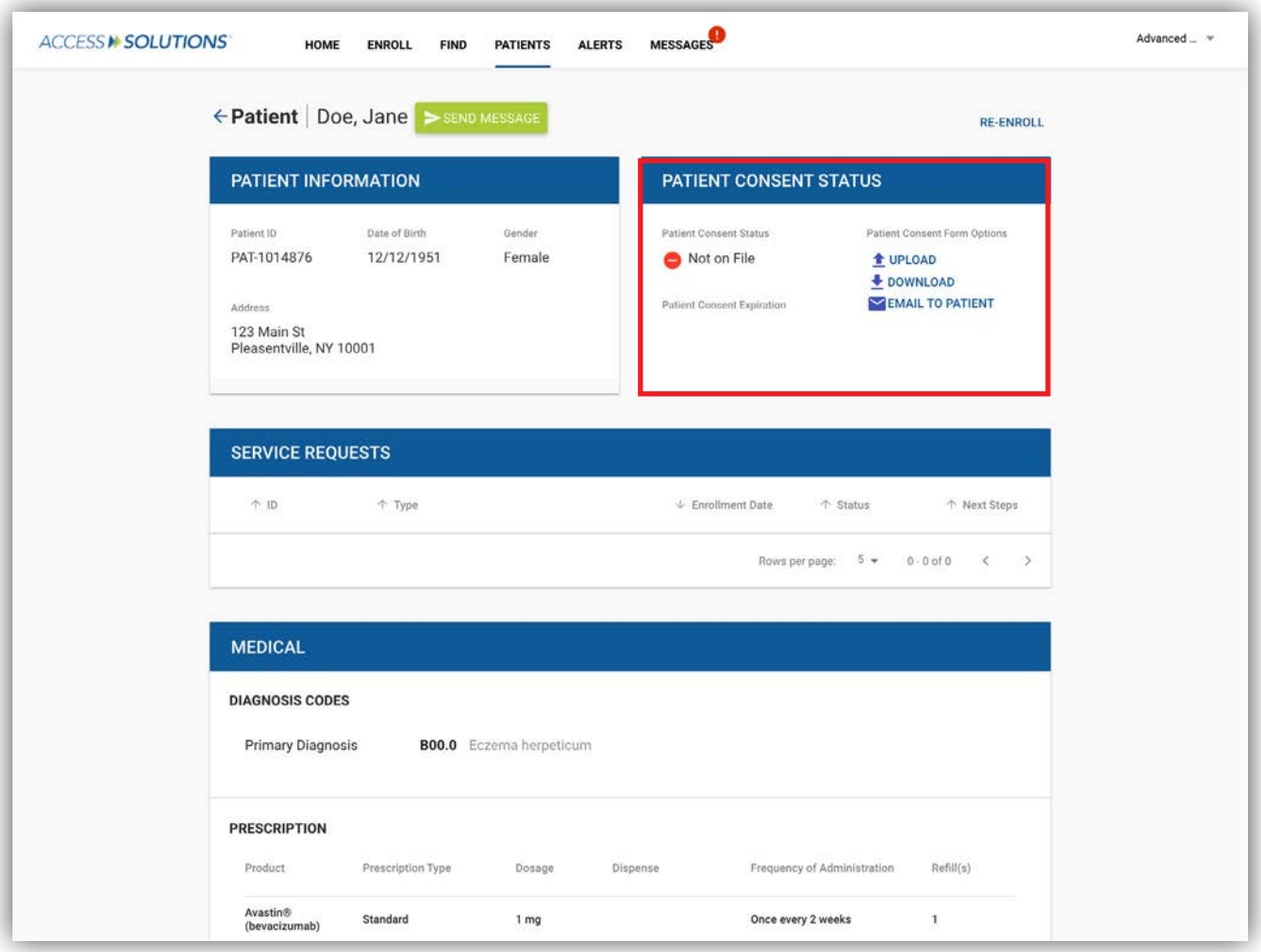
Important points to remember about your patient list

- If a patient is missing from a list, check your location preferences in MY SETTINGS to ensure the appropriate practice location is enabled and that all prescribers and locations are entered in the system
- From the FIND tab, you can search your patient list by additional criteria (name, date of birth or phone number)
- When customizing your patient list, please be aware that some columns are available for certain brands only
- The Patient Name, Re-enroll and Actions columns are static and cannot be moved or removed
- Additional columns will not be seen unless users select CUSTOMIZE TABLE
- Changing prescriber information from the patient list will update prescriber information for **all** patients

Navigate Your Patient's Profile

Patient profiles have been designed to clearly highlight the next steps necessary to complete your service request(s). Please note: The Patient Profile screen for OCREVUS will look slightly different and have additional features. Please see Treatment Coordination Milestones and Manage Infusion Dates for more information.

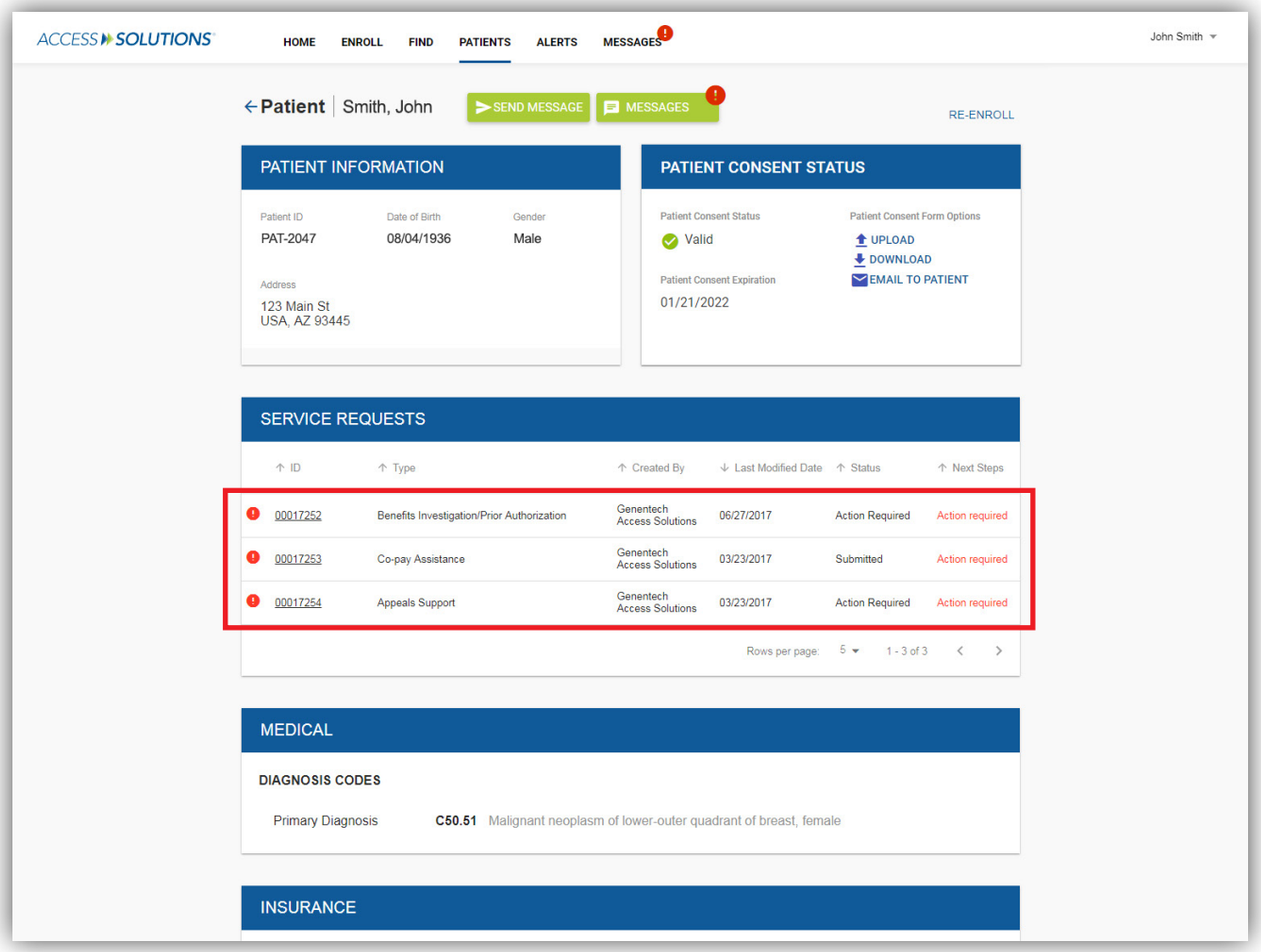
Submit a Patient Consent Form from the patient profile



- If you have not yet submitted a Patient Consent Form, you can do so from the patient profile screen
- Select UPLOAD or EMAIL TO PATIENT within the PATIENT CONSENT STATUS box at the top right

Navigate Your Patient's Profile (cont)

View service requests



- Determine which service requests require action
  - Any service request requiring action will be highlighted with a ! icon and the words "Action Required" in the Next Steps column

Navigate Your Patient's Profile (cont)

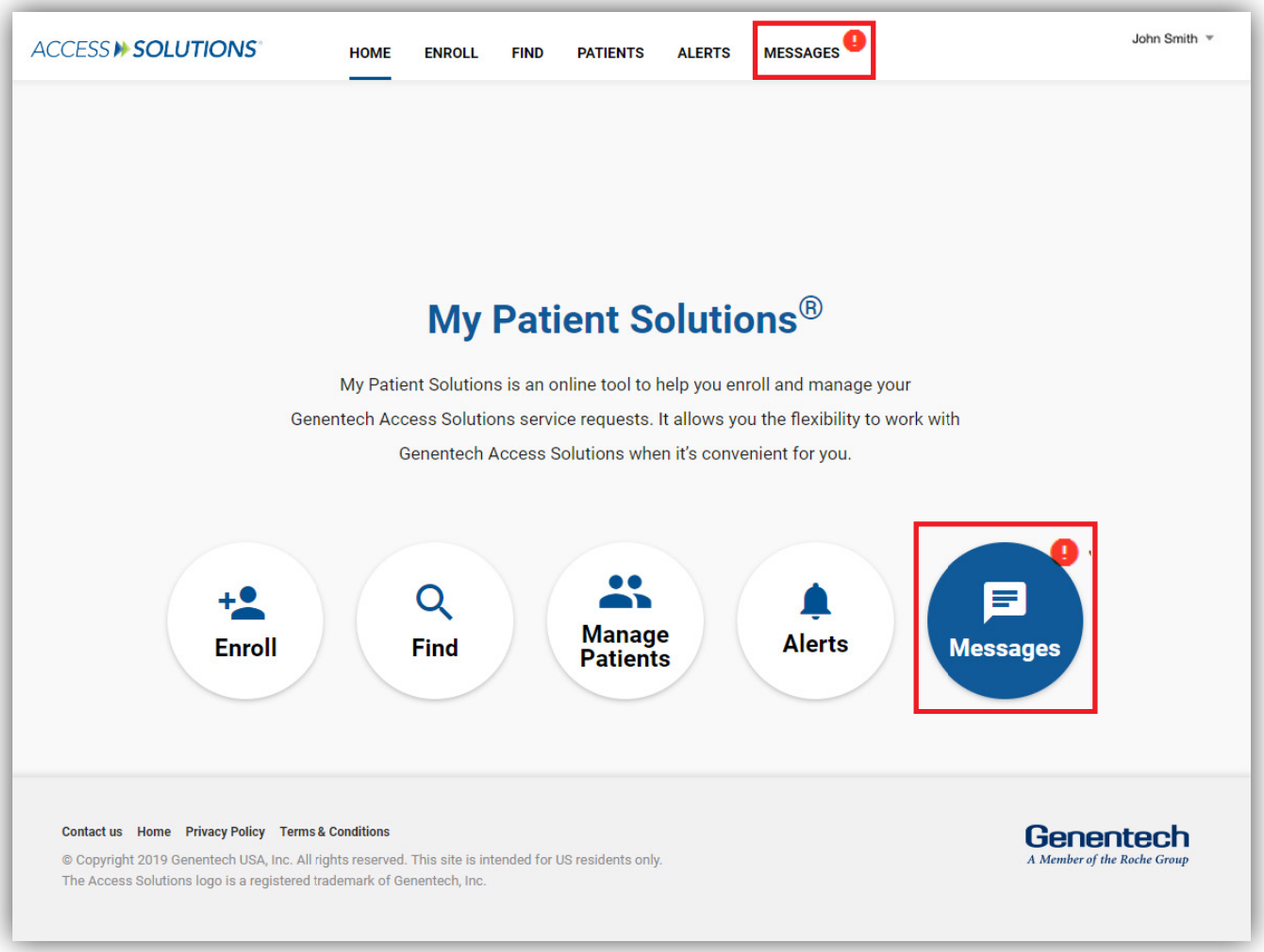
Important points to remember about your patient's profile

- You can sort the service request list by any of the column headers, including Next Steps
- The default sort for the service requests is the Last Modified Date

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist

Using the messaging feature, you can communicate with your Genentech Access Solutions Specialist securely through the system.

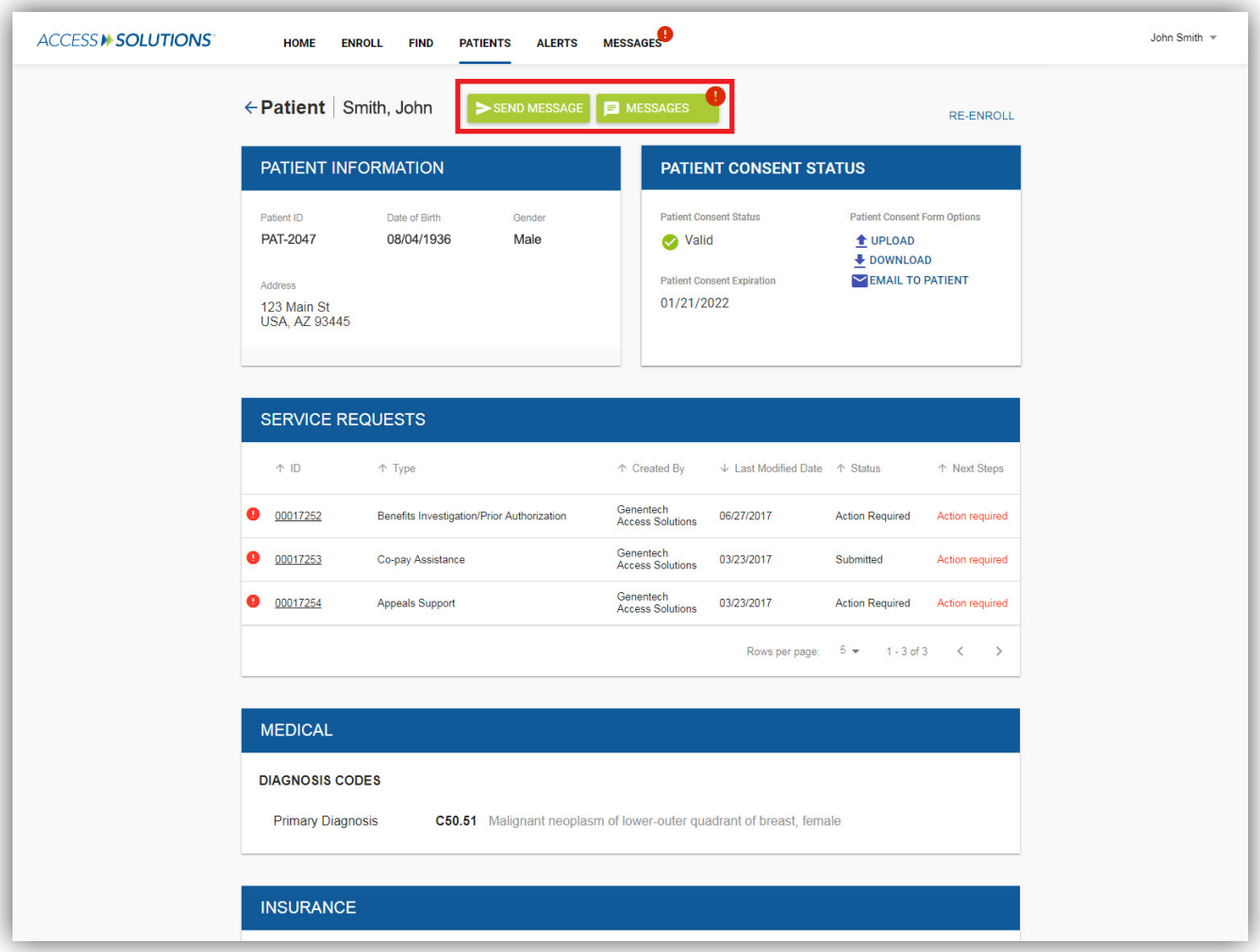
Access the messaging feature from the home screen



- Select MESSAGES from the center of the screen or from the top navigation bar
  - — A ! icon notifies you when you have unread messages

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

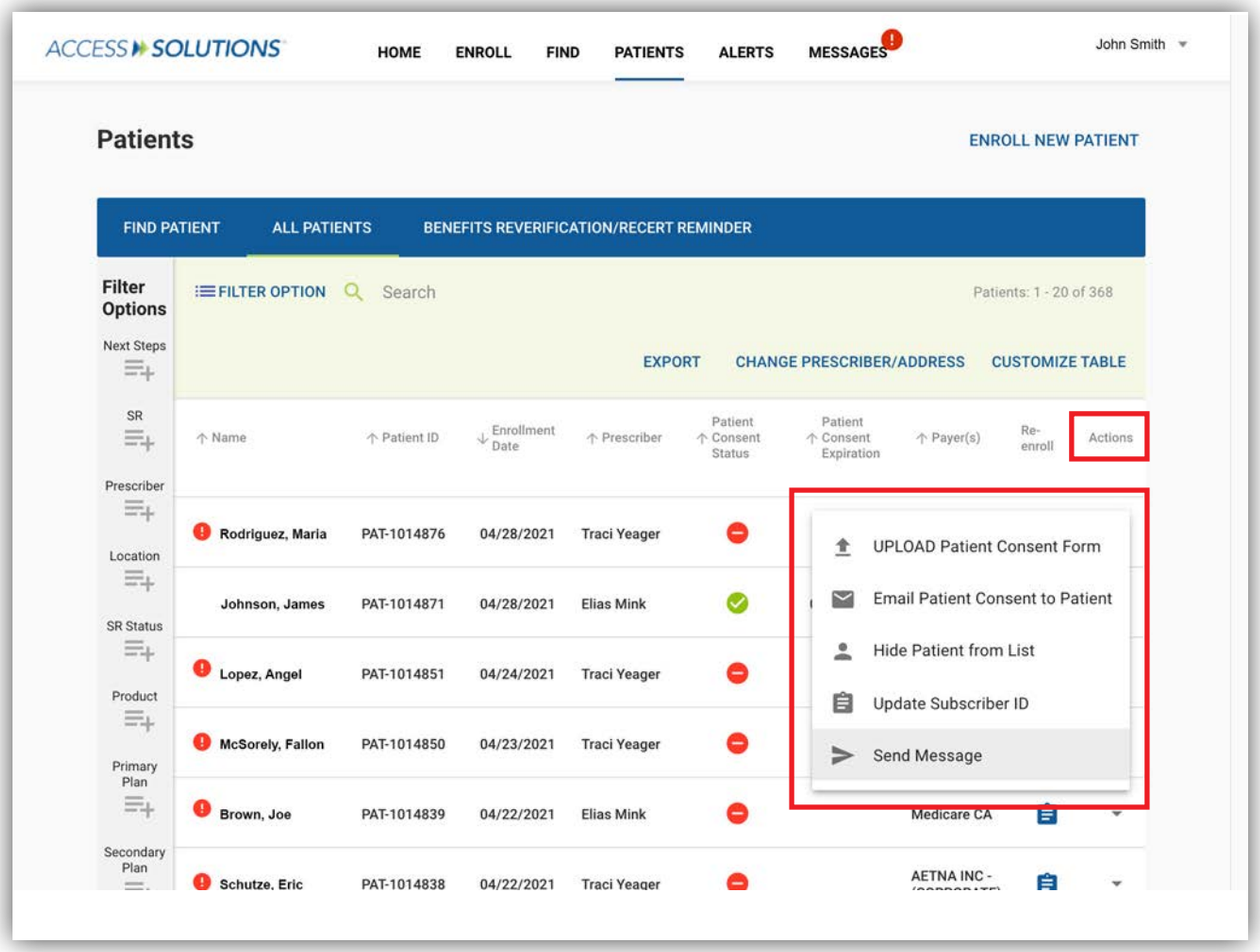
Access the messaging feature from the patient profile



- Select the SEND MESSAGES button to initiate a new message linked to the Patient ID
- Select the MESSAGES button to view or send messages
  - This button appears only when a message has been sent or received about a specific patient

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

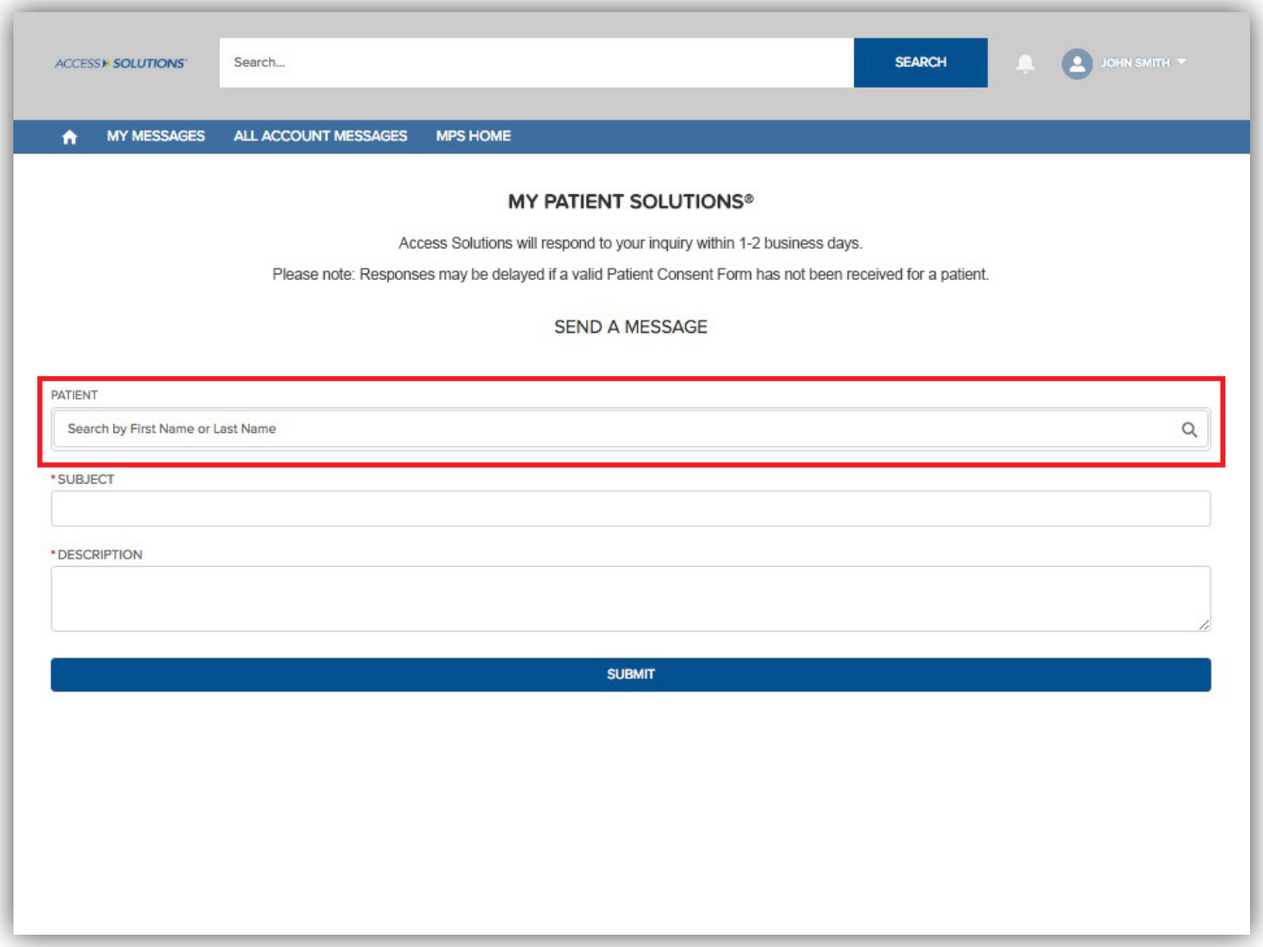
Access the messaging feature from the patient list



Select SEND MESSAGE from the ACTIONS dropdown menu in the Patient List to initiate a new message linked to the Patient ID.

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

Send a message to your Genentech Access Solutions or Genentech Patient Foundation Specialist

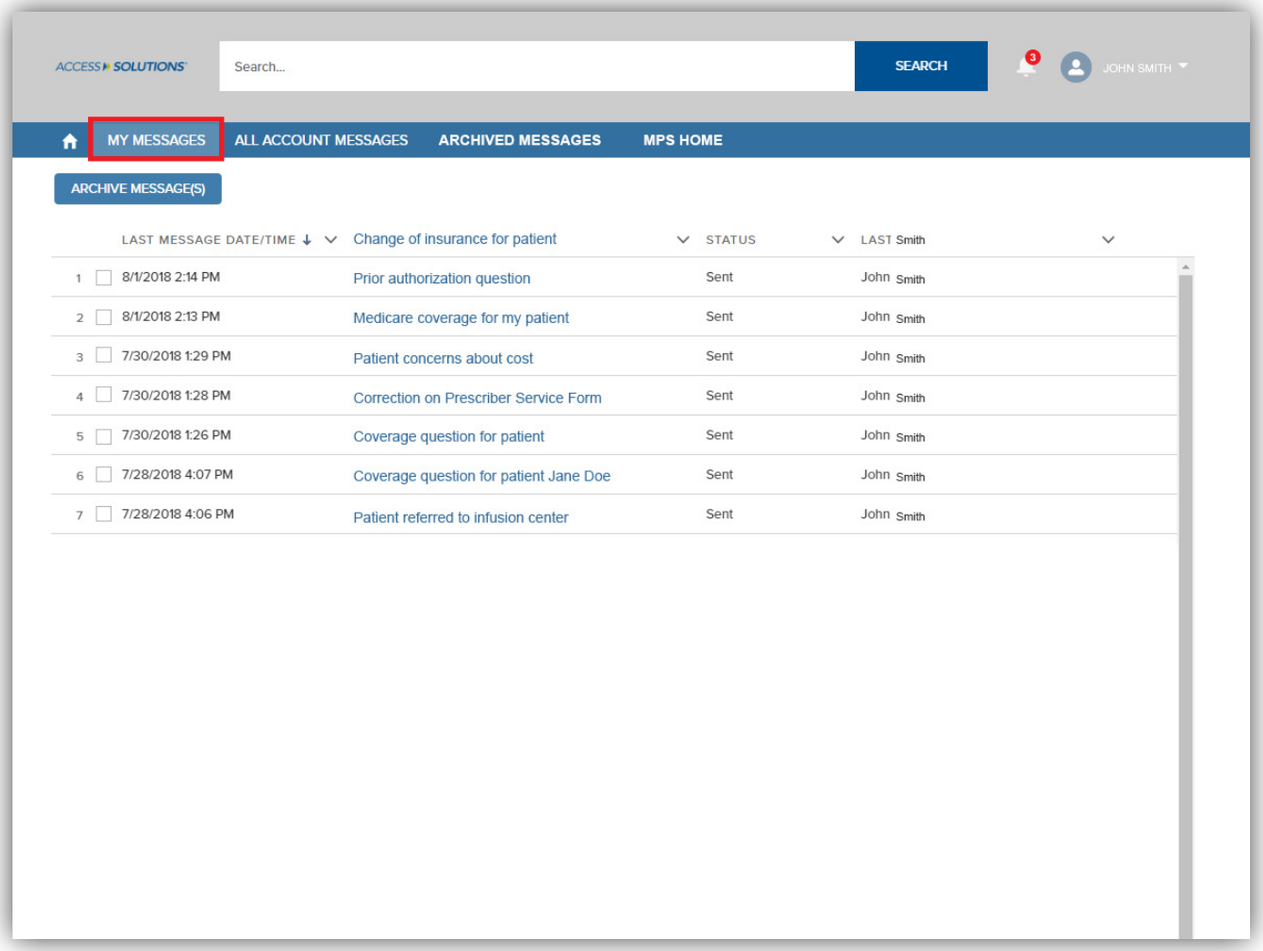


Search for the patient you are sending a message for (if available) and enter the message subject and comments:

- If you have a question about the Genentech Patient Foundation, please specify in the subject line
- Within 1 business day, a Genentech Access Solutions or Genentech Patient Foundation Specialist will respond within the system
- You will receive an email notifying you that your response is waiting (if this setting is enabled)
- If your message is not linked to a Patient ID, you must specify your Genentech Access Solutions or Genentech Patient Foundation Specialist or the product the patient has been prescribed

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

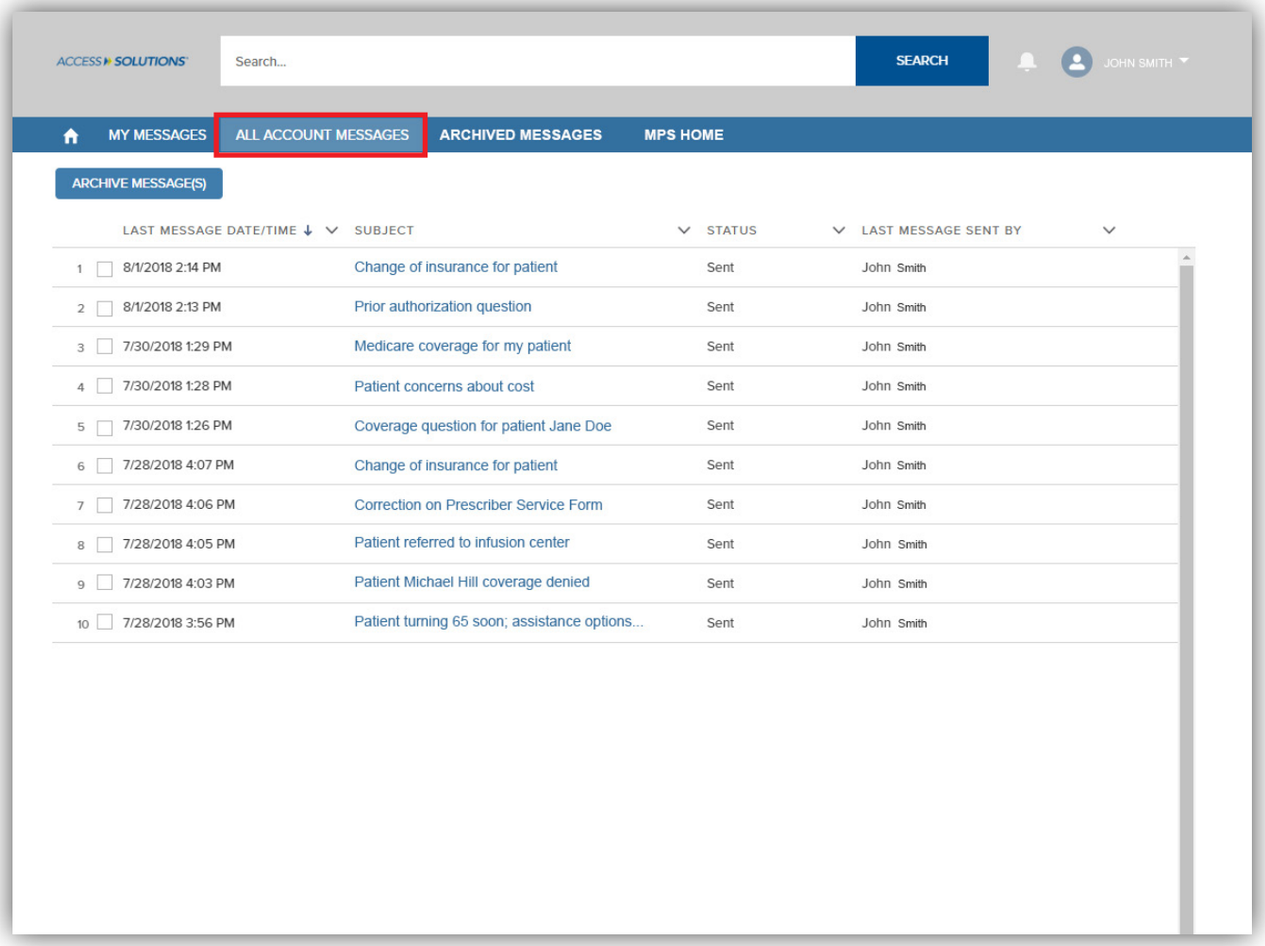
Check messages sent between you and your Genentech Access Solutions or Genentech Patient Foundation Specialist



Select MY MESSAGES from the navigation bar.

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

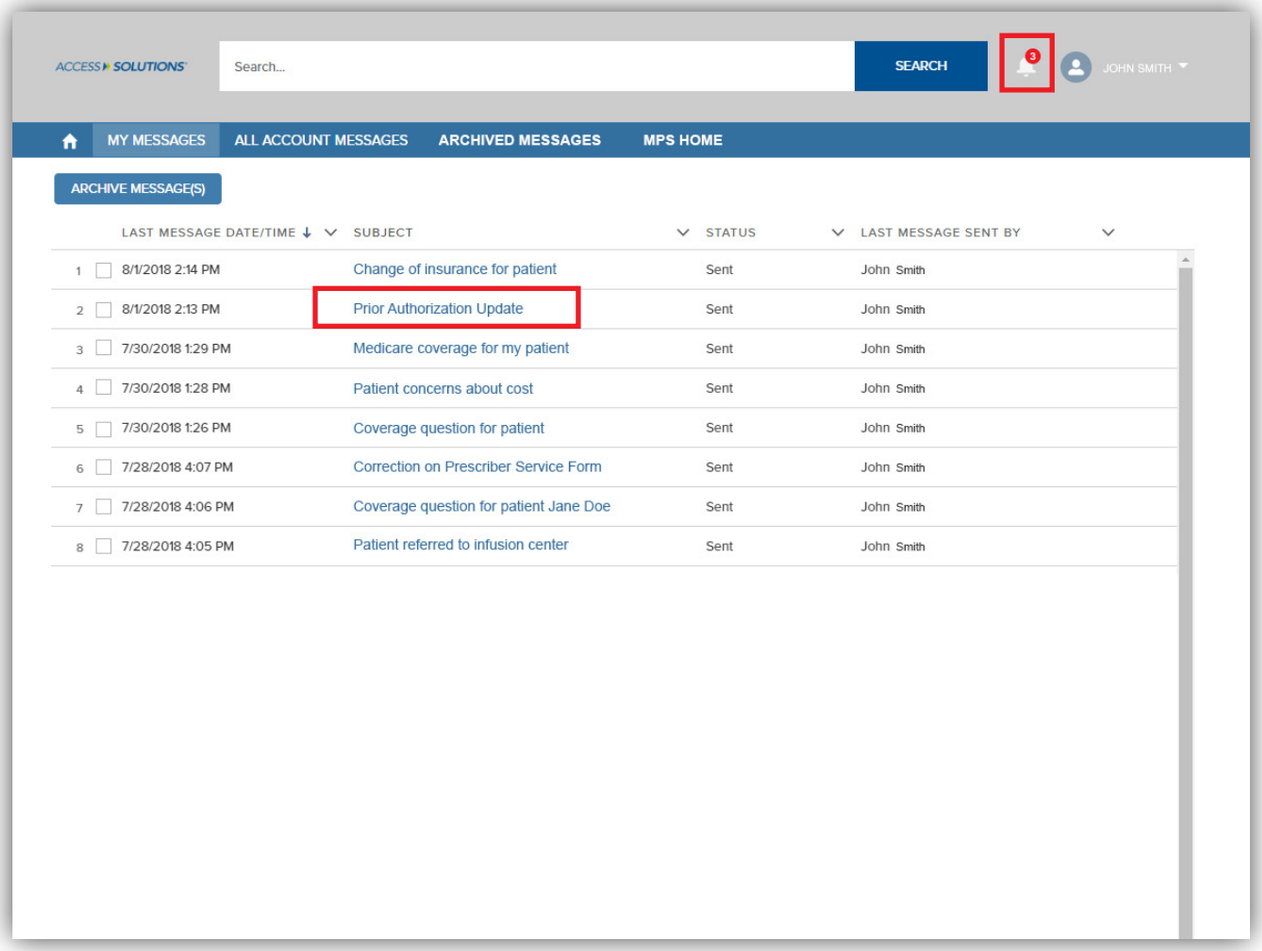
Check messages sent between anyone in the practice and the Genentech Access Solutions or Genentech Patient Foundation Specialist



Select ALL ACCOUNT MESSAGES from the navigation bar.

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

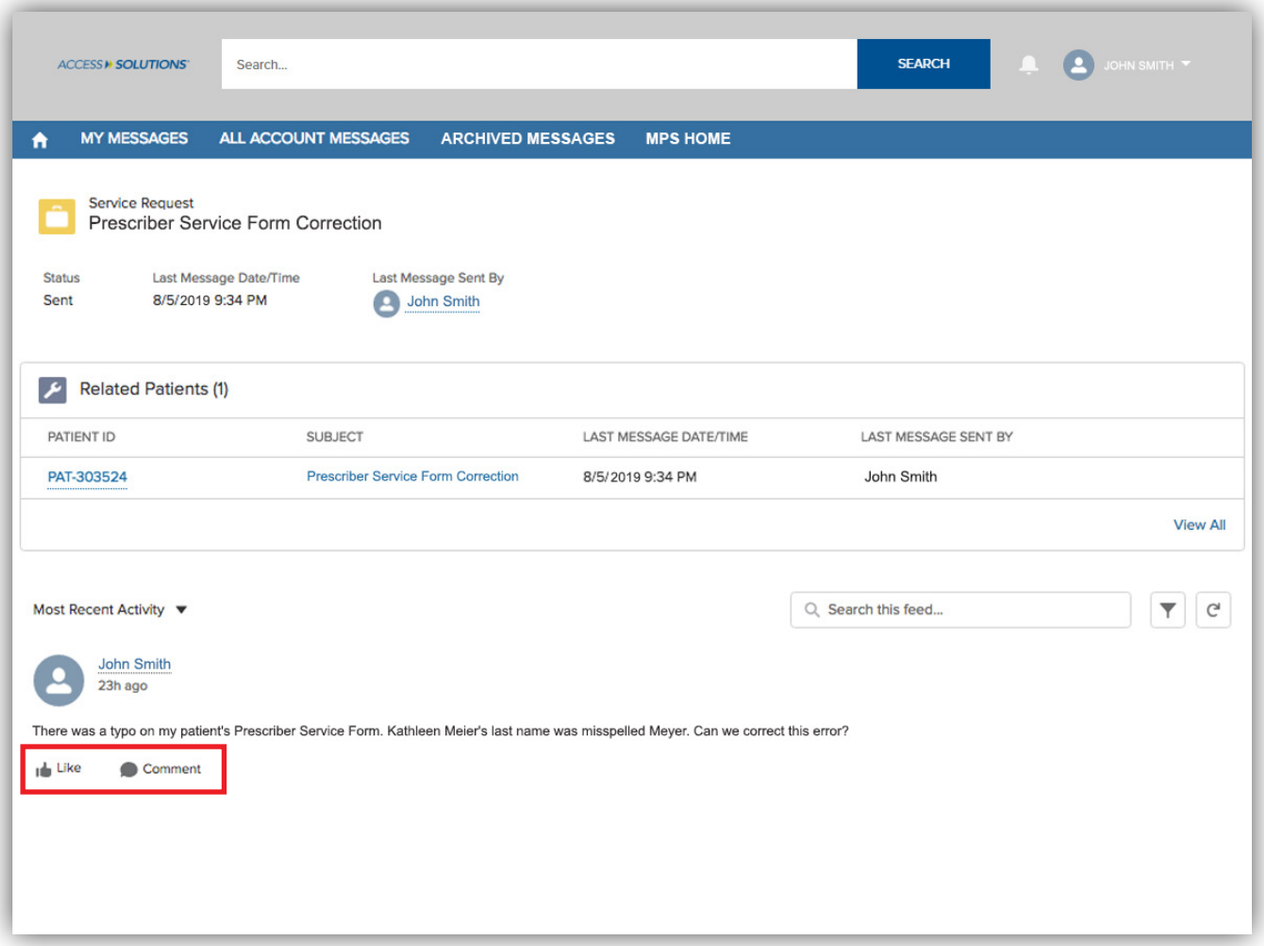
View your messages



- Select a messaging thread to read your messages from your Genentech Access Solutions or Genentech Patient Foundation Specialist
  - If you have a message waiting for you, the icon in the top right corner will have a red number icon next to it

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

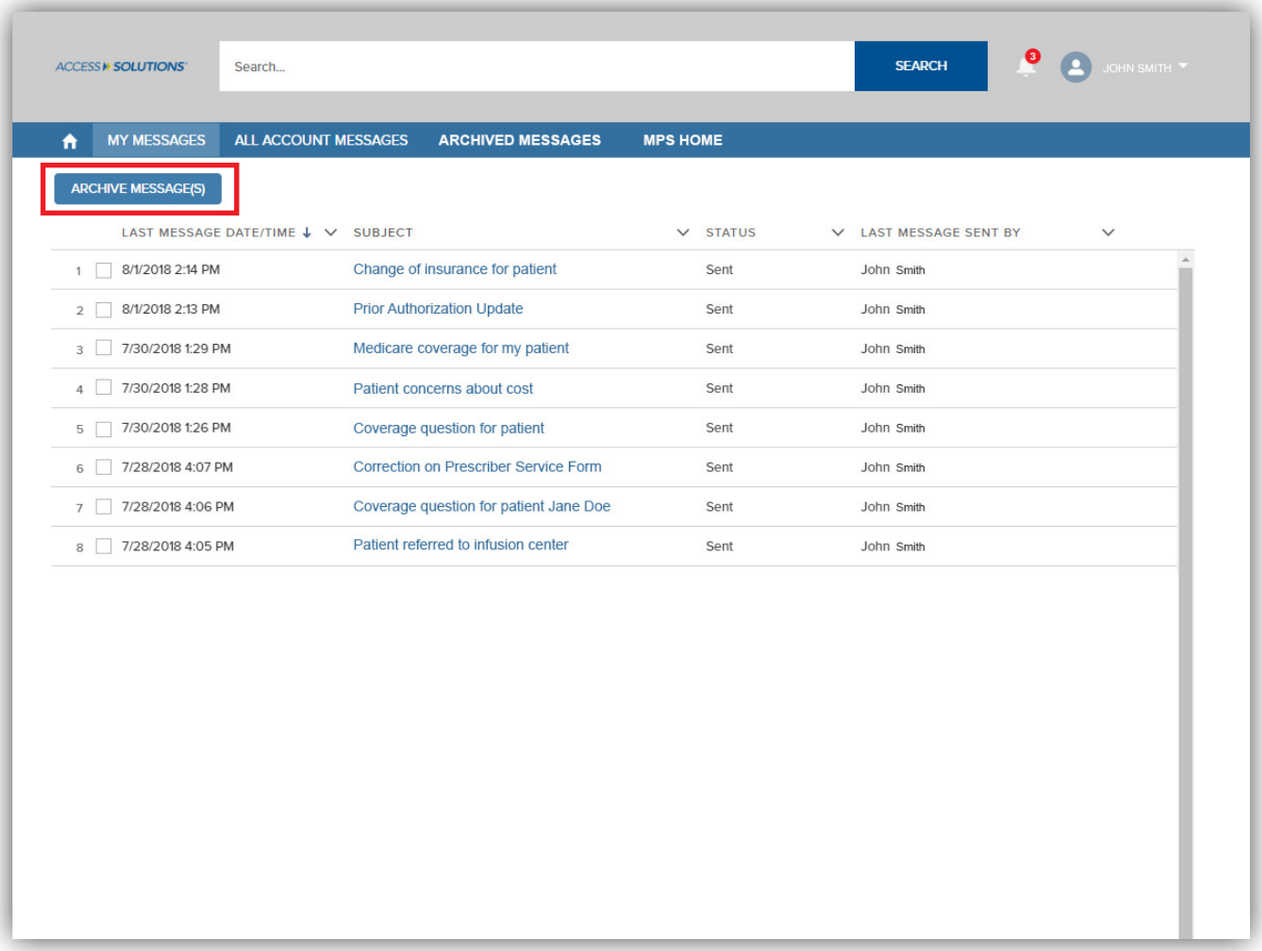
View your messages (cont)



- Your messages will appear similar to a social media feed
  - The platform used to send messages via My Patient Solutions® for Health Care Practices includes a feed layout with LIKE and COMMENT buttons
- Use COMMENT to respond to previous questions or provide additional information
- No follow-up action will occur from using the LIKE button
  - We do not recommend using this functionality

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

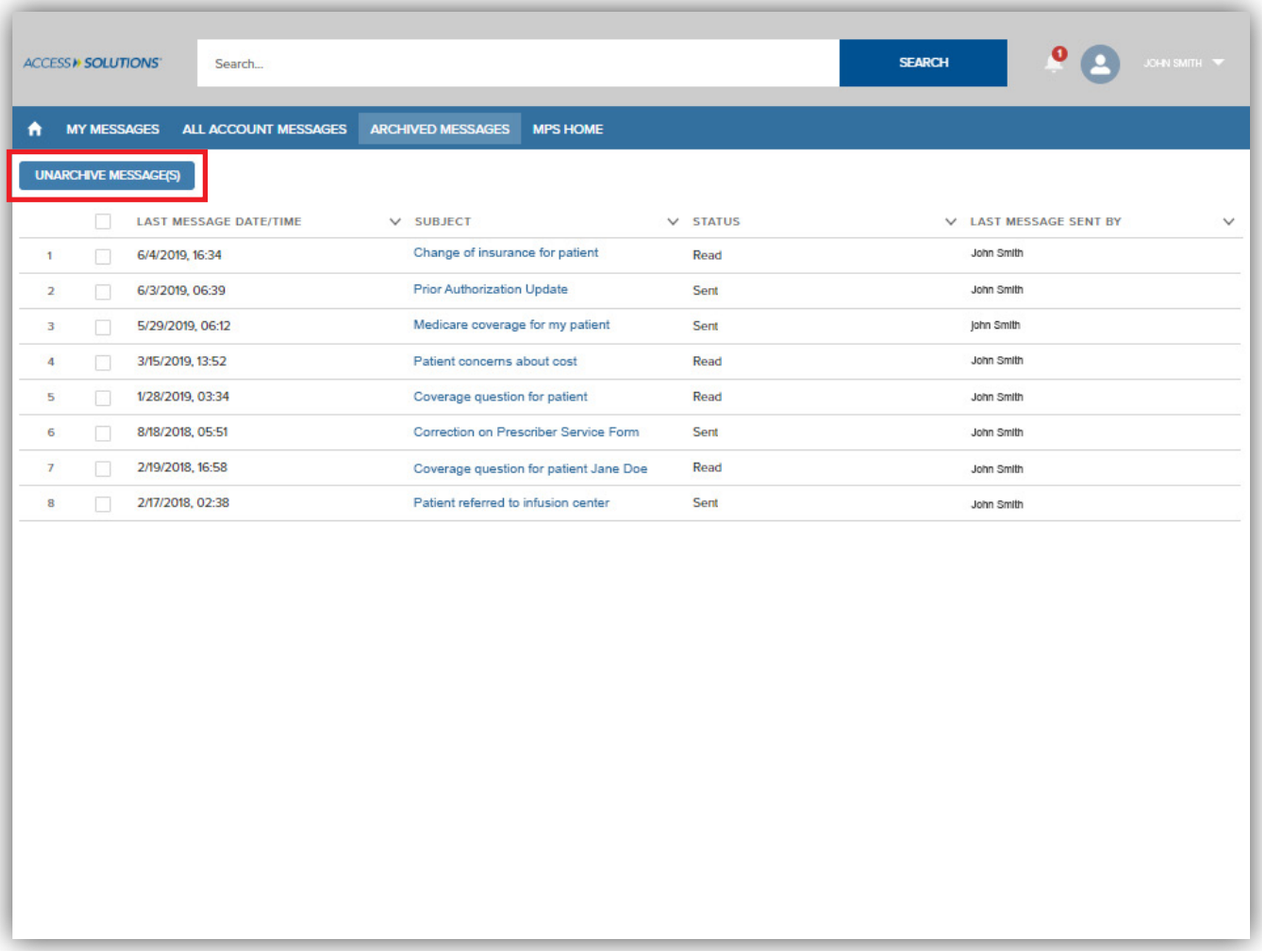
Archive your messages



- Go to MY MESSAGES
- Select the messages you would like to archive using the checkboxes to the left of the message
- Select the ARCHIVE button
  - — Messages will be removed from MY MESSAGES and appear in ARCHIVED MESSAGES

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

Unarchive your messages



- View your archived messages by selecting ARCHIVED MESSAGES from the navigation bar
- Select the messages you would like to unarchive using the checkboxes to the left of the message
- Select the UNARCHIVE button
  - Messages will appear in MY MESSAGES

Message Your Genentech Access Solutions or Genentech Patient Foundation Specialist (cont)

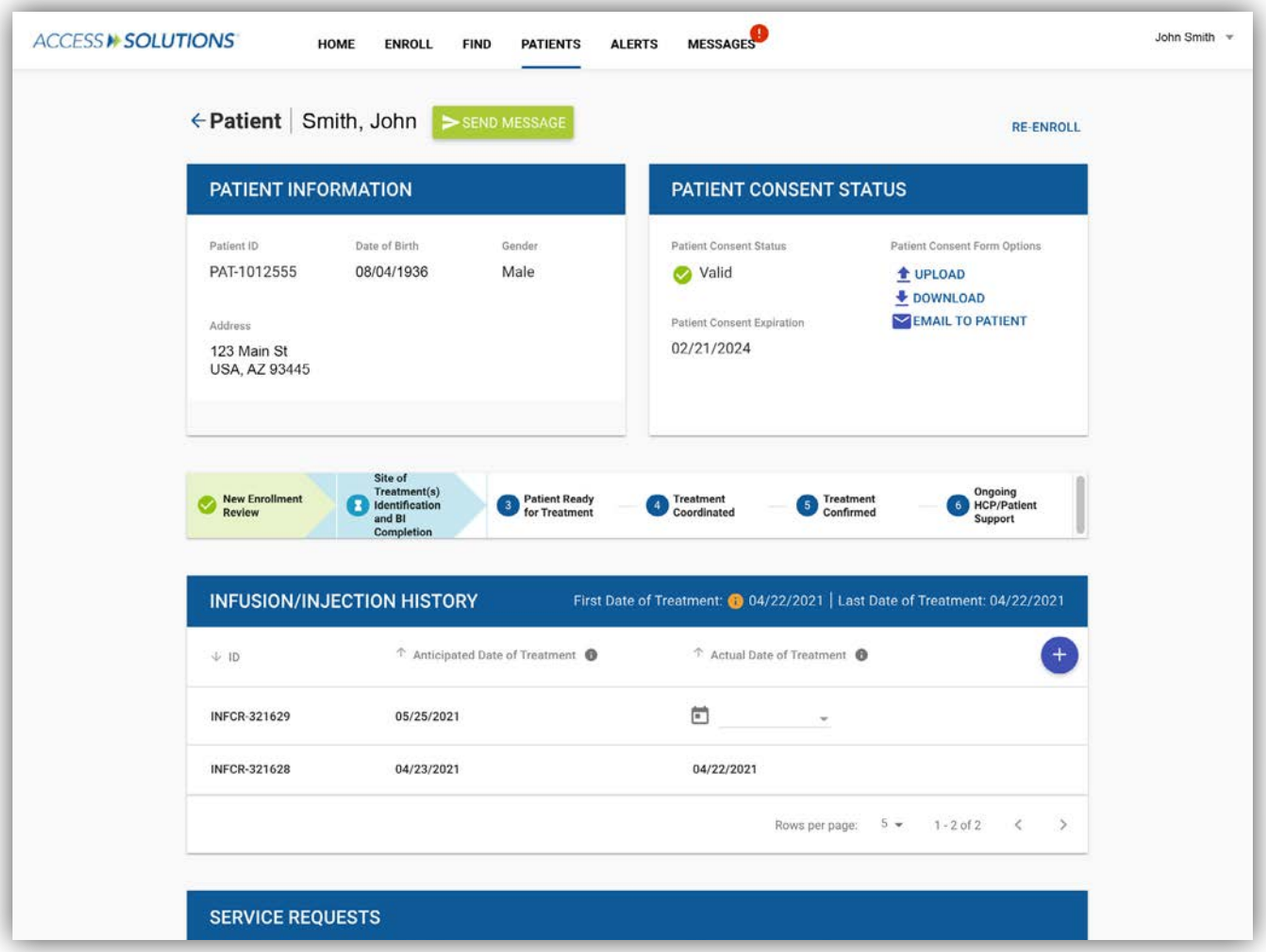
Important points to remember about messaging

- Messages between the practice and the Genentech Access Solutions or Genentech Patient Foundation Specialist are secure and will remain confidential
- The messaging feature may be used to address corrections or outstanding information on the Prescriber Service Form or Patient Consent Form
- If you send a message directly from the patient profile or from the ACTIONS dropdown menu in the patient list, the patient will be automatically linked to the message
- You can view messages sent by anyone in your practice
- Specialists typically respond within 1 business day
- If you do not wish to receive email notifications of messages, you can opt out in SETTINGS

For OCREVUS® (ocrelizumab) only

Treatment Coordination Milestones

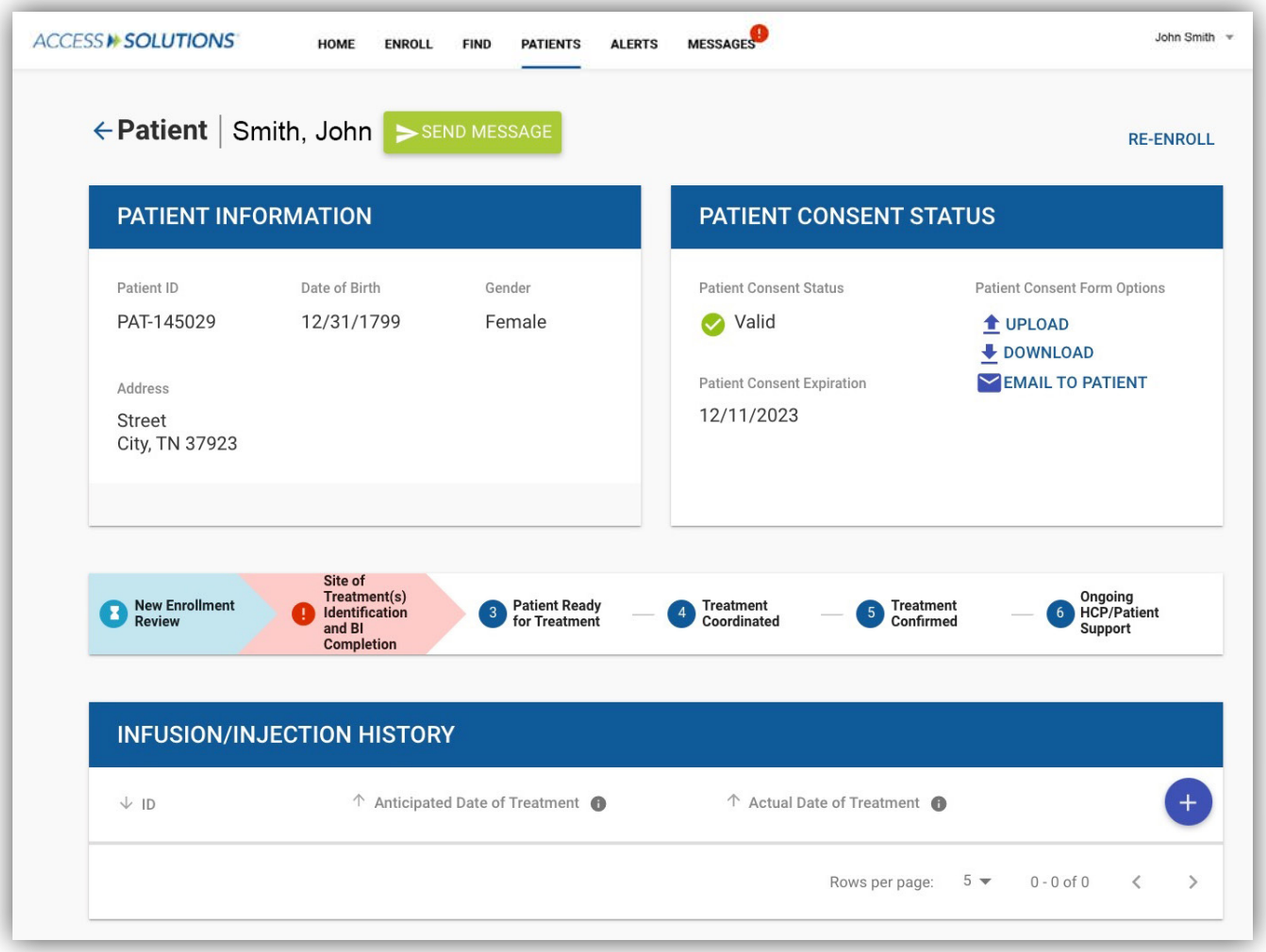
An OCREVUS patient profile screen will look slightly different and include a few more features than patients who have been prescribed other Genentech medicines. Within an OCREVUS patient's profile, patient treatment coordination milestones clearly display the patient's status.



Use the treatment coordination milestones to determine where your patient is in the treatment process.

For OCREVUS® (ocrelizumab) only

Treatment Coordination Milestones (cont)



- If there is a delay at any point in the process, it will appear in red and be marked with a ! icon
- Hover your cursor over a step to determine if any action needs to be taken and/or find out additional information about the treatment milestone

For OCREVUS® (ocrelizumab) only

Treatment Coordination Milestones (cont)

Important points to remember about treatment coordination milestones

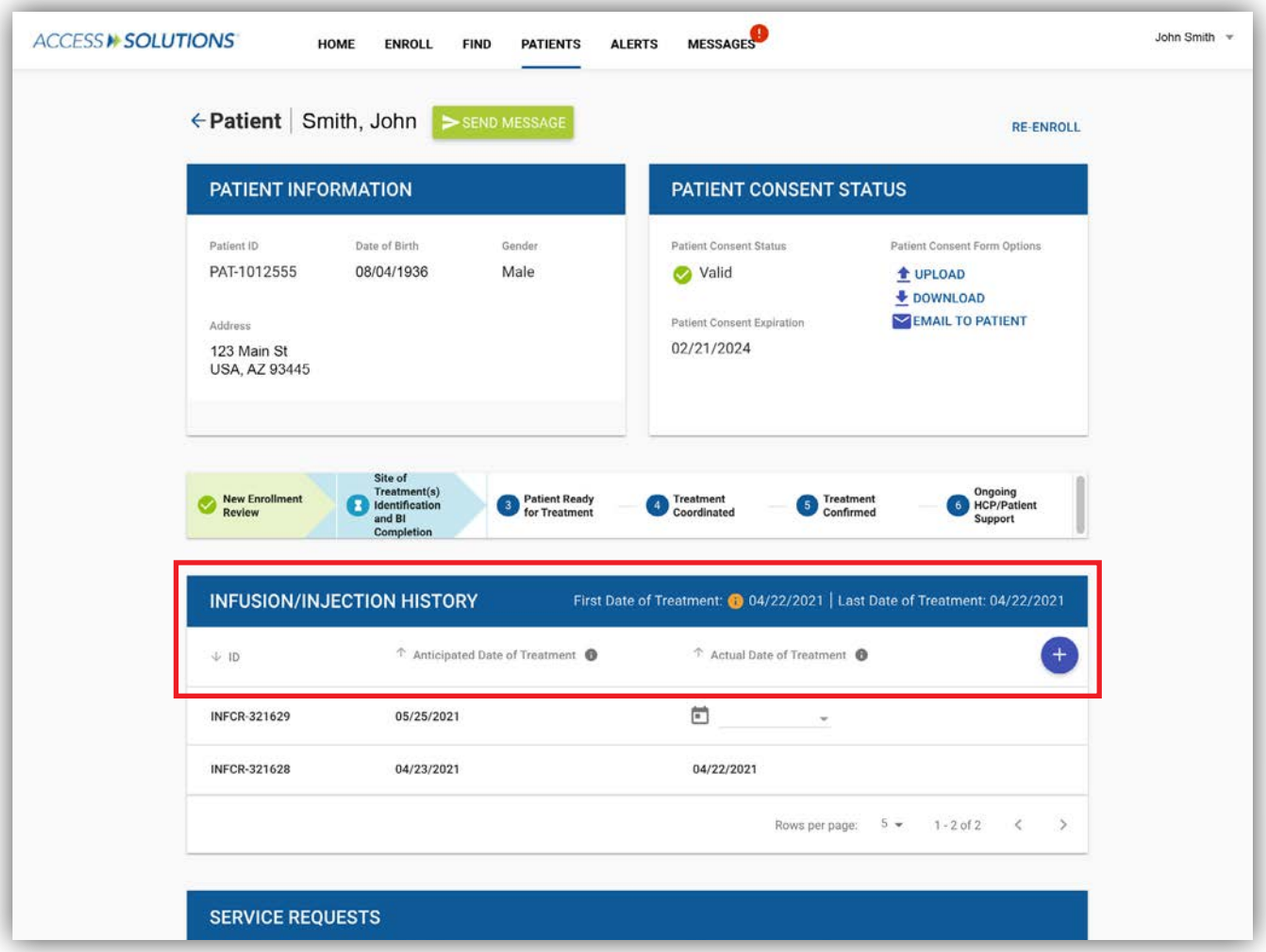
- Treatment Coordination Milestones are available in the patient profiles for OCREVUS patients only
- Completed milestones will appear in green and be marked with a icon
- Milestones that are in progress will be marked with blue icons

For OCREVUS® (ocrelizumab) only

Manage Infusion Dates

My Patient Solutions® users have the ability to create an infusion record for OCREVUS patients from the patient's profile.

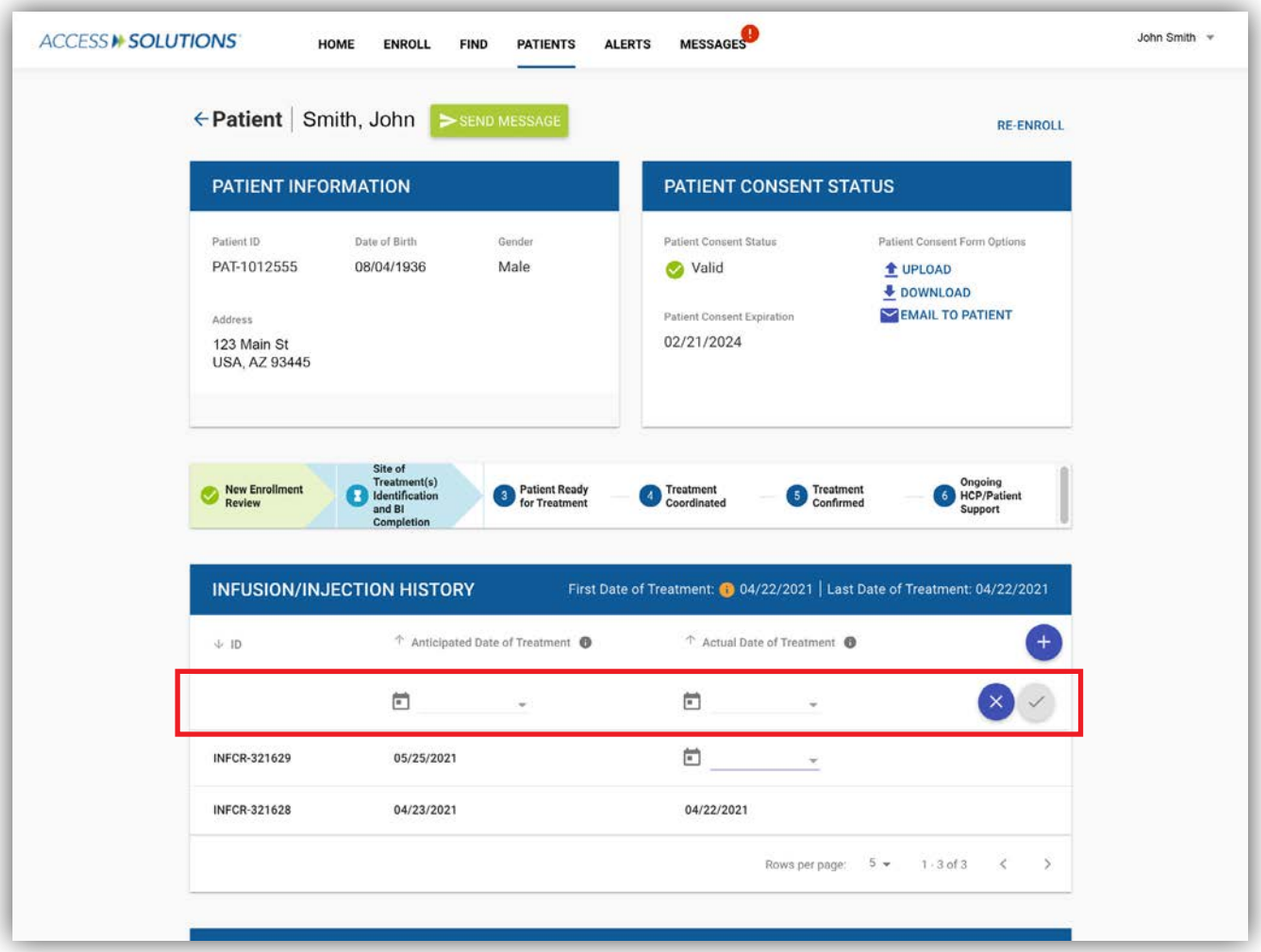
View previous treatment dates



- Open the OCREVUS patient's profile
- Select the + icon in the Infusion/Injection History table

Manage Infusion Dates (cont)

Enter infusion dates



- Enter the patient's anticipated date of treatment or actual date of treatment
  - — You can save or cancel the record after it has been created using the ✕ and ✓ icons

For OCREVUS® (ocrelizumab) only

Manage Infusion Dates (cont)

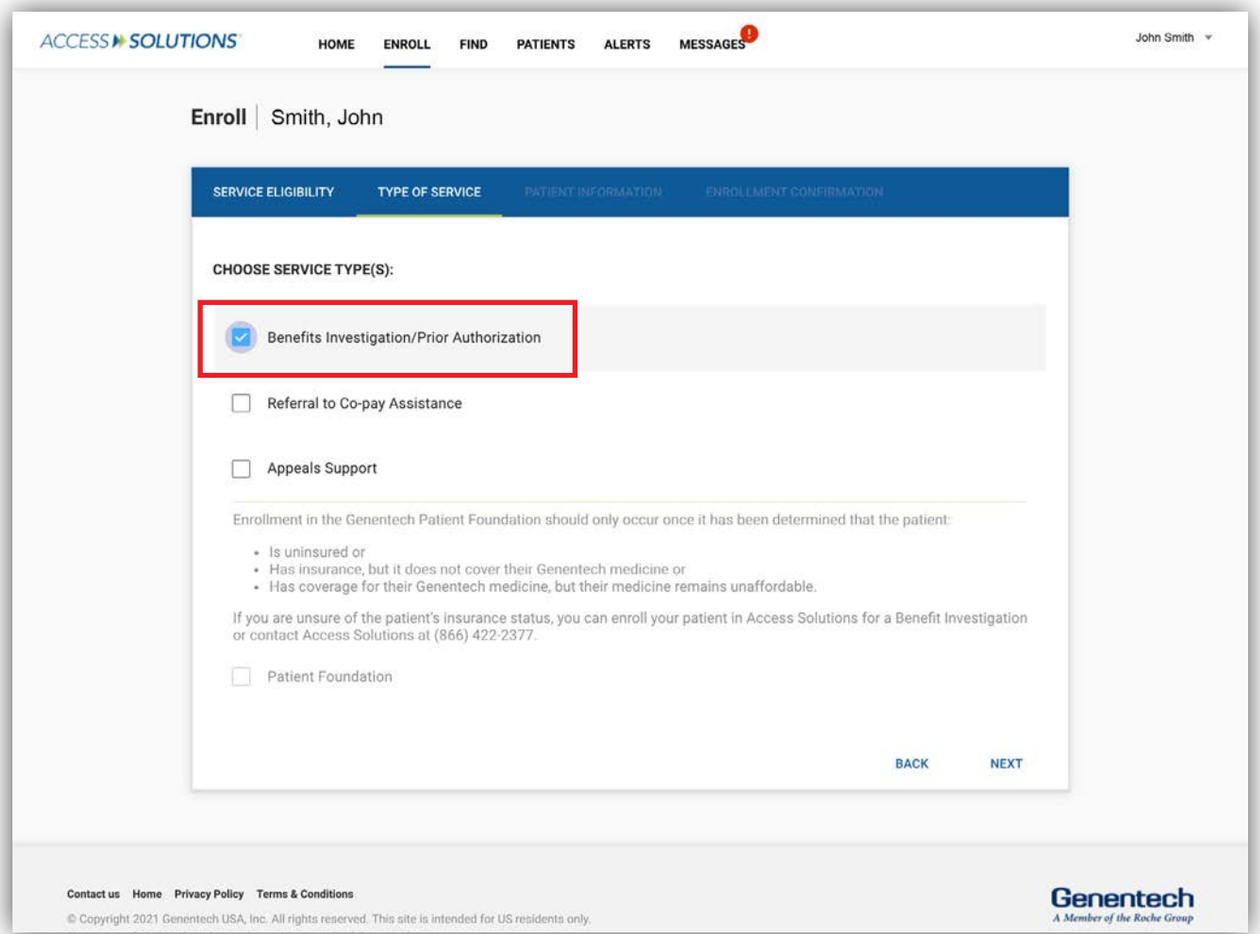
Important points to remember about creating infusion records

- This feature is available for OCREVUS patients only
- Within My Patient Solutions® for Health Care Practices, you will be able to view anticipated and actual dates of treatment that have been created by the Patient Navigator from other sites of treatment (via My Patient Solutions for Infusion Sites)
- Genentech Access Solutions will perform the benefits reverification approximately 6 to 8 weeks before the anticipated date of treatment (4 months and 2 weeks after the date of treatment if no next anticipated date of treatment is entered)
- The practice or the Patient Navigator may enter treatment dates to help with treatment coordination

Service Requests: Benefits Investigations and Prior Authorizations

You can request benefits investigations (BIs) and prior authorization (PA) resources, as well as view coverage details, within My Patient Solutions® for Health Care Practices.

Request a BI

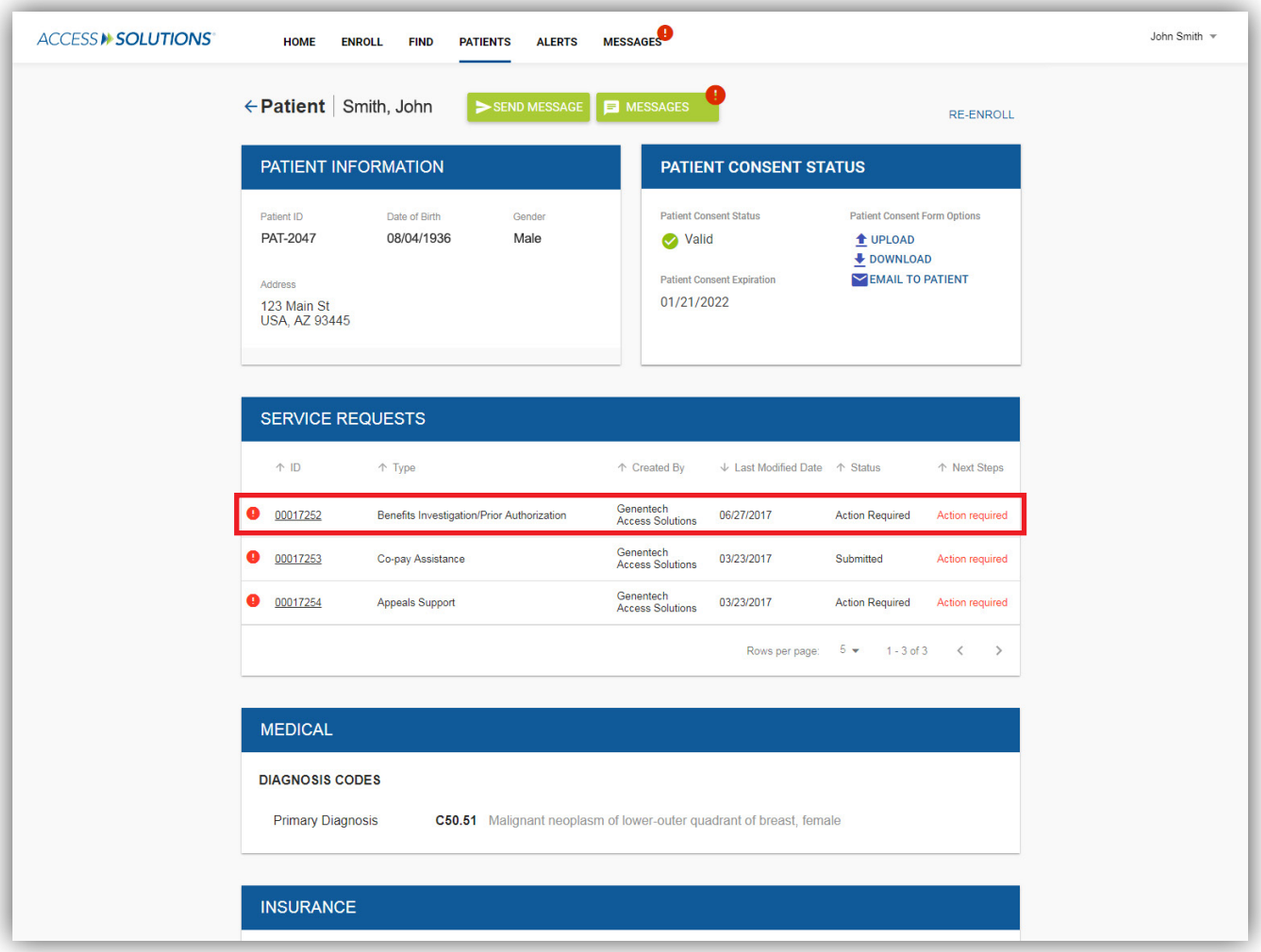


- Begin the enrollment or re-enrollment process
- Include BENEFITS INVESTIGATION/PRIOR AUTHORIZATION when selecting service requests under TYPE OF SERVICE

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

Service Requests: Benefits Investigations and Prior Authorizations (cont)

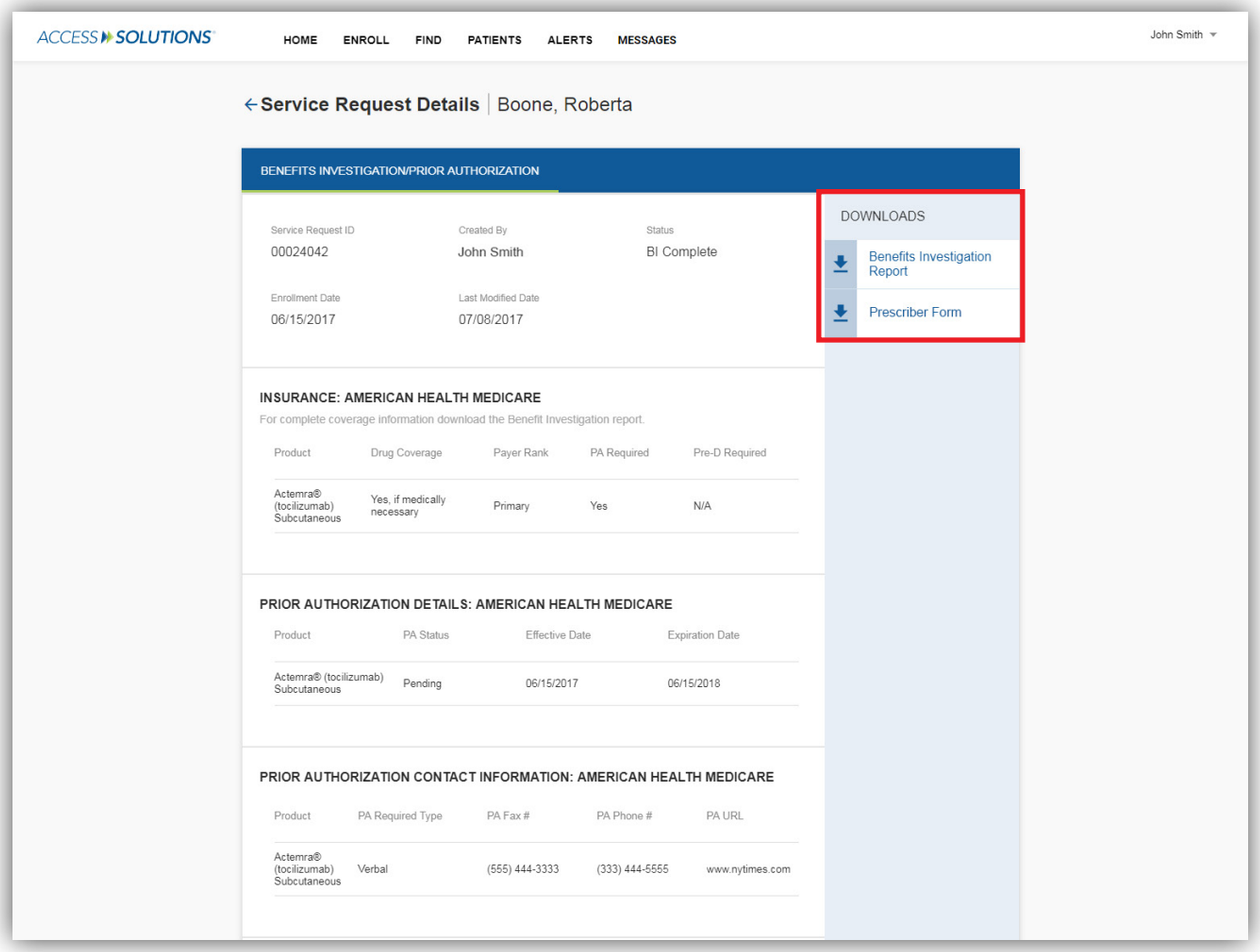
View service request details (BIs/PAs)



Select the BENEFITS INVESTIGATION/PRIOR AUTHORIZATION service request within the patient profile to see a high-level overview of the patient's coverage.

Service Requests: Benefits Investigations and Prior Authorizations (cont)

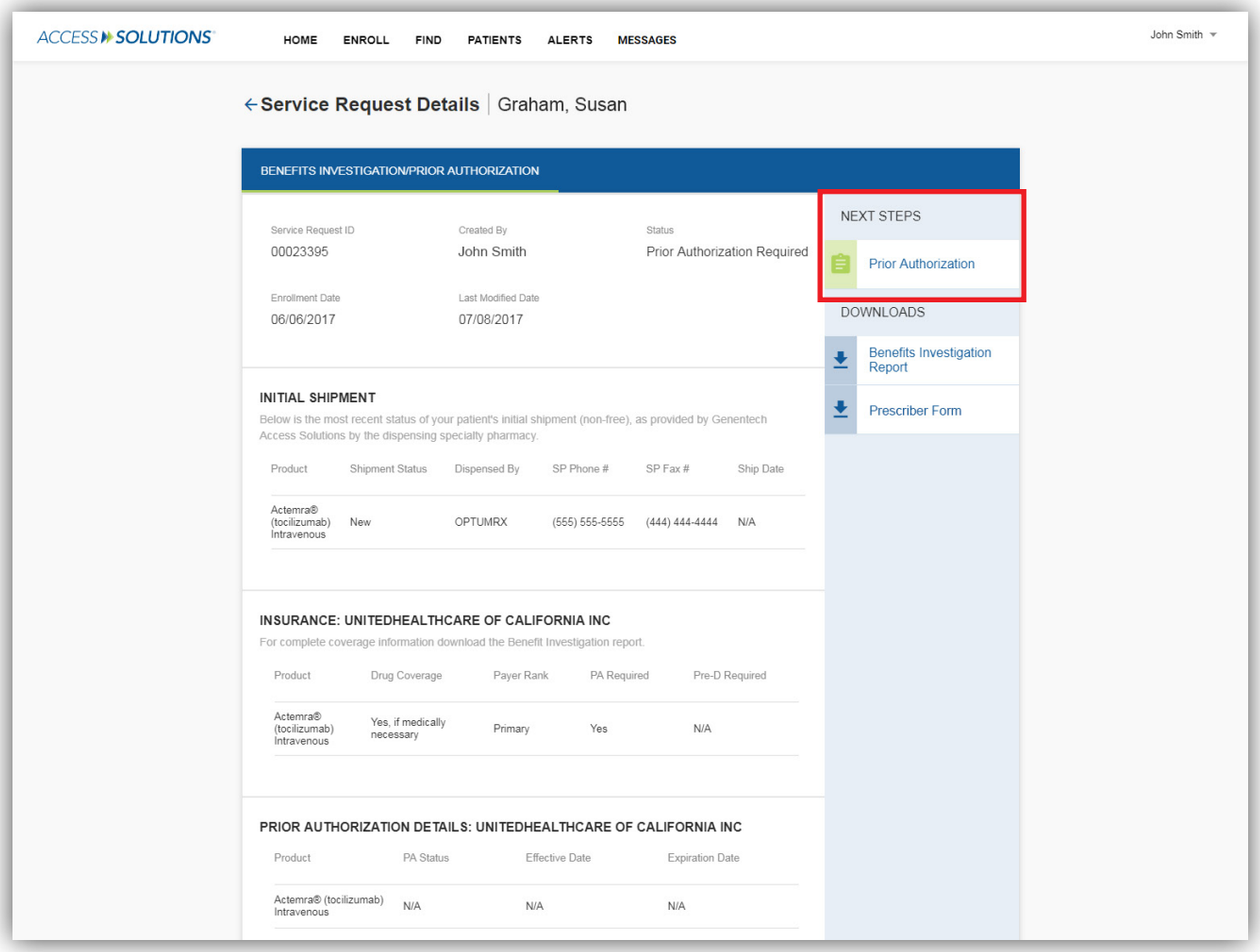
View service request details (BIs/PAs) (cont)



- Select BENEFITS INVESTIGATION REPORT under DOWNLOADS
  - The Prescriber Service Form submitted for this service request and PA forms (if available/applicable) will also be available under DOWNLOADS

Service Requests: Benefits Investigations and Prior Authorizations (cont)

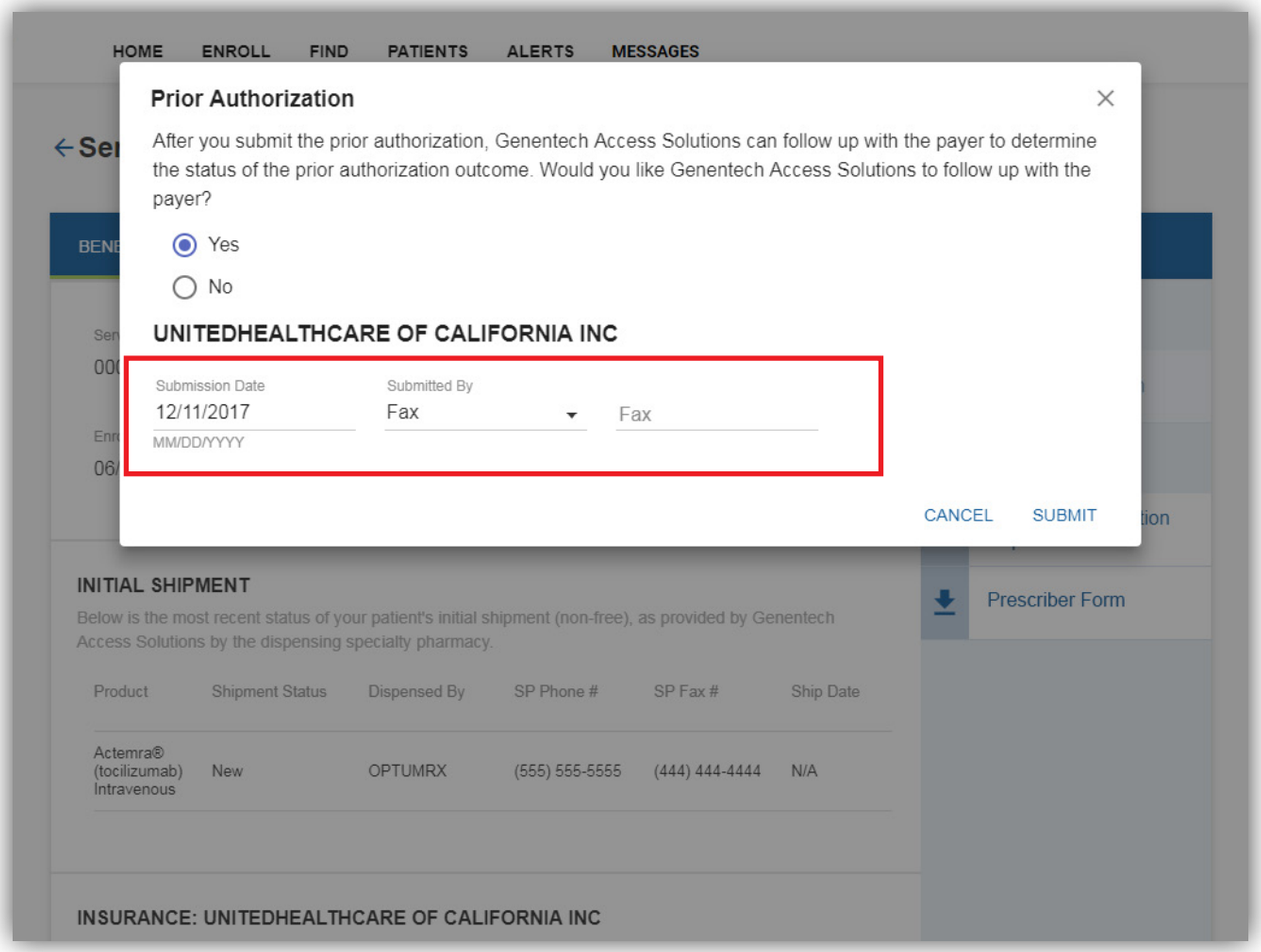
Request PA status follow-up



Select PRIOR AUTHORIZATION under NEXT STEPS to ask Genentech Access Solutions to follow up with the health insurance plan regarding the status of your patient's PA.

Service Requests: Benefits Investigations and Prior Authorizations (cont)

Request PA status follow-up (cont)



- Complete the details regarding when the PA was submitted
- Select SUBMIT
- Genentech Access Solutions will follow up with the patient's health insurance plan regarding the status of the PA

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

Service Requests: Benefits Investigations and Prior Authorizations (cont)

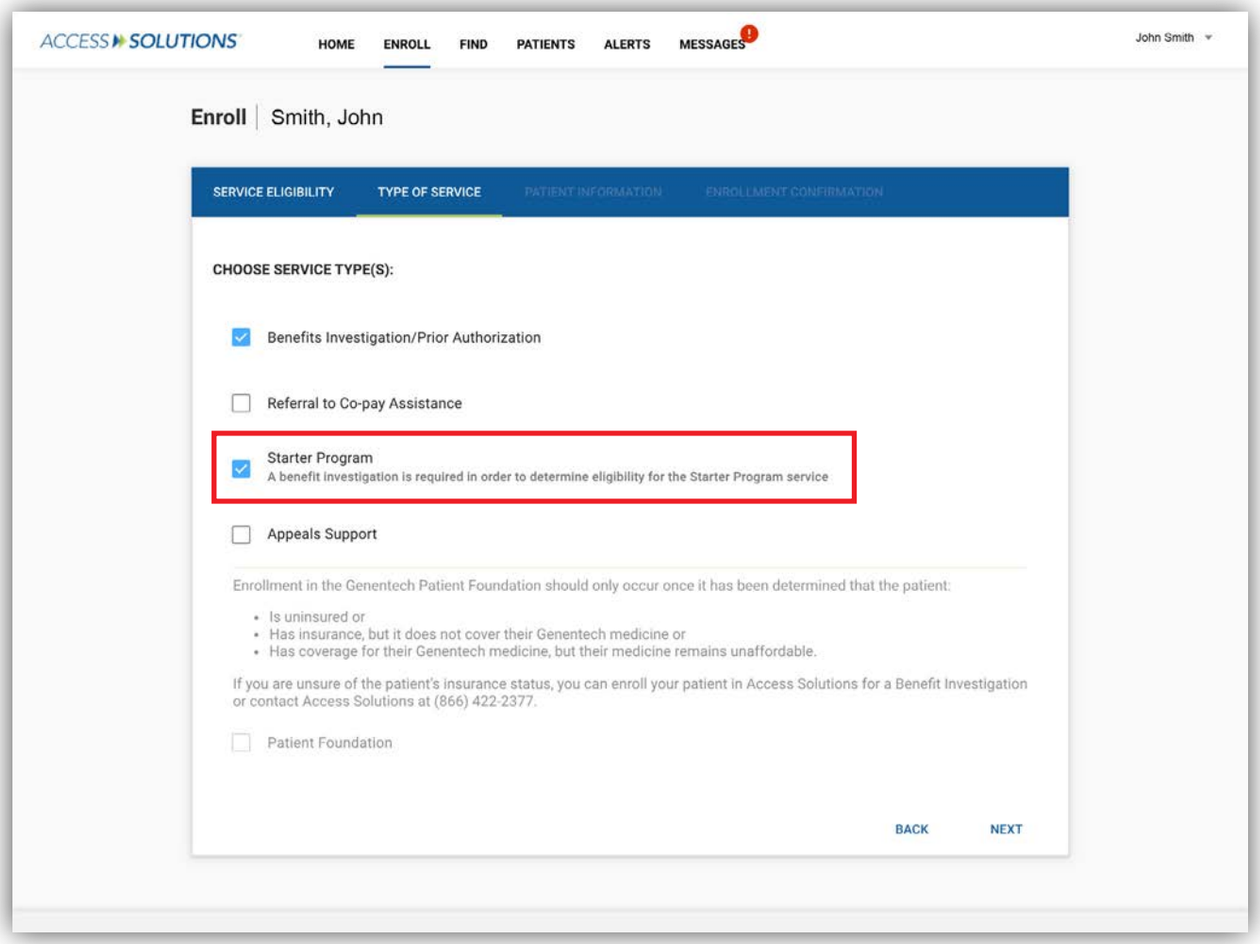
Important points to remember about service requests for BIs/PAs

- Required actions that can be completed via My Patient Solutions® for Health Care Practices for a selected service request are listed under NEXT STEPS
- BI Reports are only available for patients for whom a Prescriber Service Form has been completed and submitted
- The Prescriber Service Form submitted for a selected service request and PA forms (if available/applicable) are available under DOWNLOADS
- Once a PA determination is received, this information will be updated and available on the BI/PA service request details page
  - Users will also receive a fax to notify them of the patient's PA status

Service Requests: Starter Programs

With My Patient Solutions® for Health Care Practices, you can request for eligible patients to be enrolled in brand-specific starter programs as well as check the shipping status of any starter drug for patients enrolled in a starter program.

Enroll in a starter program

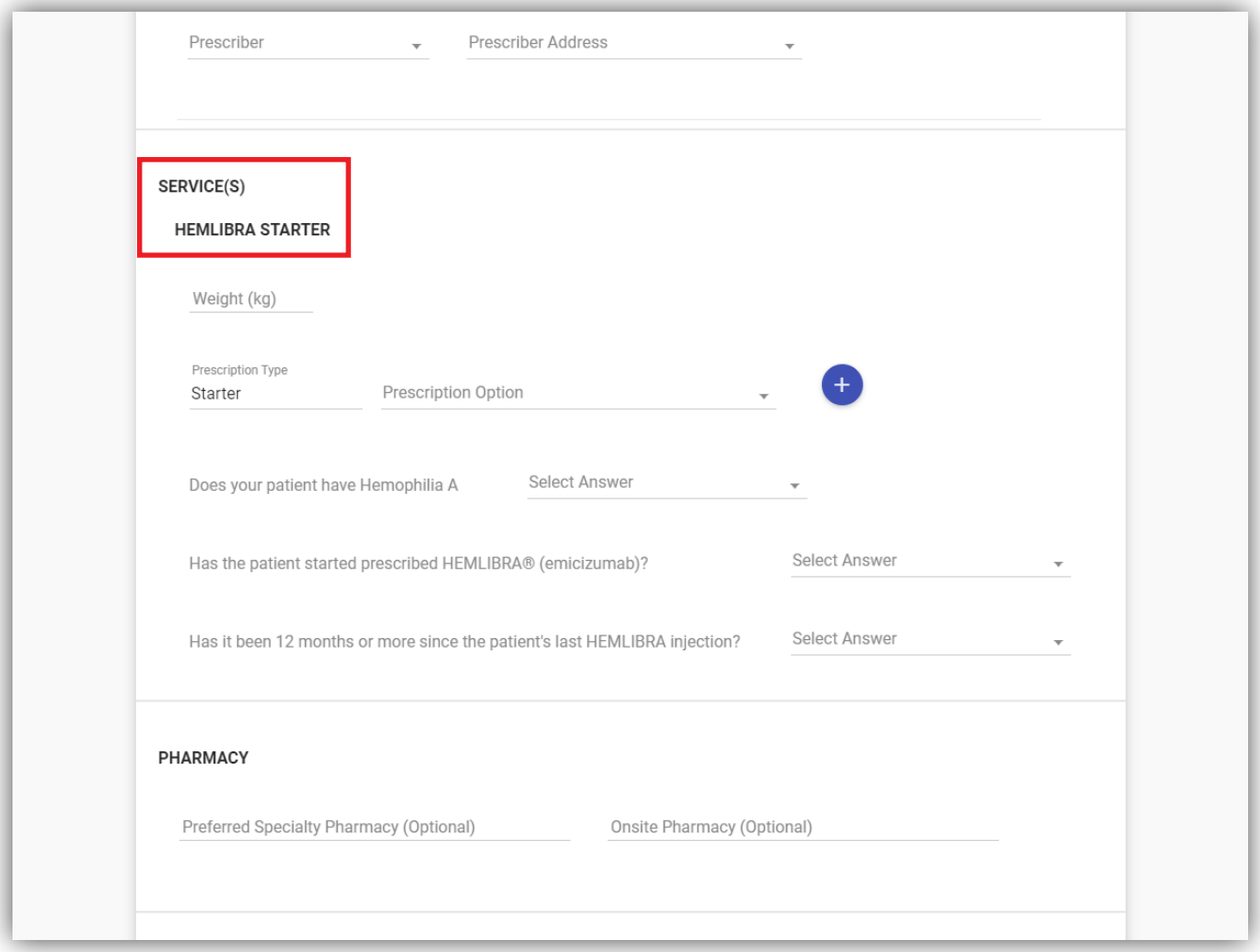


- Include STARTER PROGRAM when selecting service requests under TYPE OF SERVICE
  - — Genentech Access Solutions must also perform a benefits investigation (BI) as part of the starter program enrollment

Note: Starter programs are available on a brand-by-brand basis. Not all products have these programs available. Patients must meet eligibility criteria. For more information, contact your Field Reimbursement Manager (FRM).

Service Requests: Starter Programs (cont)

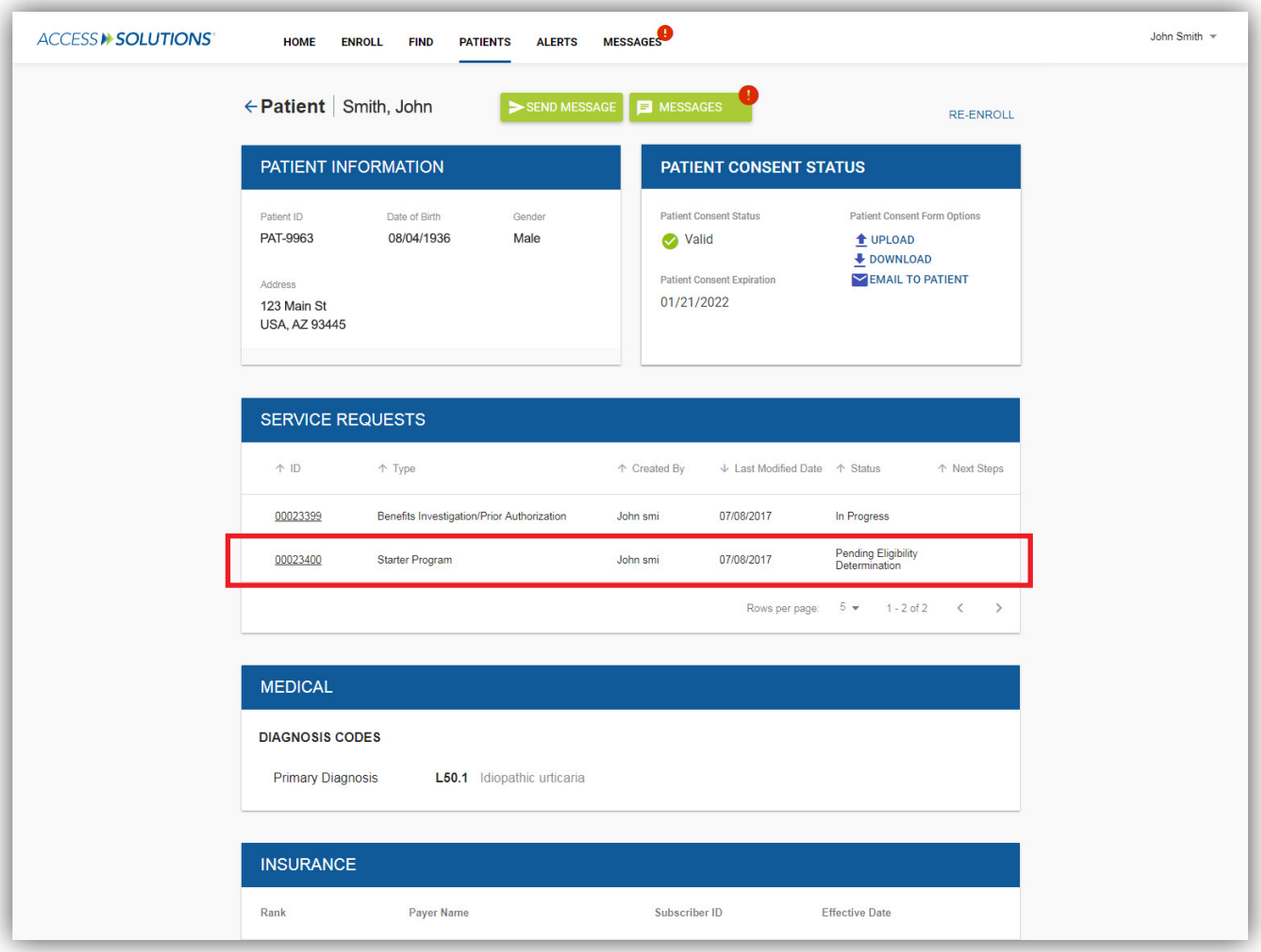
Enroll in a starter program (cont)



Answer the additional required questions regarding the starter program and shipping information.

Service Requests: Starter Programs (cont)

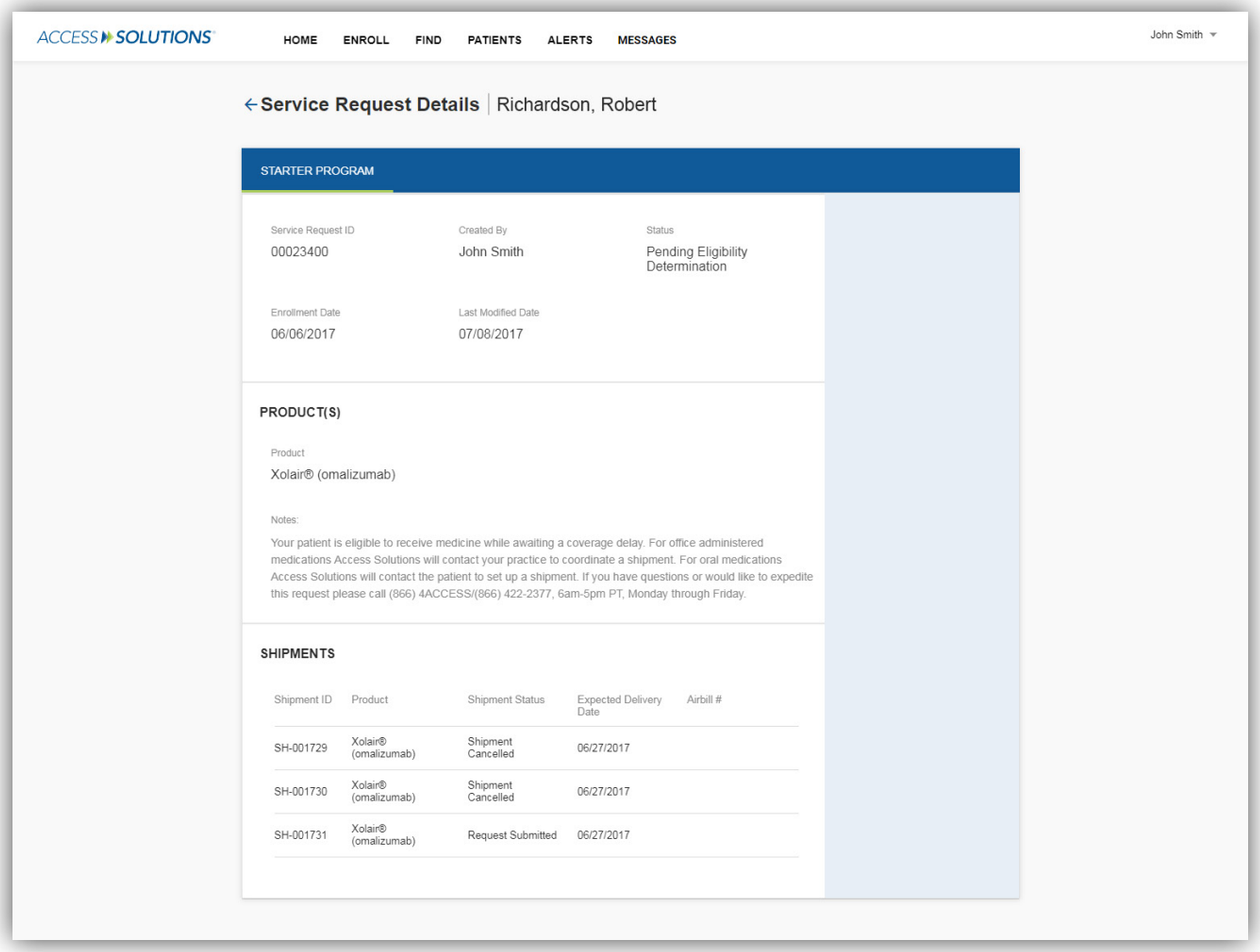
View the patient's status



Select the STARTER PROGRAM service request to see a detailed report.

Service Requests: Starter Programs (cont)

View the patient's status (cont)

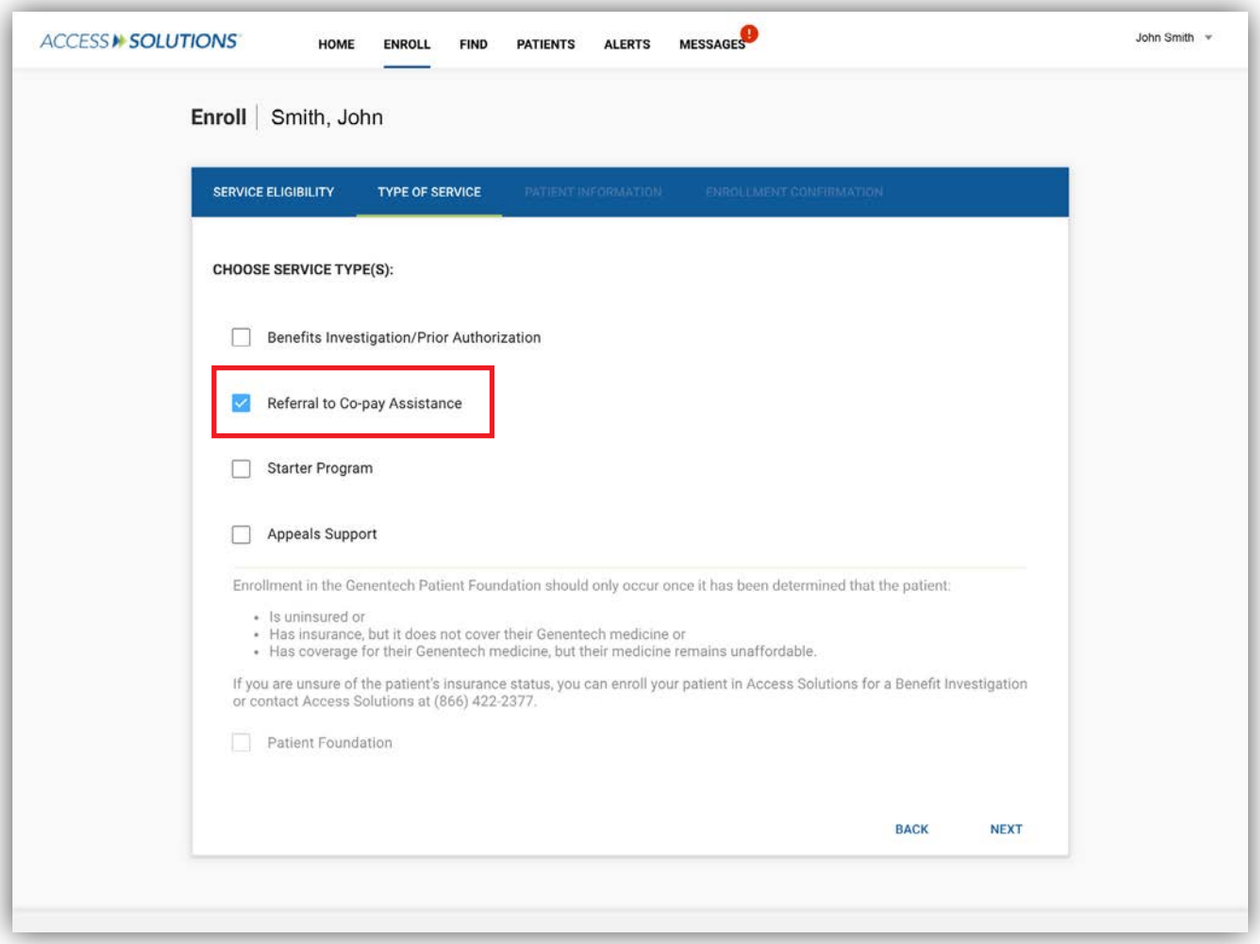


- View the patient's status in the SERVICE REQUEST DETAILS, including:
  - The patient's enrollment status
  - Next steps required to complete enrollment
  - Shipment details
  - Delivery status (if available)

Service Requests: Co-pay Assistance

You can request referrals to affordability options such as co-pay card programs or independent co-pay assistance foundations as well as view where the patient has been referred.

Request a referral to co-pay assistance



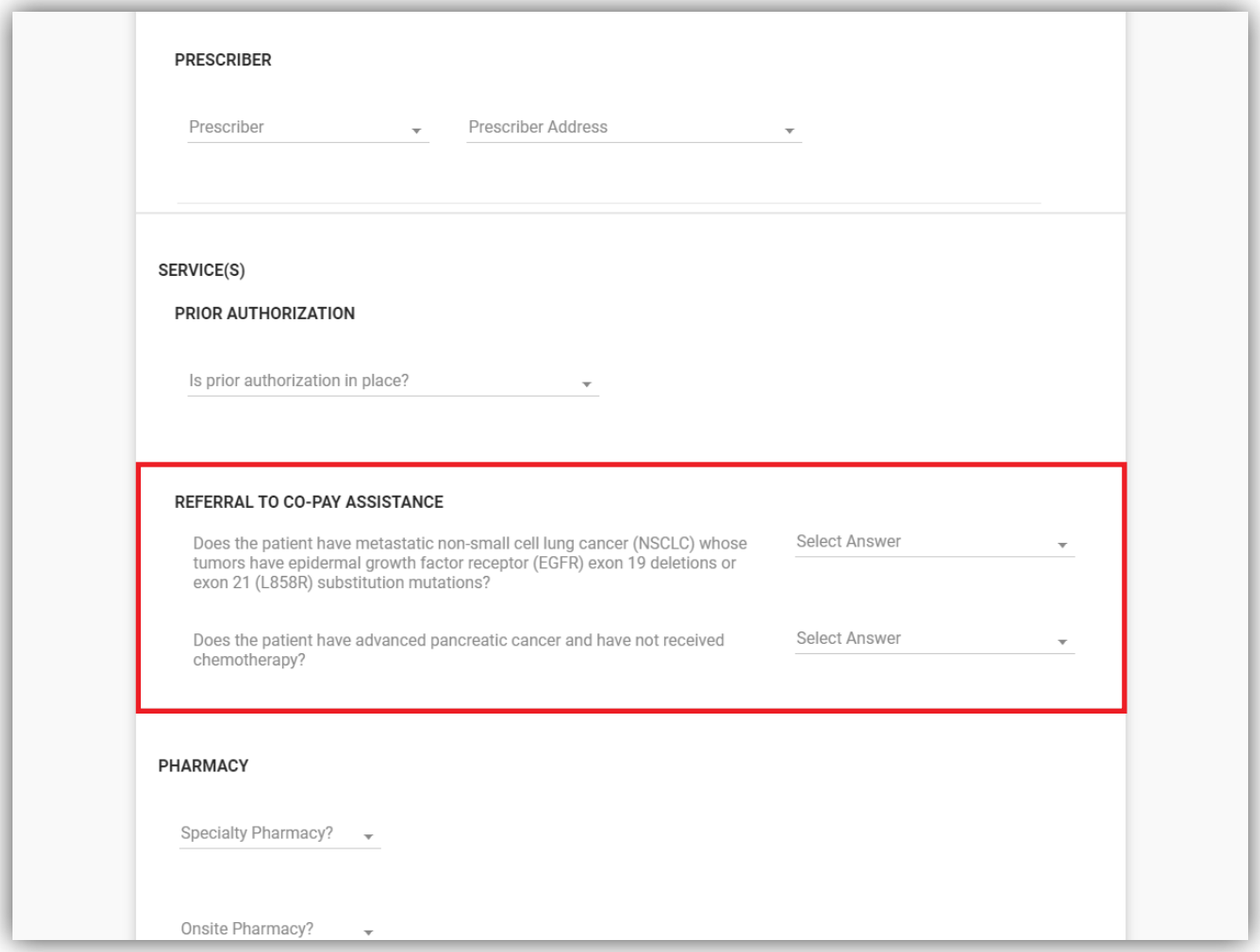
Include REFERRAL TO CO-PAY ASSISTANCE when selecting service requests under TYPE OF SERVICE.

Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications. Patient must be taking the Genentech medication for a FDA-approved indication. See full terms and conditions at the individual brand's website.

Genentech does not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation and cannot guarantee co-pay assistance after a referral from Genentech Access Solutions. The foundations to which we refer patients are not exhaustive or indicative of Genentech's endorsement or financial support. There may be other foundations to support the patient's disease state.

Service Requests: Co-pay Assistance (cont)

Request a referral to co-pay assistance (cont)



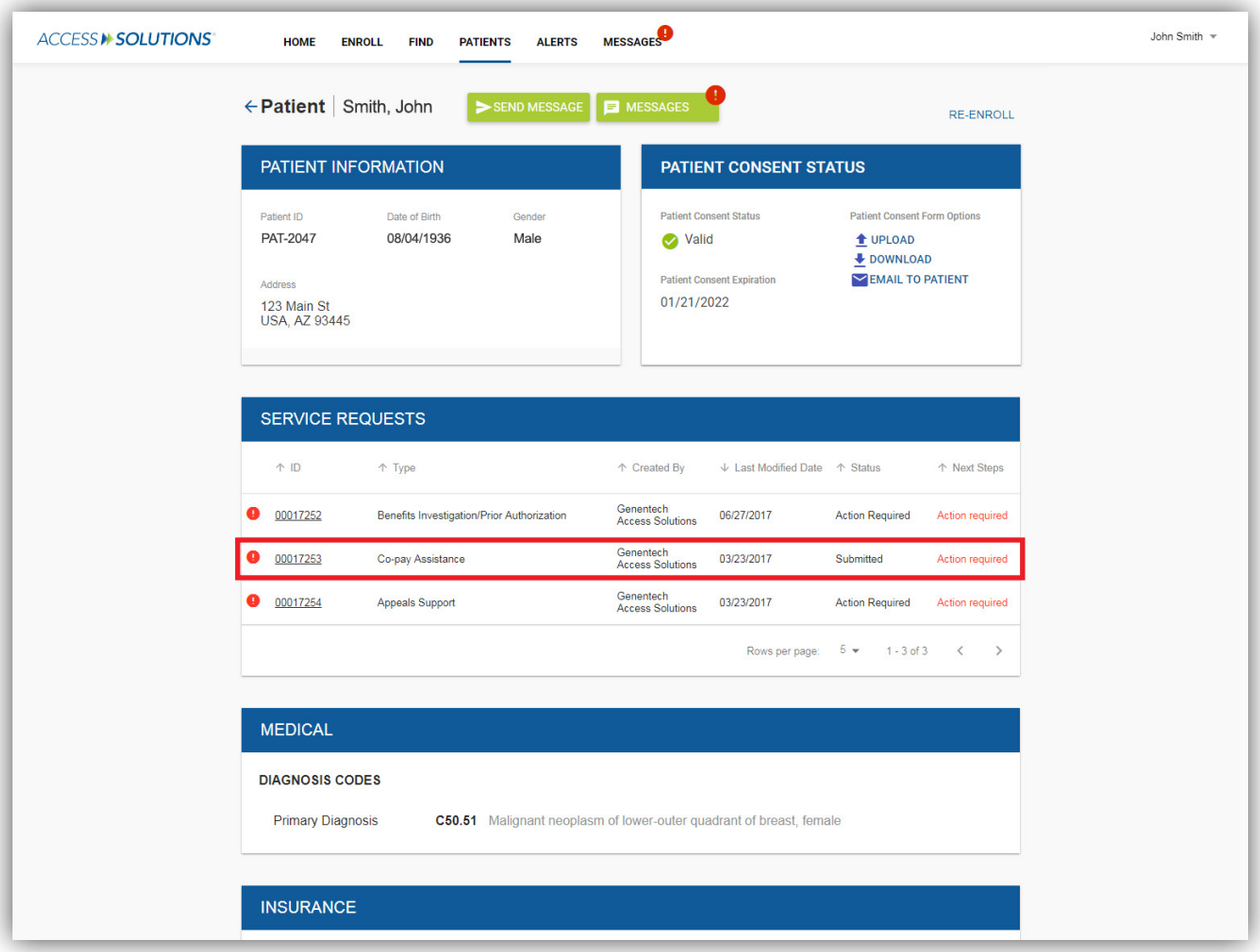
Certain products may require you to answer a few additional questions to request co-pay assistance. These will appear only if necessary.

Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications. Patient must be taking the Genentech medication for a FDA-approved indication. See full terms and conditions at the individual brand's website.

Genentech does not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation and cannot guarantee co-pay assistance after a referral from Genentech Access Solutions. The foundations to which we refer patients are not exhaustive or indicative of Genentech's endorsement or financial support. There may be other foundations to support the patient's disease state.

Service Requests: Co-pay Assistance (cont)

View the patient's status



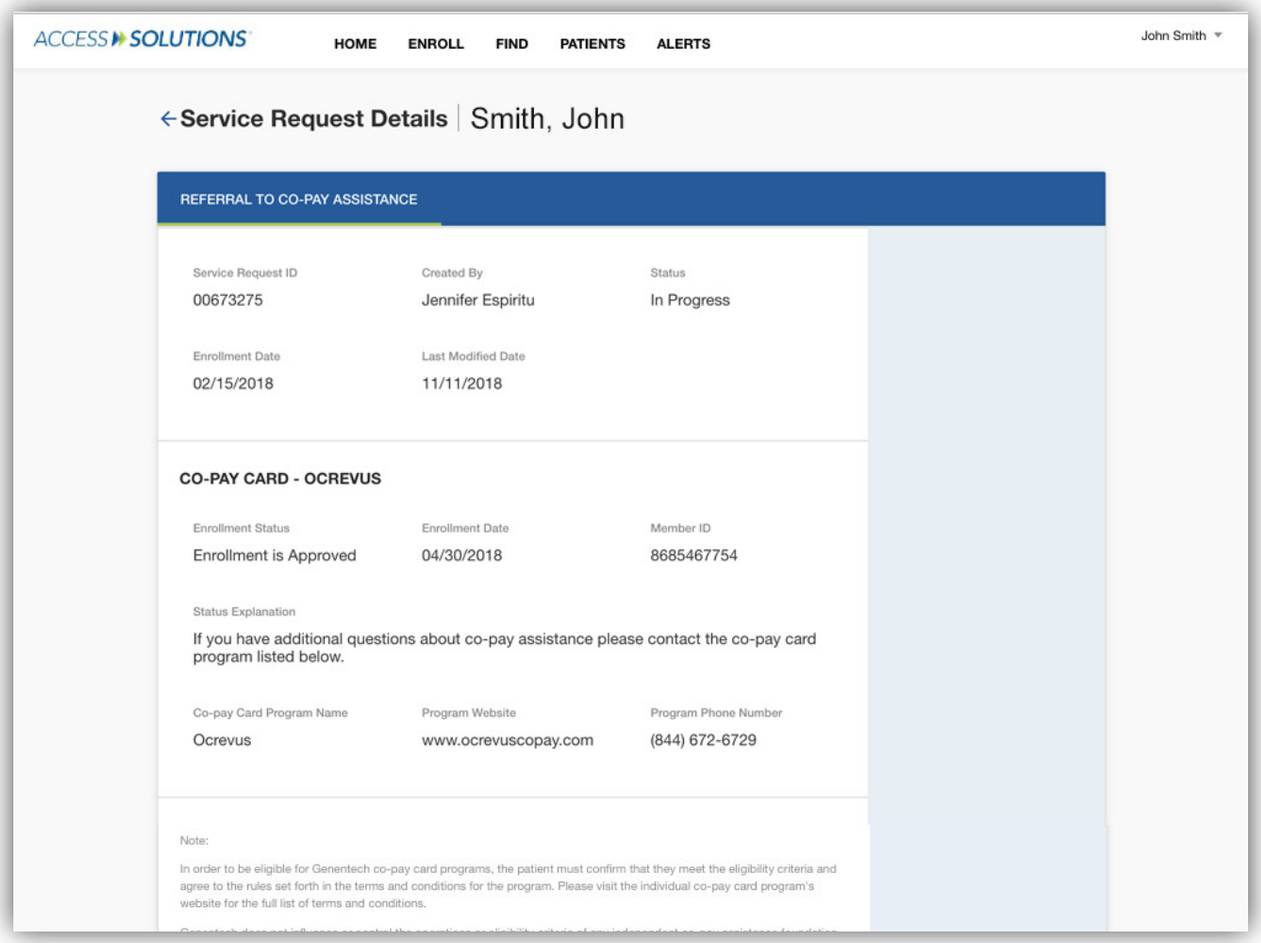
Select the CO-PAY ASSISTANCE service request within the patient profile to see a detailed report.

Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications. Patient must be taking the Genentech medication for a FDA-approved indication. See full terms and conditions at the individual brand's website.

Genentech does not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation and cannot guarantee co-pay assistance after a referral from Genentech Access Solutions. The foundations to which we refer patients are not exhaustive or indicative of Genentech's endorsement or financial support. There may be other foundations to support the patient's disease state.

Service Requests: Co-pay Assistance (cont)

View the patient's status (cont)



- View the patient's status as well as any next steps required to proceed with getting assistance in the SERVICE REQUEST DETAILS page
- If the patient has been enrolled in certain programs, his or her enrollment date will be displayed

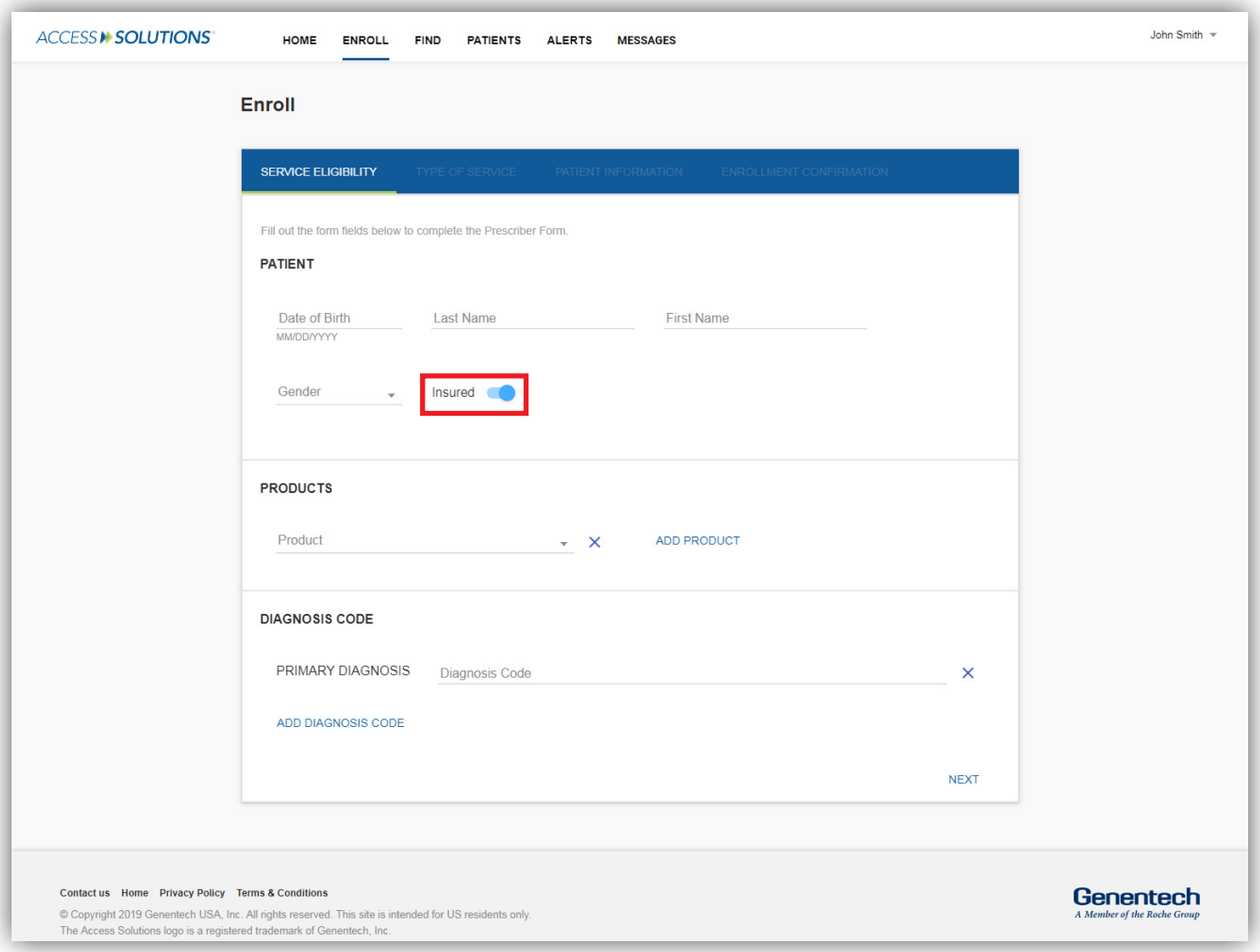
Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications. Patient must be taking the Genentech medication for a FDA-approved indication. See full terms and conditions at the individual brand's website.

Genentech does not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation and cannot guarantee co-pay assistance after a referral from Genentech Access Solutions. The foundations to which we refer patients are not exhaustive or indicative of Genentech's endorsement or financial support. There may be other foundations to support the patient's disease state.

Service Requests: Genentech Patient Foundation

When you enroll a patient, you can request assistance from the Genentech Patient Foundation. If patients are approved, you can track eligibility and coordinate shipping within My Patient Solutions® for Health Care Practices.

Request assistance from the Genentech Patient Foundation

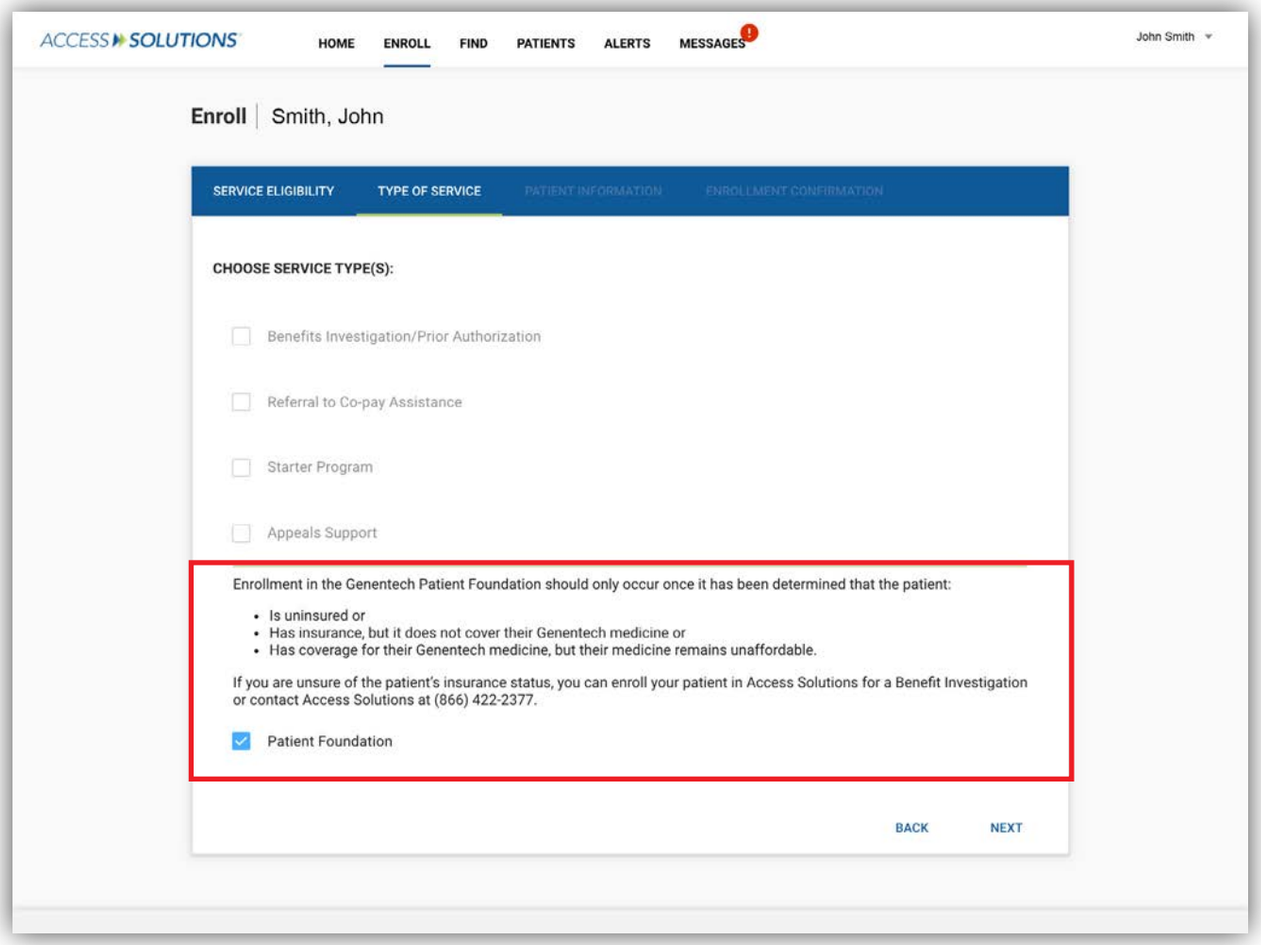


- Begin enrollment
- Identify if the patient is insured or not insured

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

Request assistance from the Genentech Patient Foundation (cont)

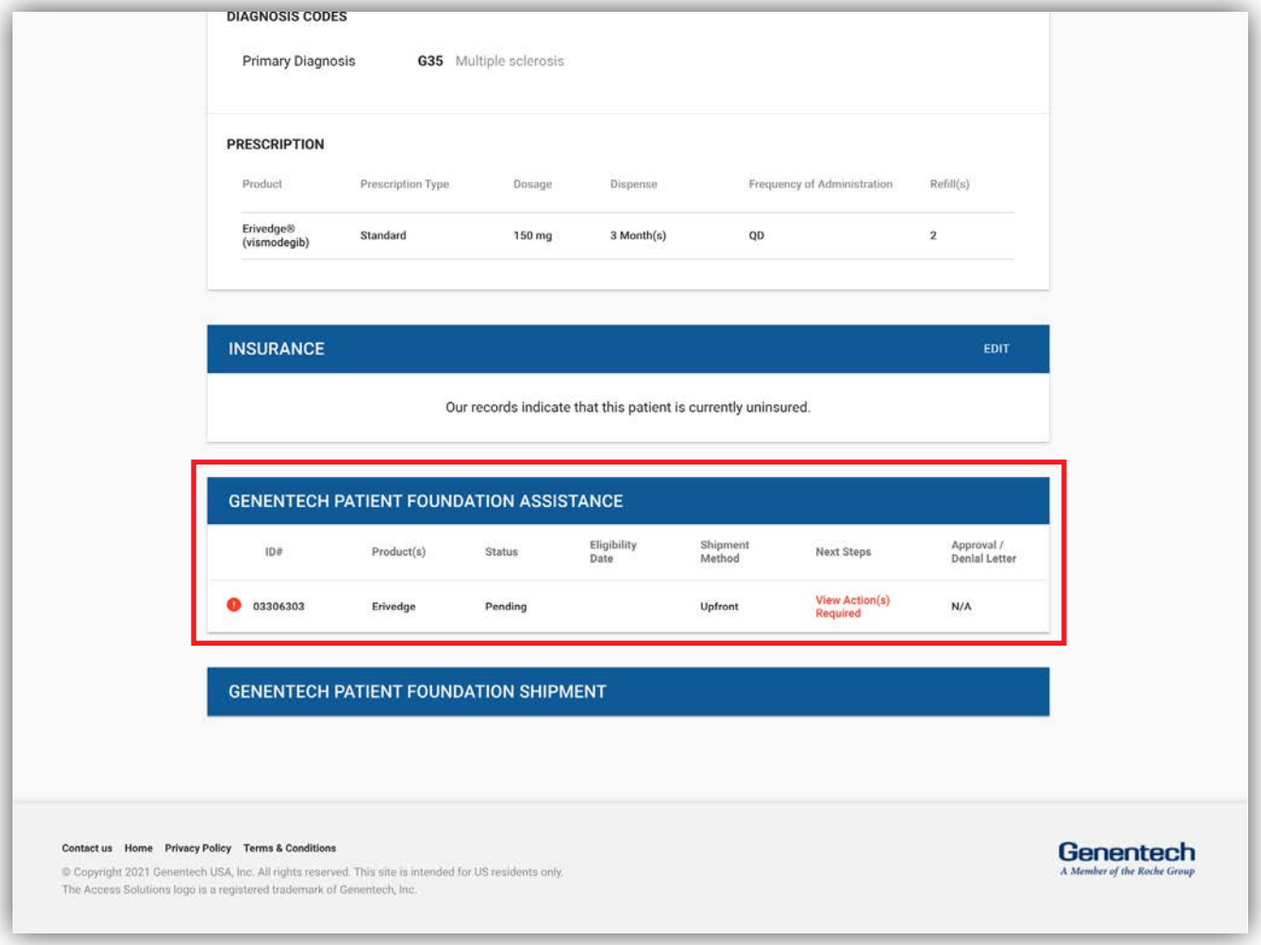


- Select Genentech Patient Foundation from the service request list
- If the patient does not have insurance, this will be the only option on the list
- You will be prompted to complete the rest of the Prescriber Foundation Form on the next screen
  - A signature is required

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

View eligibility information

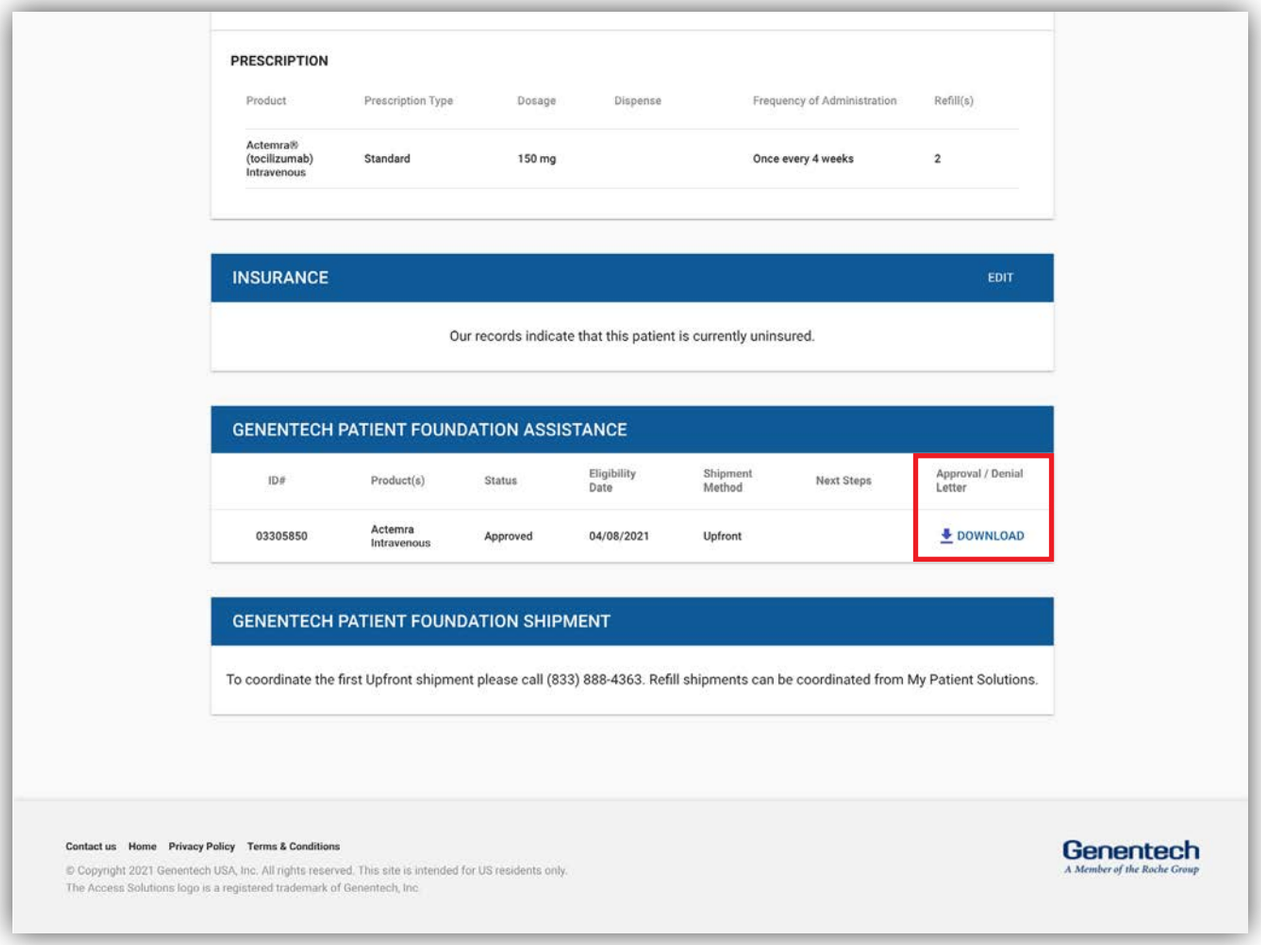


- Go to the patient's profile
- Scroll down to view the Genentech Patient Foundation Assistance table
  - — Here you can view details about the patient's eligibility status, including the date of enrollment and the type of shipment (i.e., upfront, replacement)

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

Download the approval letter

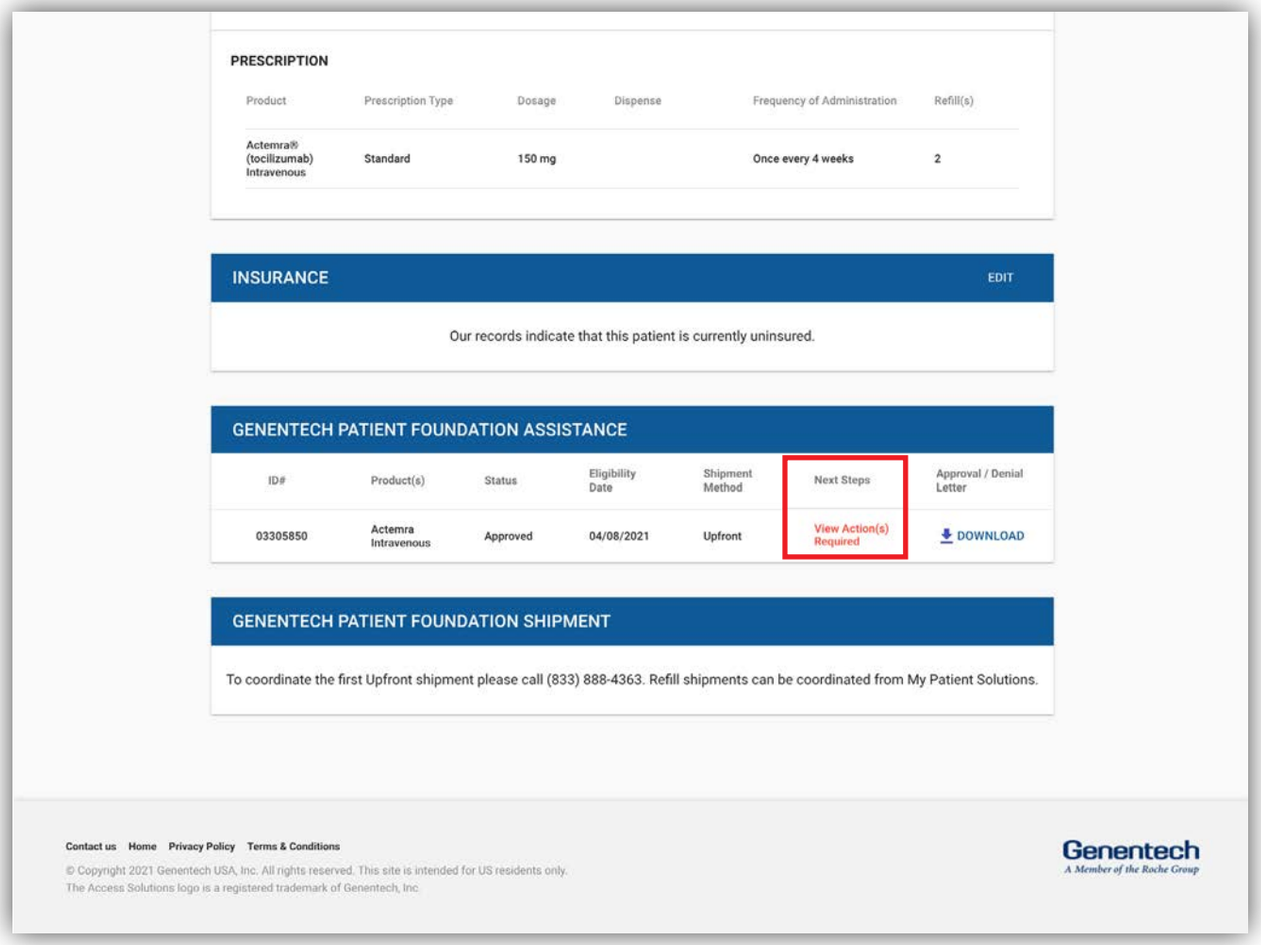


Select the link in the Approval Letter column to download the Genentech Patient Foundation approval letter.

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

Address missing information/next steps

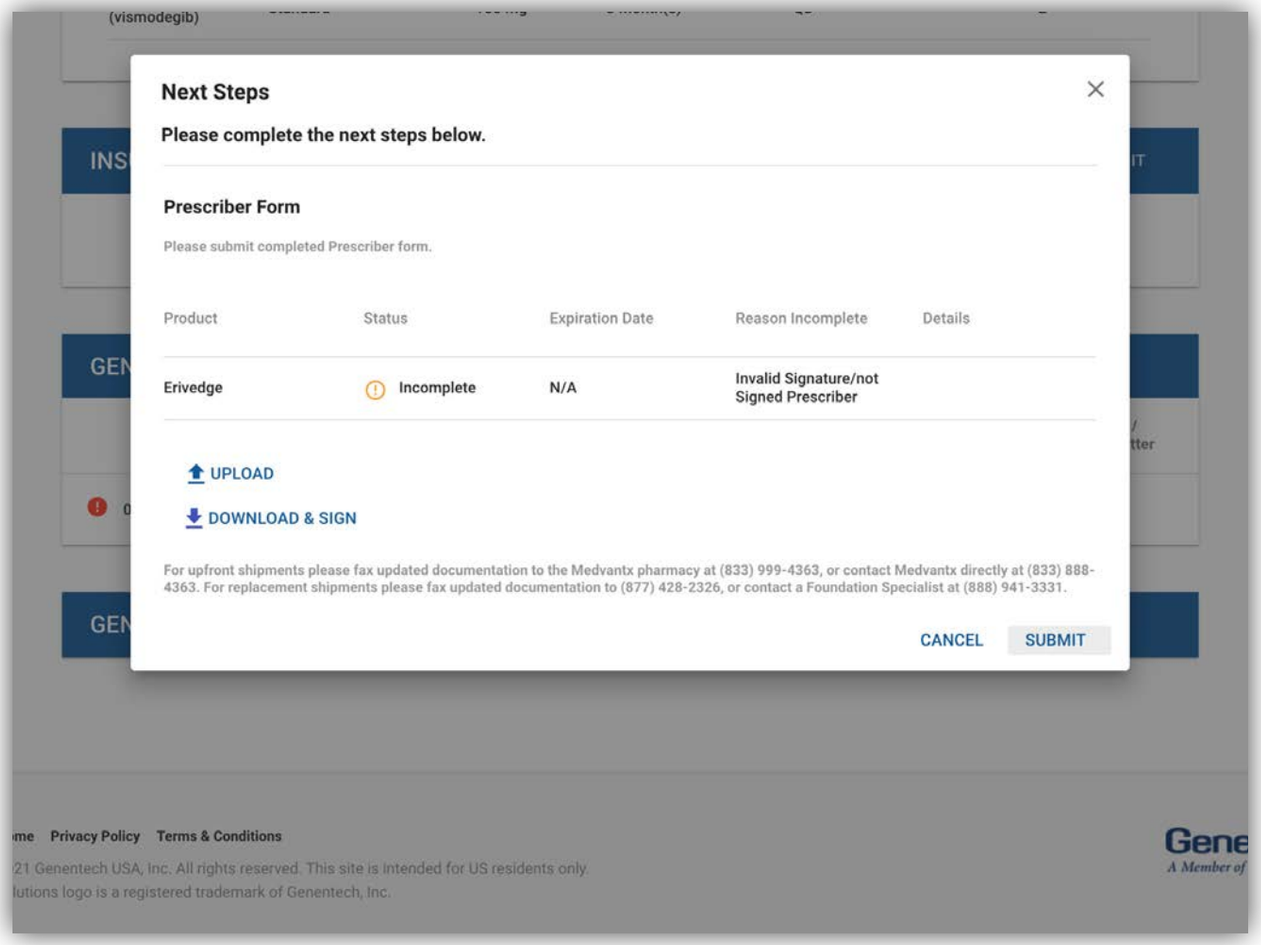


- Select the link in the Next Steps column
  - This link will only appear if an action is required

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

Address missing information/next steps (cont)

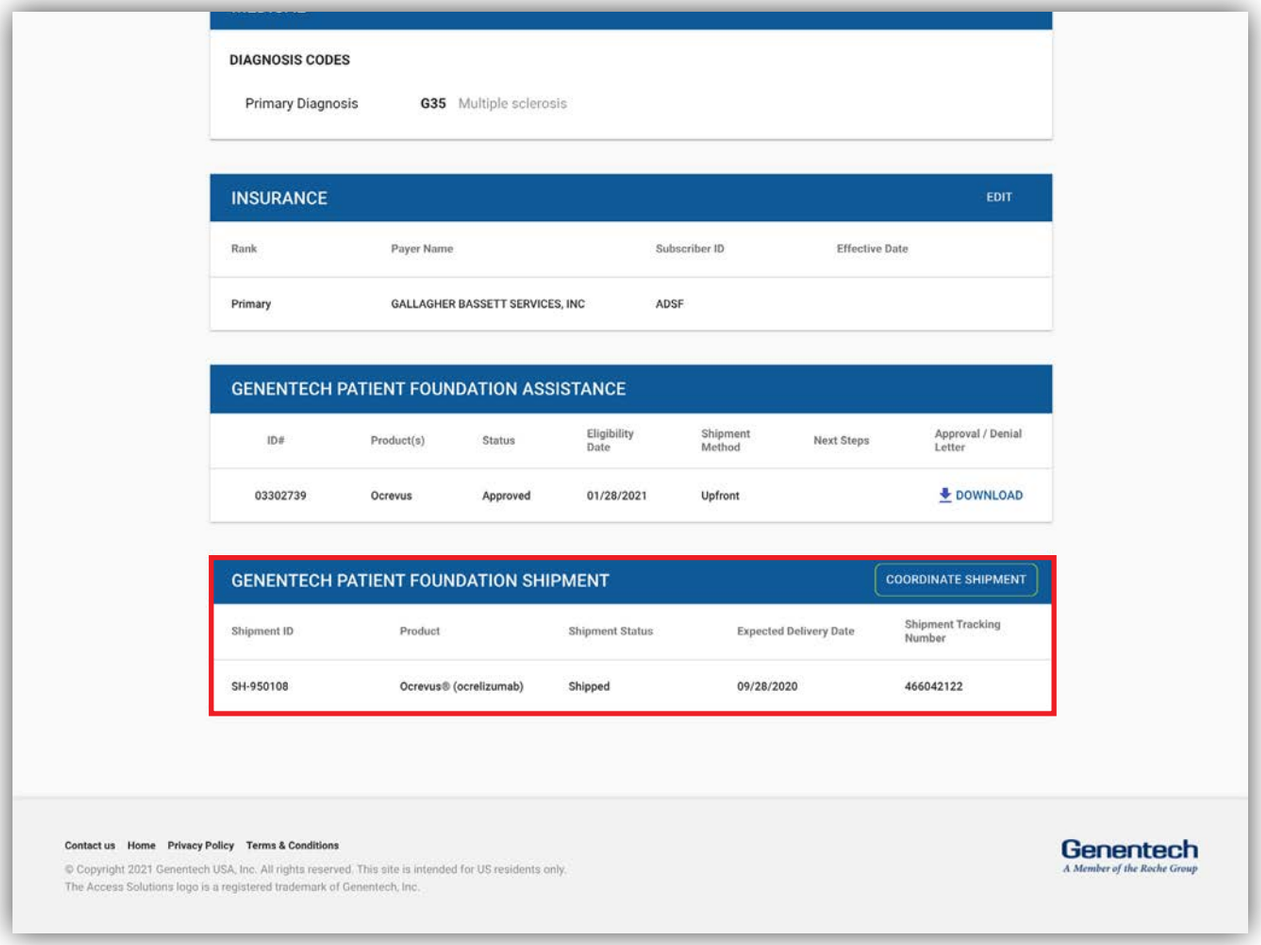


View the actions required and address them accordingly.

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

Coordinate refill shipments



- Go to the patient's profile
- Scroll down to view the Genentech Patient Foundation Shipment table
- View the expected shipment date, tracking number and shipment status

Note: Only refill shipments can be coordinated from My Patient Solutions® for Health Care Practices. To coordinate the first upfront shipment, please call (833) 888-4363.

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Genentech Patient Foundation (cont)

Important points to remember about Genentech Patient Foundation service requests

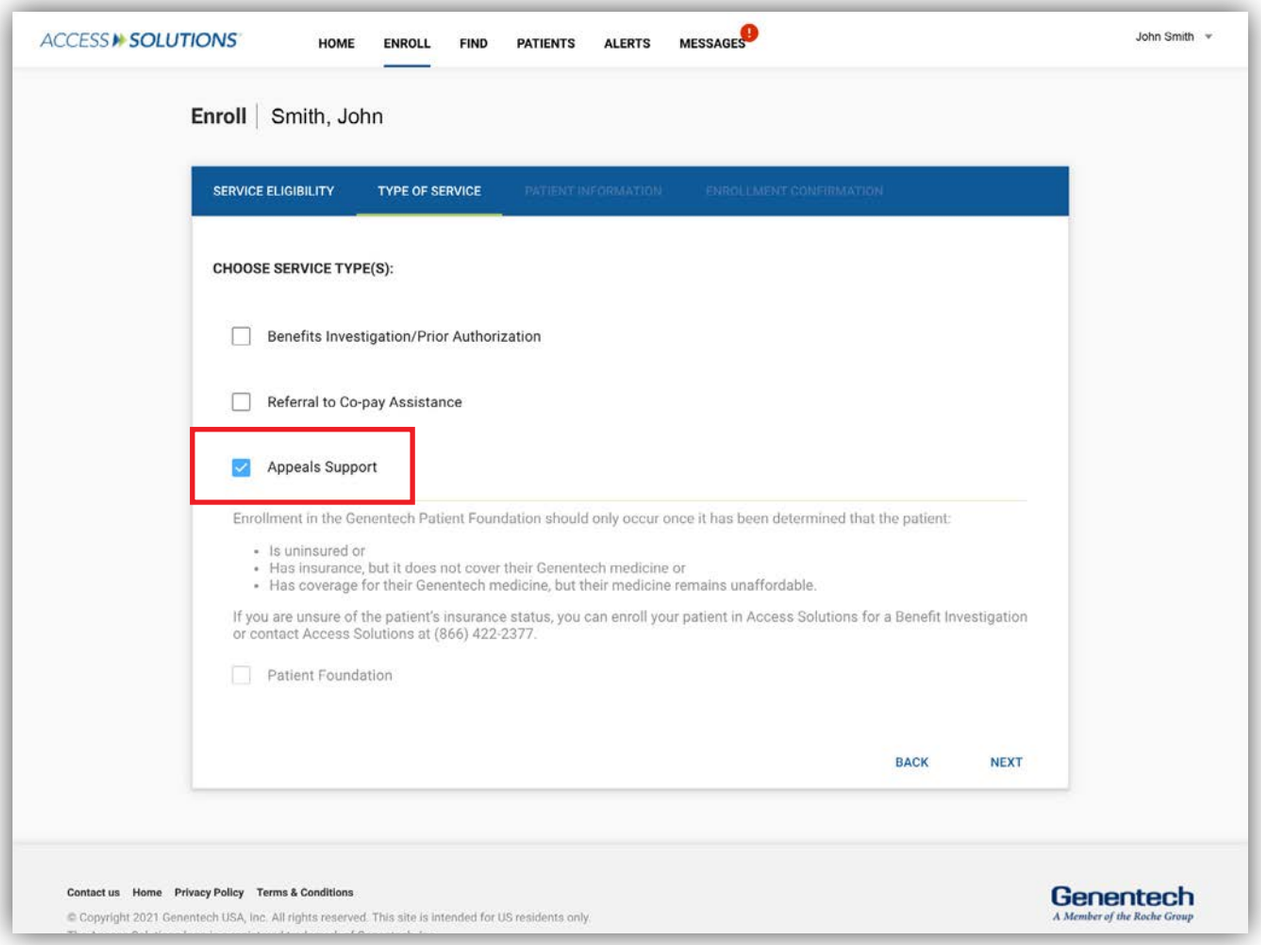
- An eSigned Prescriber Foundation Form cannot be used as a prescription for upfront shipments
  - — You may provide verbal prescriptions by calling (833) 888-4363, faxing a prescription with a "wet" signature to (833) 999-4363 or submitting an ePrescription to Medvantx (AmeriPharm), NCPDP/NABP: 4351968, NPI: 1073692745
- If you have additional questions about your Genentech Patient Foundation patients, you can message your Foundation Specialist via the messaging feature
- You may also enroll patients in the Genentech Patient Foundation by downloading and faxing the Prescriber Foundation Form or using Quick Enroll
  - — Patients must still complete the Patient Consent Form and fill out Section 2

To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Service Requests: Appeals Support

If your patient faces a coverage or claim denial, you can request resources for appeals via My Patient Solutions® for Health Care Practices.

Request appeals resources

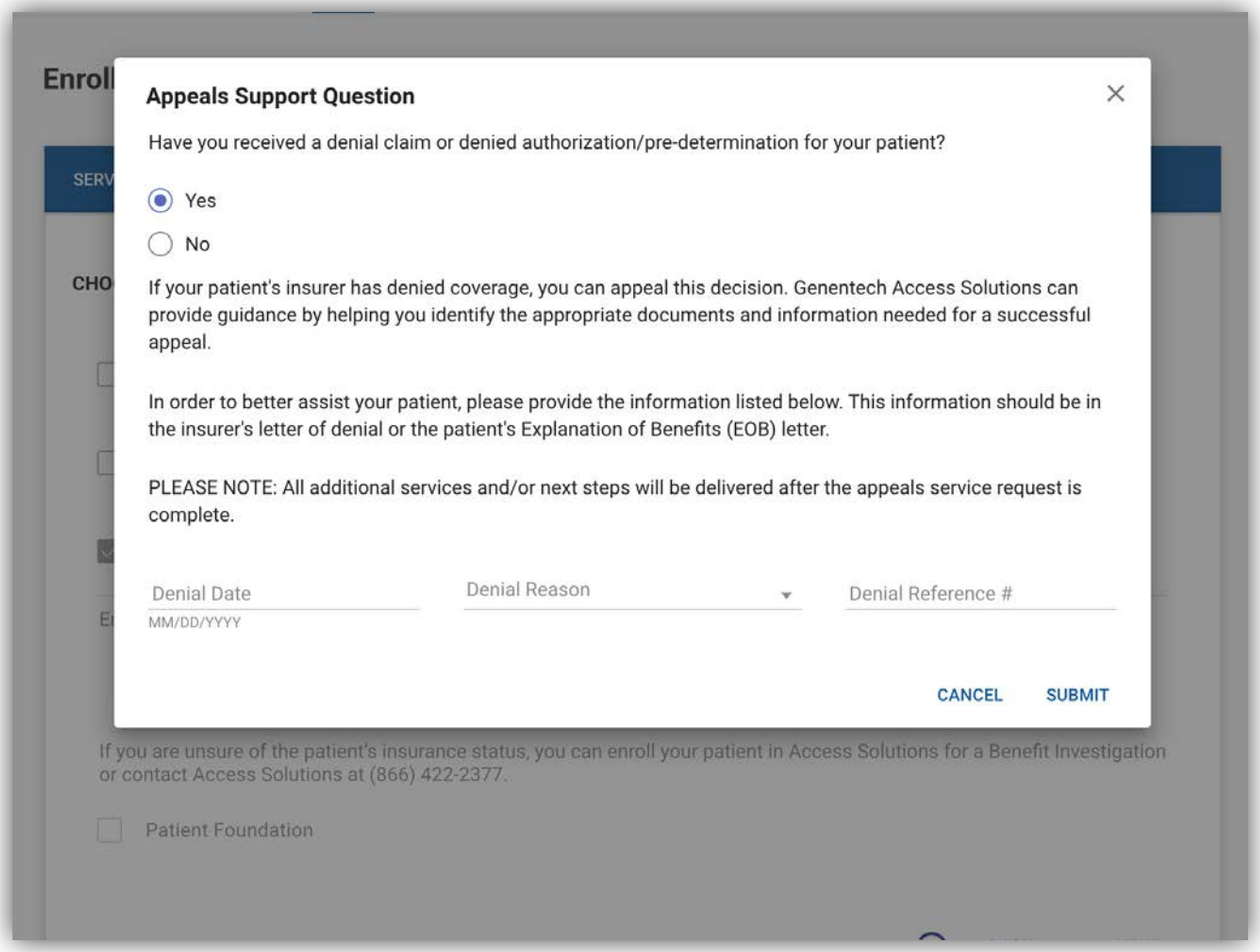


Include APPEALS SUPPORT when selecting service requests under TYPE OF SERVICE.

Note: Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Service Requests: Appeals Support (cont)

Request appeals resources (cont)

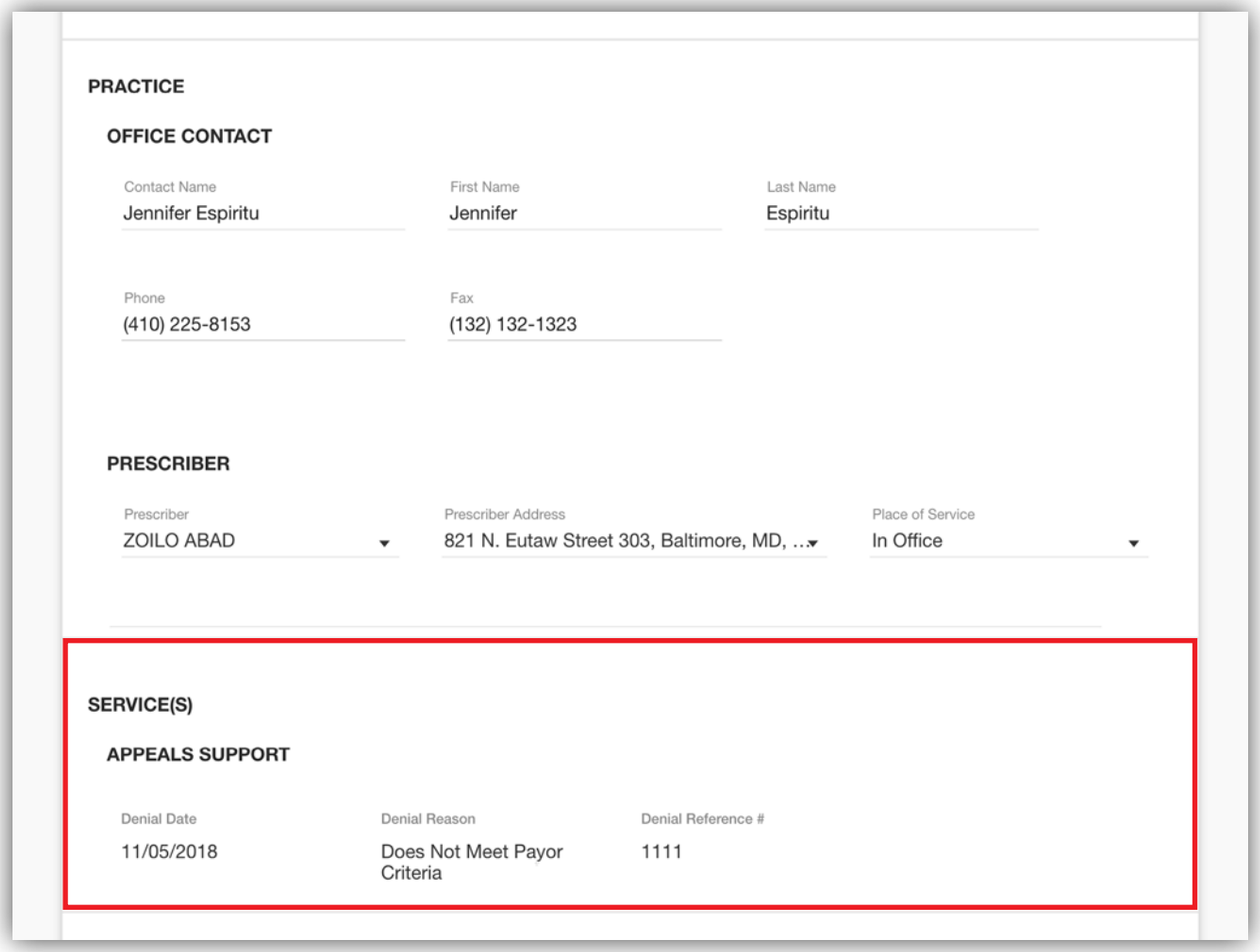


- Enter additional information about the patient's denial, including:
  - Whether you have received a claim denial or a denied prior authorization/predetermination
  - The denial date
  - The denial reason
  - The denial reference number

Note: Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Service Requests: Appeals Support (cont)

Request appeals resources (cont)

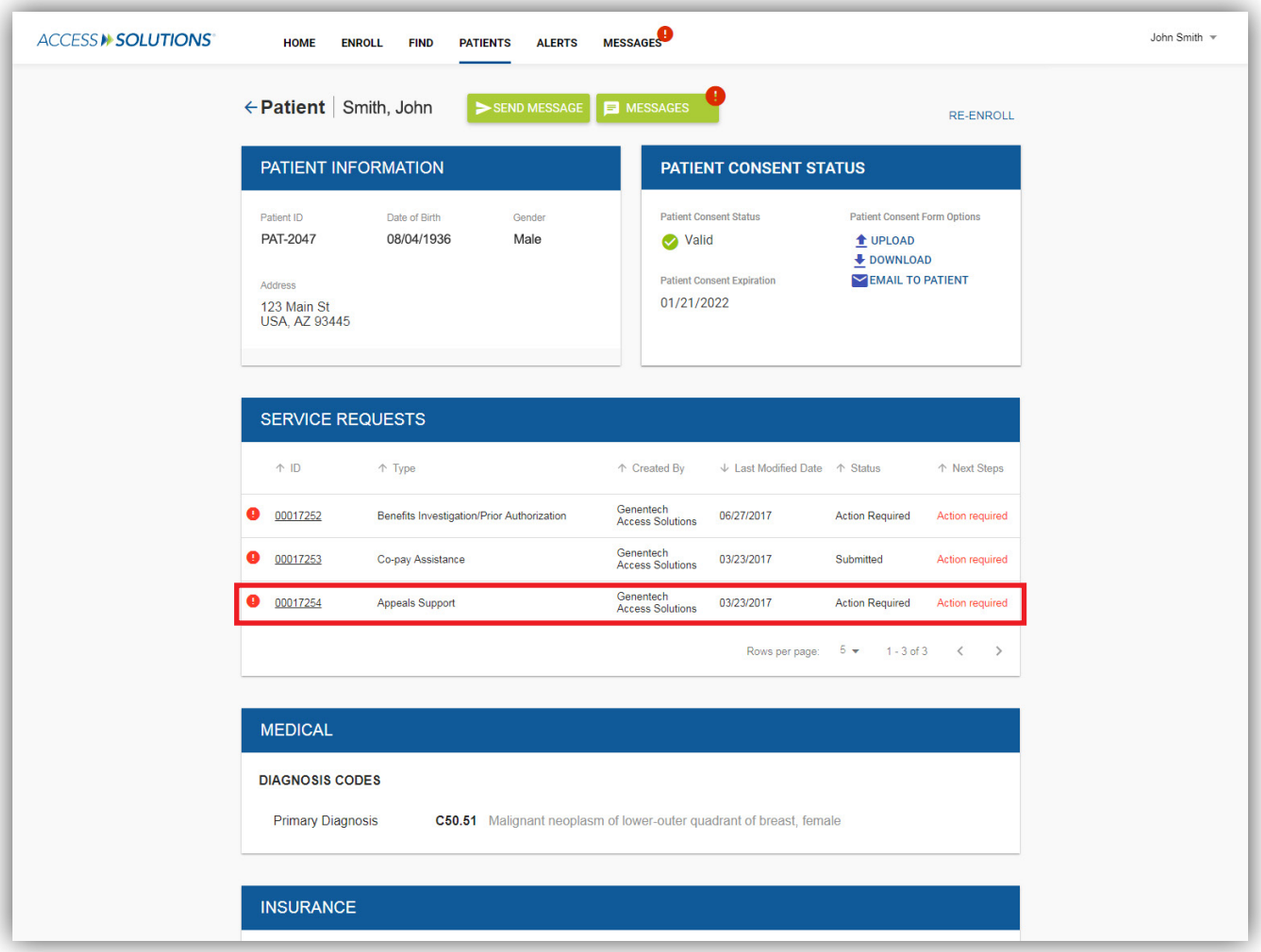


Confirm this information is correct on the patient information screen.

Note: Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Service Requests: Appeals Support (cont)

View the patient's status

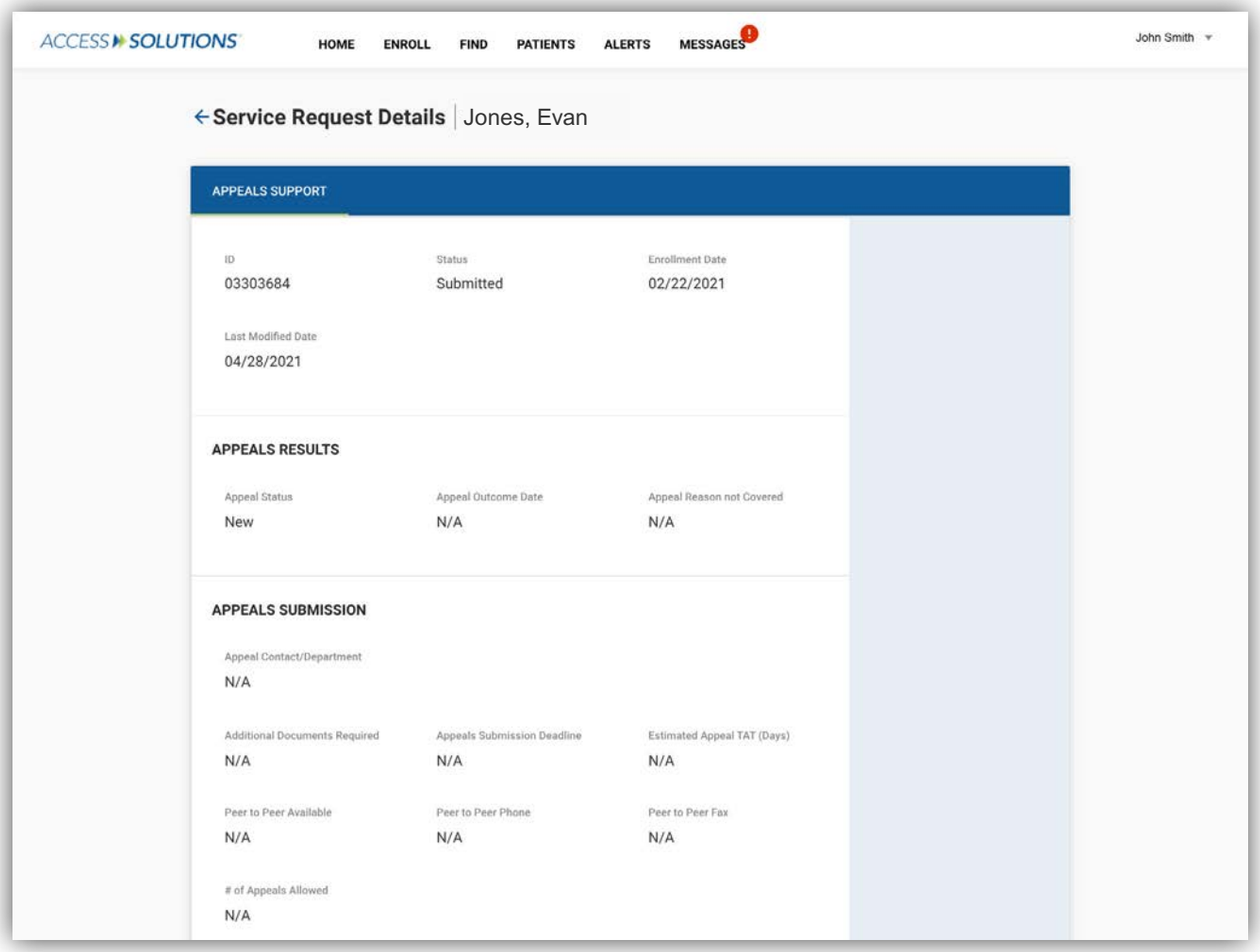


Select the APPEALS SUPPORT service request within the patient profile to see a detailed report.

Note: Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Service Requests: Appeals Support (cont)

View the patient's status (cont)



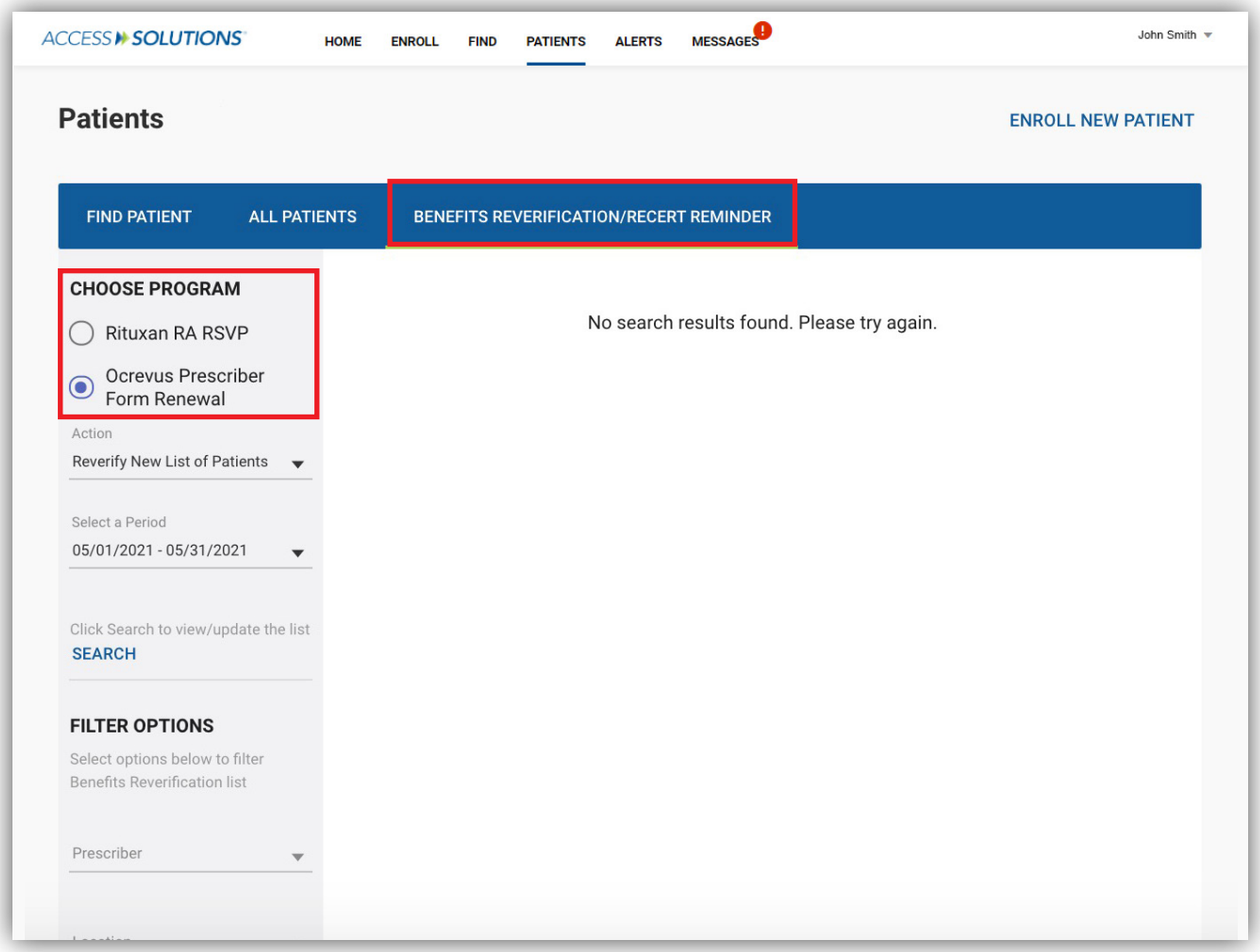
View additional information about the appeal once it has been submitted by the practice.

Note: Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Service Requests: Reverification/Recertification

Through My Patient Solutions® for Health Care Practices, you can request reverification of benefits for multiple patients at once. This feature is only available for certain brands.

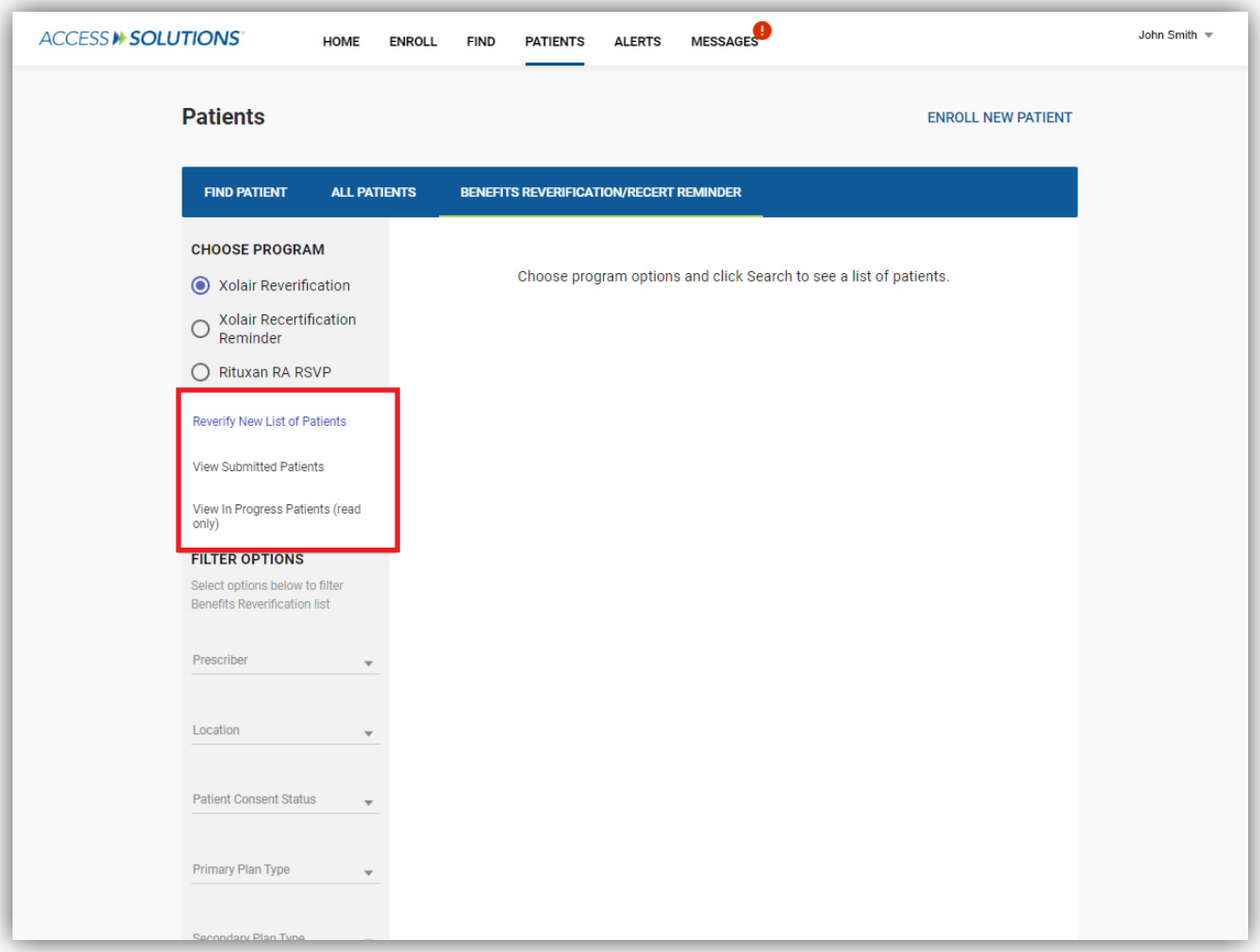
Specify the reverification/recertification program



- Select BENEFITS REVERIFICATION/RECERT REMINDER from the patient list view
- Choose a benefits reverification program

Service Requests: Reverification/Recertification (cont)

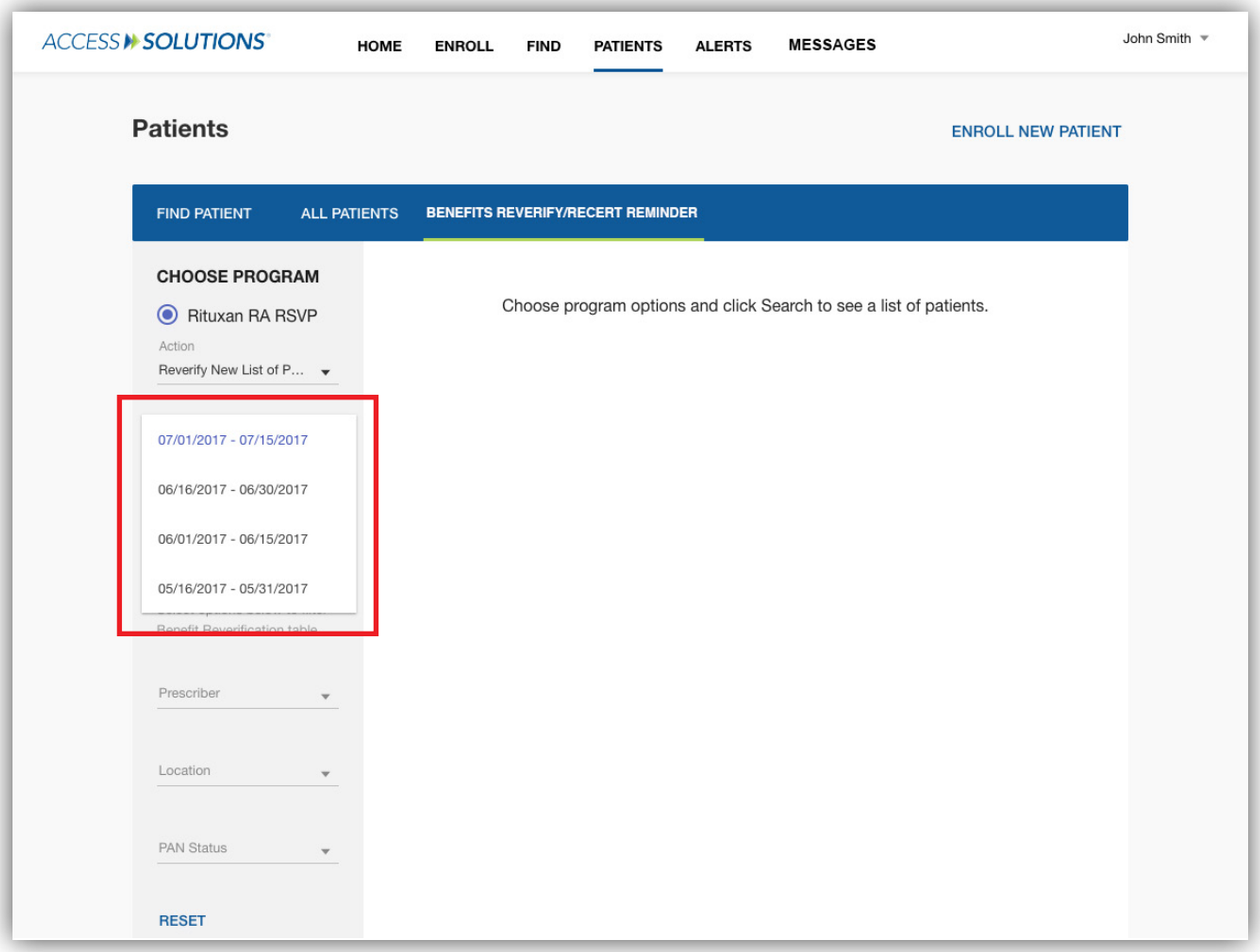
Choose your next action



Choose your next action from the dropdown menu options for the program you have selected.

Service Requests: Reverification/Recertification (cont)

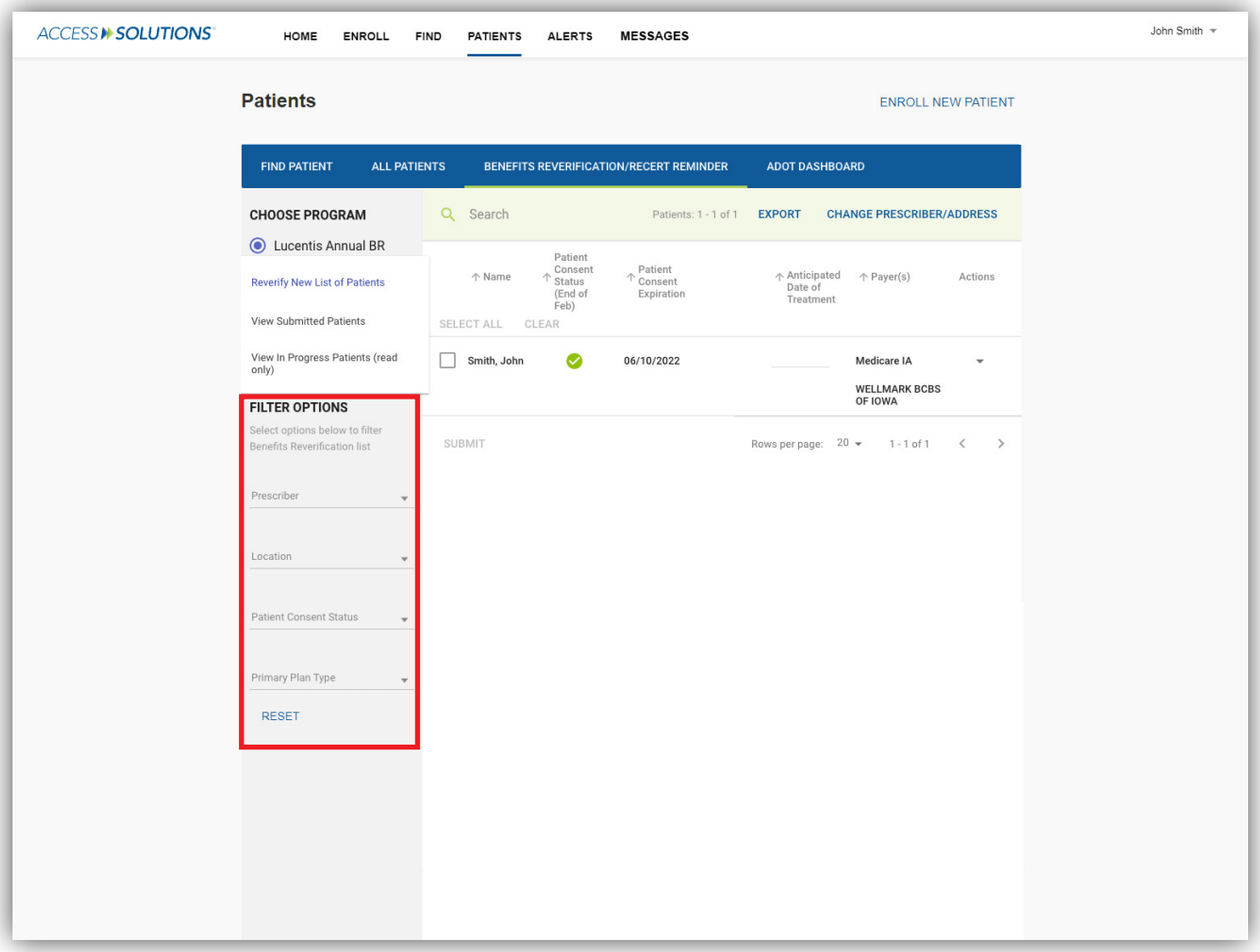
Select date range



- Choose an eligibility period
- Select SEARCH
  - — A list of patients meeting your criteria is returned

Service Requests: Reverification/Recertification (cont)

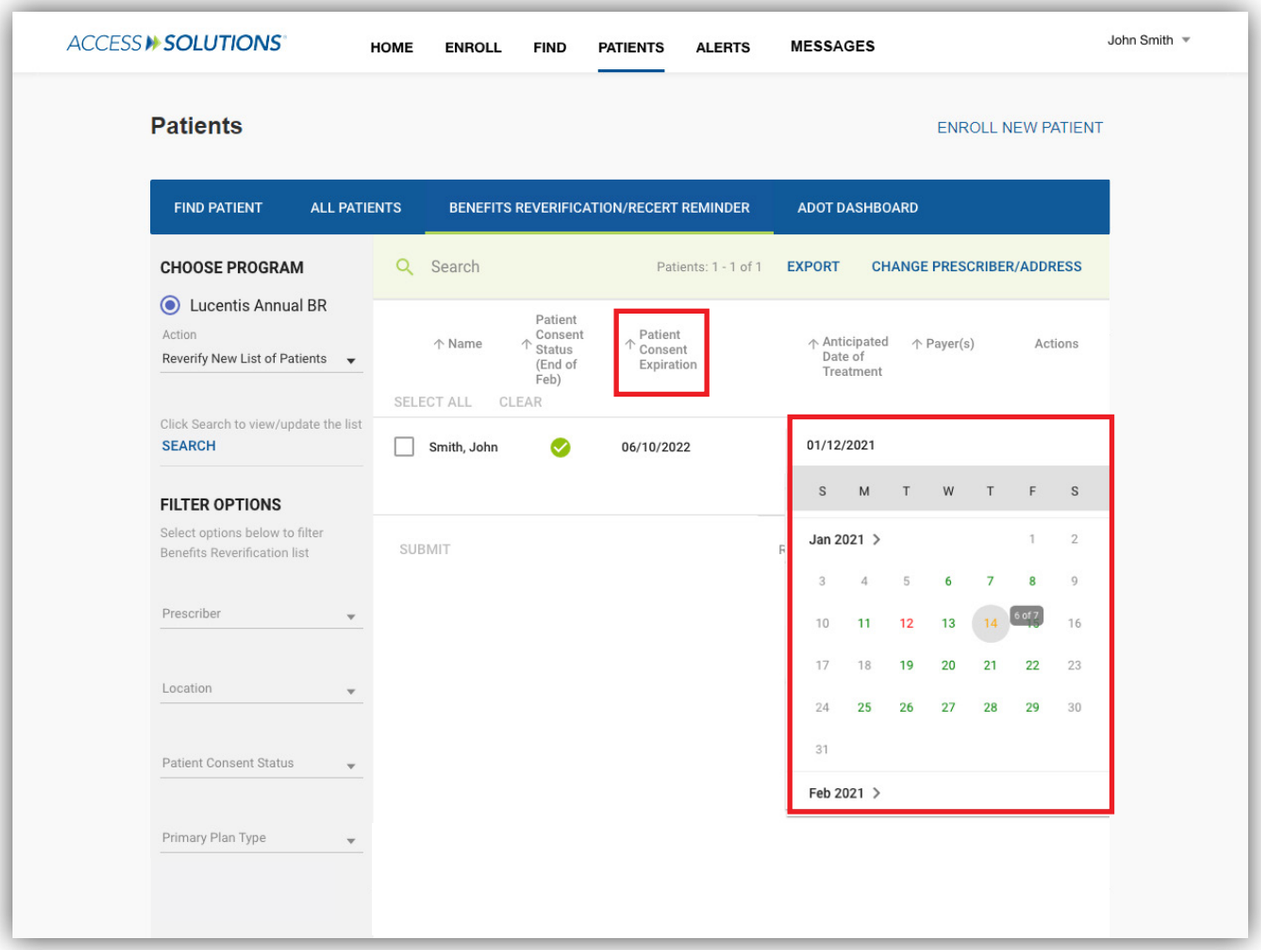
Sort and filter patients to reverify/recertify



- Sort this list using the column headers
- Filter this list using the criteria in the left column
- Icons help you immediately determine the patient's Patient Consent status

Service Requests: Reverification/Recertification (cont)

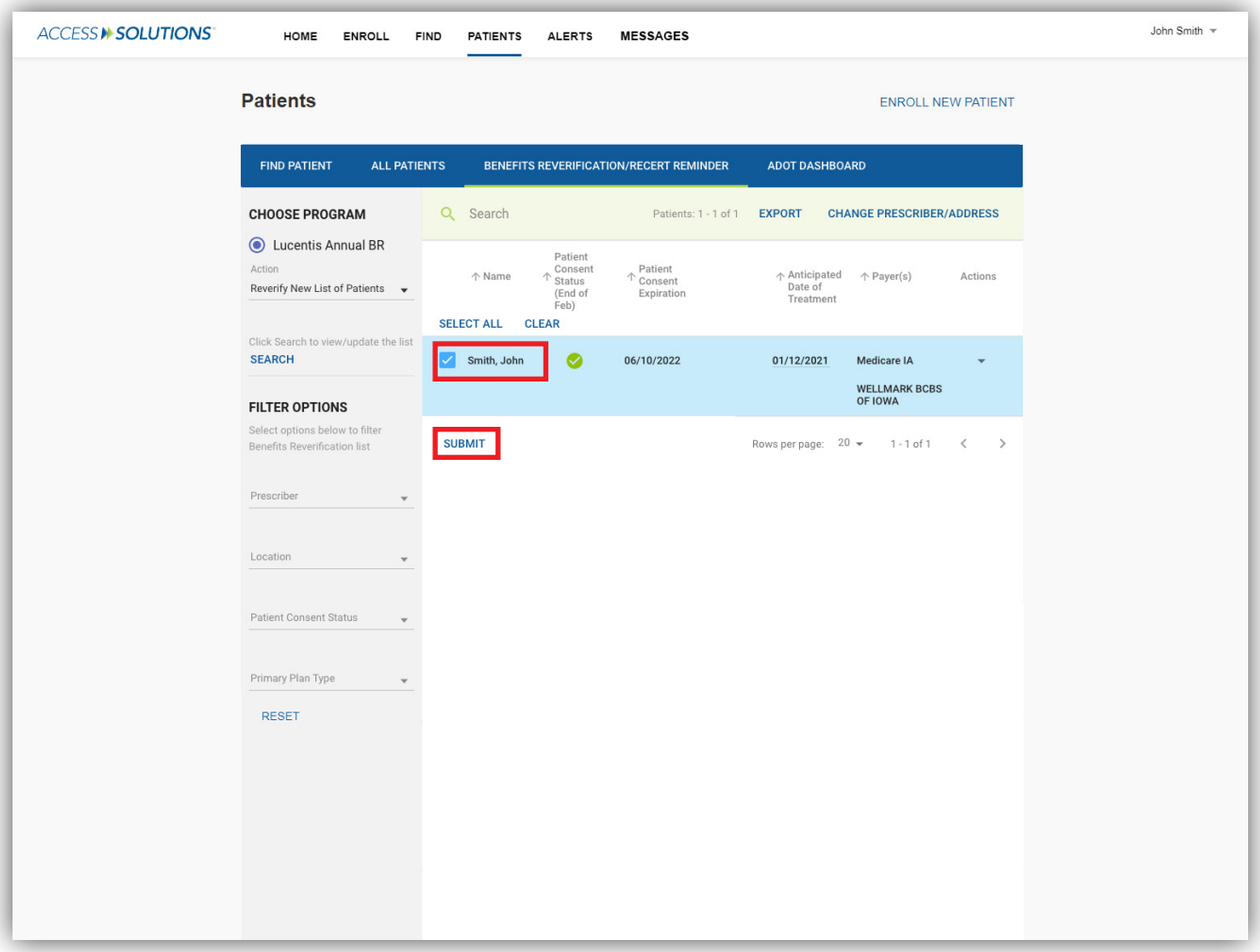
Review treatment date



- Modify the ANTICIPATED DATE OF TREATMENT within the REVERIFY NEW LIST OF PATIENTS returned list
- During specific times of the year, an ADOT DASHBOARD tab will be available for certain brands, showing which days have availability for appointments

Service Requests: Reverification/Recertification (cont)

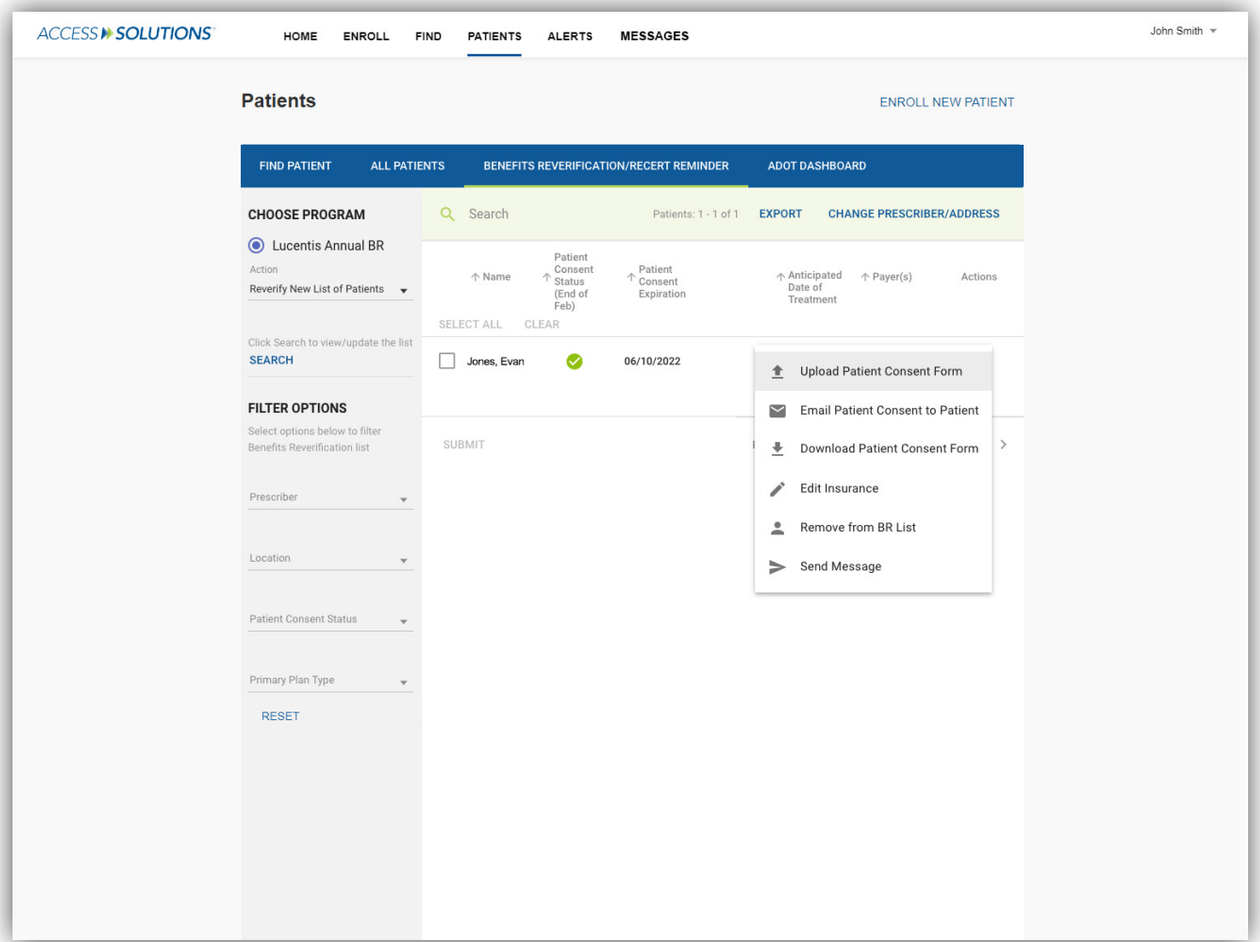
Select which patients to reverify/recertify



- Finish editing patient information
- Select the patients you would like to reverify by checking the boxes to the left of their names
- Select SUBMIT at the bottom of the list

Service Requests: Reverification/Recertification (cont)

The ACTIONS dropdown menu



- Use the ACTIONS dropdown menu to:
  - — Upload the Patient Consent Form
  - — Email the patient a link to the paperless Patient Consent Form
  - — Edit the patient's insurance information

Service Requests: Reverification/Recertification (cont)

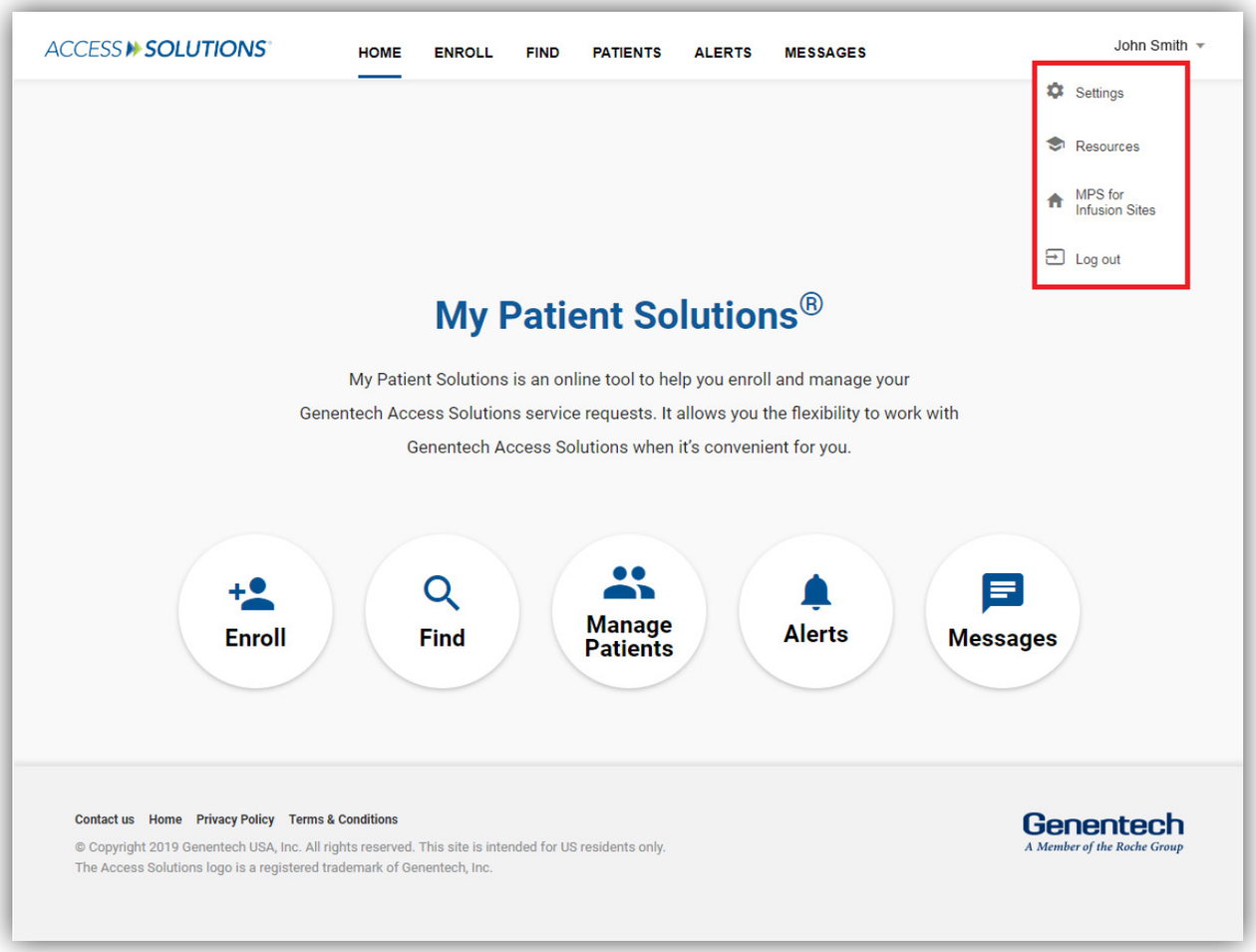
Important points to remember about benefits reverifications/recertifications

- Access to this feature is product-specific
- For some products, this feature is available throughout the year, while for others, it is only available during certain times of the year
- For certain brands, the calendar is color-coded:
  - — Green indicates the date is available
  - — Orange indicates the date is available, but more than 80% of the allocated time is used
  - — Red indicates the maximum number of patients have been selected
  - — Hover over the date to show how many patients may be assigned this date of treatment
  - — You will not be able to select weekends or holidays as anticipated dates of treatment
- During specific times of the year, an ADOT DASHBOARD tab will be available for certain brands. This dashboard shows which calendar days have:
  - — Reached the maximum number of patients that may be scheduled for treatment
  - — Not yet reached the maximum allowable treatment appointments

Resources

Additional resources are available to help you navigate the features of My Patient Solutions® for Health Care Practices.

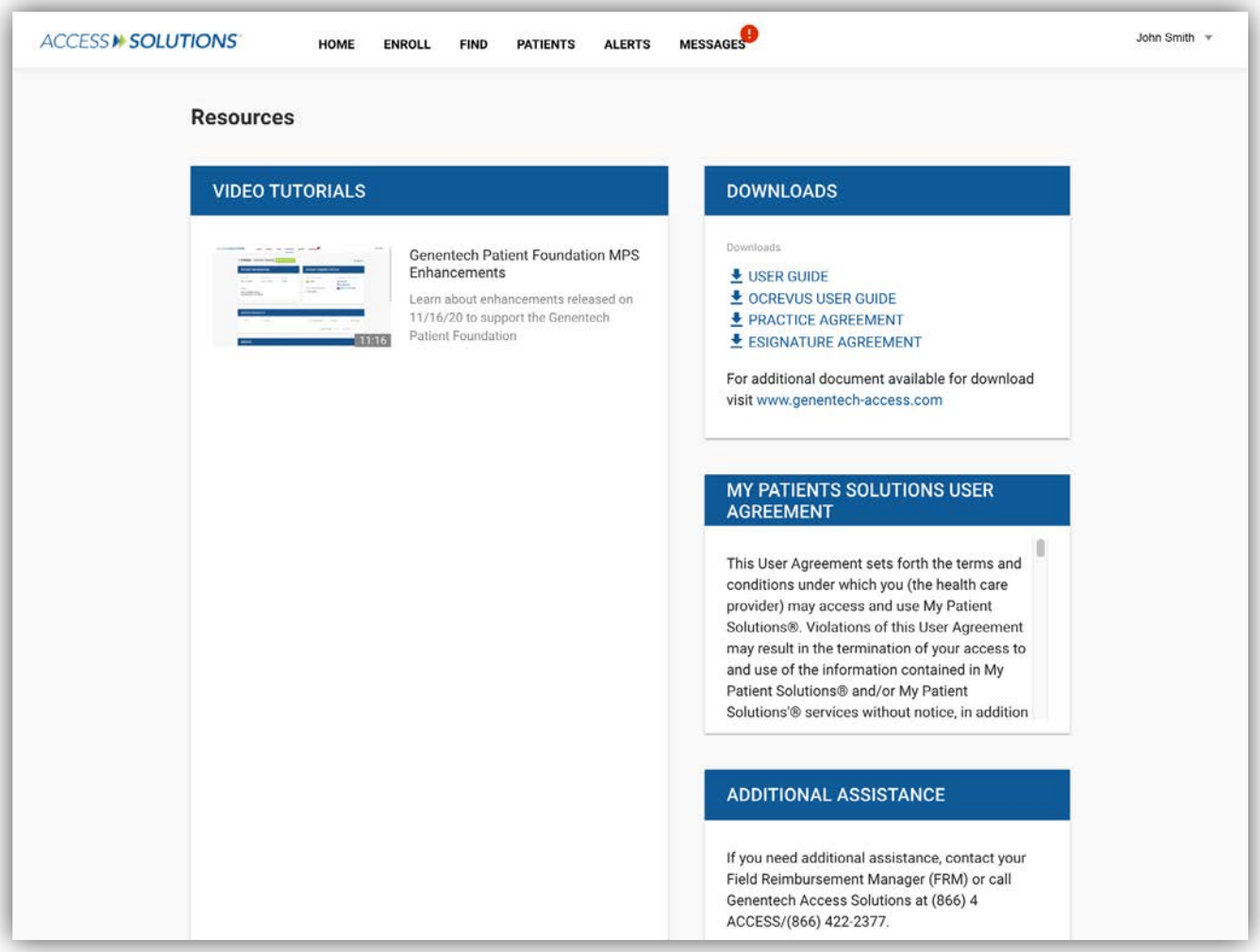
View additional resources



Select your name in the top right corner of the screen and select RESOURCES.

Resources (cont)

View additional resources (cont)



- The RESOURCES section includes:
  - Instructional videos
  - This user guide
  - Copies of the Practice and eSignature Agreements

Frequently Asked Questions

Q. I prescribe OCREVUS® (ocrelizumab). Can I submit the OCREVUS Start Form via My Patient Solutions® for Health Care Practices?

A. Yes. The practice portion of the OCREVUS Start Form is submitted the same way you submit the Prescriber Service Form. The patient portion is submitted the same way you submit the Patient Consent Form. Please see Enroll Patients for more information.

Q. Via My Patient Solutions, can I view all of my patients enrolled in Genentech Access Solutions and/or the Genentech Patient Foundation or only the ones enrolled via the website?

A. You can view all of your patients enrolled in Genentech Access Solutions and/or the Genentech Patient Foundation via My Patient Solutions, even the ones enrolled via fax within the past 18 months.
Please note: For new practice registrations, there will be a delay of 1 business day for all patients to appear in the system.

Q. Can the Patient Consent Form be submitted via My Patient Solutions?

A. Yes, you can upload a scanned copy of the Patient Consent Form while you're completing the enrollment form, within the patient list view or within the individual patient profile. The patient can also access the Patient Consent Form electronically at Genentech-Access.com/PatientConsent or a link to the Patient Consent Form can be emailed from My Patient Solutions.

Q. How do I submit a copy of the patient's insurance card?

A. Completing the patient's insurance information on the Prescriber Service Form is preferred, but you may also send Genentech Access Solutions a copy of the patient's insurance card (front and back) as a scanned attachment. This may be sent in the same manner as an uploaded Patient Consent Form.

Q. Some of the prescribers in my practice don't want to participate in eSignature, but some do. Can I enroll only the prescribers who do or does the entire practice have to participate?

A. Not all prescribers within a practice who use My Patient Solutions have to enroll in eSignature for the practice to use the feature. This is done on an individual basis. However, if prescribers want to designate proxies to sign on their behalf, they must have a My Patient Solutions account and be signed up for eSignature.

Frequently Asked Questions (cont)

Q. What do the various icons in the patient list view mean?

A. = Additional action required

= Patient Consent Form is valid

= No Patient Consent Form on file

= Patient Consent Form is pending Genentech Access Solutions review

= Patient Consent Form has expired

= Incomplete

= Re-enroll a patient

Q. How do I correct a patient's profile (e.g., misspelled name)?

A. If a patient's name is incorrect, you can send a message to your Genentech Access Solutions or Genentech Patient Foundation Specialist and ask to correct this error. You may also download the Prescriber Service Form or Prescriber Foundation Form from the SERVICE REQUEST DETAILS page, make any necessary updates and fax it to Genentech Access Solutions or the Genentech Patient Foundation.

Q. Can I have alerts emailed to me instead of logging in to My Patient Solutions® for Health Care Practices?

A. At this time, all of your alerts will be centralized in My Patient Solutions.

Q. What are the system requirements for My Patient Solutions?

A. For optimal viewing, the most recent version of 1 of the following browsers is recommended when logging in to My Patient Solutions for Health Care Practices:

- Safari
- Google Chrome

Index

IF YOU HAVE QUESTIONS

About My Patient Solutions® for Health Care Practices:

Contact your Genentech reimbursement representative

Call Genentech Access Solutions at **(866) 4ACCESS**/(866) 422-2377

Visit Genentech-Access.com/MPS

Genentech
A Member of the Roche Group
Access Solutions

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VABYSMO safely and effectively. See full prescribing information for VABYSMO.

VABYSMO® (faricimab-svoa) injection, for intravitreal use
Initial U.S. Approval: 2022

————————————RECENT MAJOR CHANGES————————————

Indications and Usage, Macular Edema Following Retinal Vein Occlusion (RVO) (1.3)	10/2023
Dosage and Administration, General Dosing Information (2.1)	7/2024
Dosage and Administration, Macular Edema Following Retinal Vein Occlusion (2.4)	10/2023
Dosage and Administration, Preparation for Administration - Prefilled Syringe (2.5)	7/2024
Dosage and Administration, Injection Procedure (2.7)	7/2024
Warnings and Precautions, Retinal Vasculitis and/or Retinal Vascular Occlusion (5.4)	10/2023

————————————INDICATIONS AND USAGE————————————

VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (1.1)
- Diabetic Macular Edema (DME) (1.2)
- Macular Edema Following Retinal Vein Occlusion (RVO) (1.3)

————————————DOSAGE AND ADMINISTRATION————————————

For intravitreal injection. (2.1)

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly. (2.2)
- Diabetic Macular Edema (DME)
  - VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months). Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly. (2.3)
- Macular Edema Following Retinal Vein Occlusion (RVO)
  - The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for 6 months. (2.4)

————————————DOSAGE FORMS AND STRENGTHS————————————

- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled syringe (3)
- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose vial (3)

————————————CONTRAINDICATIONS————————————

- Ocular or periocular infection (4.1)
- Active intraocular inflammation (4.2)
- Hypersensitivity (4.3)

————————————WARNINGS AND PRECAUTIONS————————————

- Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management. (5.1)
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection. (5.2)
- There is a potential risk of arterial thromboembolic events (ATEs) associated with VEGF inhibition. (5.3)

————————————ADVERSE REACTIONS————————————

The most common adverse reactions (≥ 5%) reported in patients receiving VABYSMO were cataract (15%) and conjunctival hemorrhage (8%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin 2 (Ang-2) inhibitor indicated for the treatment of patients with:

1.1 Neovascular (wet) Age-Related Macular Degeneration (nAMD)
1.2 Diabetic Macular Edema (DME)
1.3 Macular Edema Following Retinal Vein Occlusion (RVO)

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

For intravitreal injection. VABYSMO must be administered by a qualified physician.

VABYSMO is available as:

- Prefilled syringe: A sterile injection filter needle (30-gauge x ½-inch, Extra Thin Wall) with an integrated filter in the hub is provided. Each prefilled syringe should only be used for the treatment of a single eye.
- Vial: A sterile 5-micron, blunt transfer filter needle (18-gauge x 1½-inch) is provided. Each vial should only be used for the treatment of a single eye.

[see How Supplied/Storage and Handling (16)]

2.2 Neovascular (wet) Age-Related Macular Degeneration (nAMD)

The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

2.3 Diabetic Macular Edema (DME)

VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months). Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

2.4 Macular Edema Following Retinal Vein Occlusion (RVO)

The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for 6 months.

2.5 Preparation for Administration - Prefilled Syringe

Before you start

Read all the instructions carefully before using VABYSMO.

The VABYSMO carton includes:

A sterile prefilled syringe in a sealed tray. The prefilled syringe is for treatment of a single eye.

A sterile injection filter needle (30-gauge x ½ inch, Extra Thin Wall) with an integrated filter in the hub. The injection filter needle is for single use only.

Only use the provided injection filter needle for the administration.

VABYSMO should be refrigerated at temperatures between 2ºC to 8ºC (36ºF to 46ºF).
Do not freeze.

Allow VABYSMO to reach room temperature, 20°C to 25°C (68°F to 77°F) before proceeding with the administration.

Prior to use, keep the sealed tray in the original carton to **protect the prefilled syringe from light**. The prefilled syringe may be kept at room temperature in the original carton for up to **24 hours**.

VABYSMO should be inspected visually prior to administration.

Do not use if the carton seals have been tampered with.

Do not use if the packaging, prefilled syringe, injection filter needle is expired, damaged, or have been tampered with.

Do not use if the injection filter needle is missing.

Do not remove the finger grip from the syringe.

Do not use if the syringe cap is detached from the Luer lock.

Do not use if particulates, cloudiness, or discoloration are visible. VABYSMO is a clear to opalescent and colorless to brownish-yellow liquid solution.

Prefilled Syringe Description

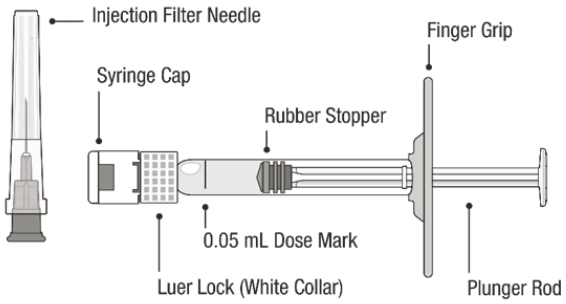


Figure A

Note: the dose must be set to the 0.05 mL dose mark.

Use aseptic technique to carry out the following preparation steps:

Open Tray and Remove Syringe Cap

1 Peel the lid off the syringe tray and aseptically remove the prefilled syringe.

2 Hold the syringe by the white collar; snap off the syringe cap (**see Figure B**).

Do not twist off the cap.

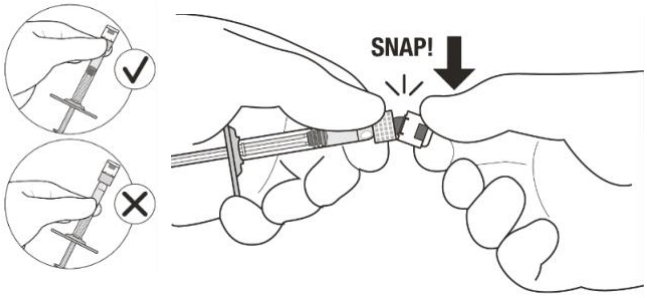


Figure B

Attach Injection Filter Needle

3 Aseptically remove the provided injection filter needle from its packaging.

4 Aseptically and firmly attach the injection filter needle onto the syringe Luer lock (**see Figure C**).

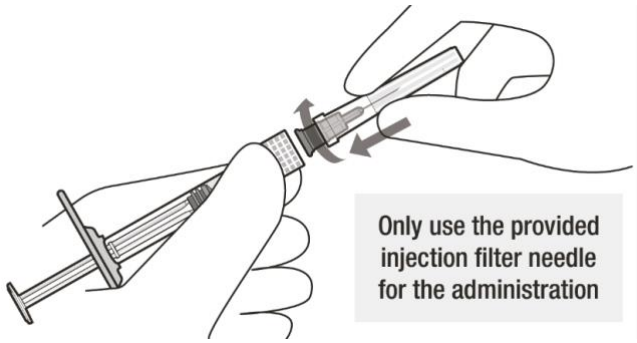


Figure C

5 Carefully remove the needle cap by pulling it straight off.

Dislodge Air Bubbles

6 Hold the syringe with the injection filter needle pointing up. Check the syringe for air bubbles.

---

7 If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (**see Figure D**).

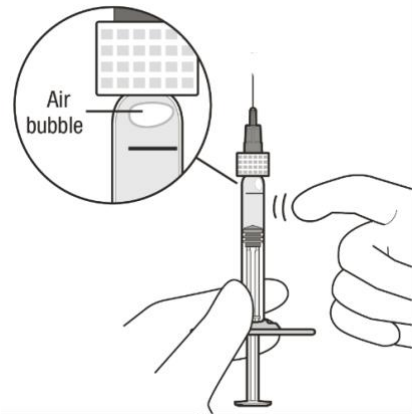


Figure D

Expel Air and Adjust the Dose

8 Hold the syringe at eye level and **slowly** push the plunger rod until the **lower edge of the rubber stopper's dome** is aligned with the 0.05 mL dose mark (**see Figure E**). This will expel the air and the excess solution and set the dose to 0.05 mL.

Ensure that the injection is given **immediately** after preparation of the dose.

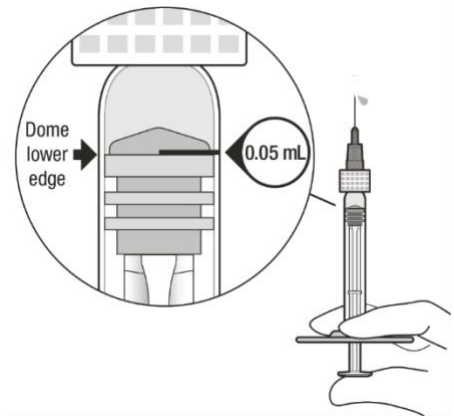


Figure E

2.6 Preparation for Administration - Vial

Before you start

Read all the instructions carefully before using VABYSMO.

The VABYSMO kit includes a glass vial and transfer filter needle. The glass vial is for a single dose only. The filter needle is for treatment of a single eye.

VABYSMO should be stored refrigerated at temperatures between 2ºC to 8ºC (36ºF to 46ºF).
Do not freeze.
Do not shake.

Allow VABYSMO to reach room temperature, 20°C to 25°C (68°F to 77°F) before proceeding with the administration. Keep the vial in the original carton to **protect from light.**
The VABYSMO vial may be kept at room temperature for up to **24 hours**.

The VABYSMO vial should be inspected visually for particulate matter and discoloration prior to administration. VABYSMO is a clear to opalescent and colorless to brownish-yellow liquid solution.
Do not use if particulates, cloudiness, or discoloration are visible.
Do not use if the packaging, vial and/or transfer filter needle are expired, damaged, or have been tampered with (see **Figure F**).

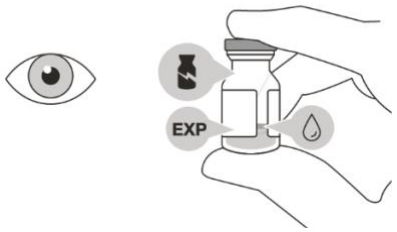


Figure F

Use aseptic technique to carry out the preparation of the intravitreal injection.

1 Gather the following supplies:

- One VABYSMO vial (included)
- One sterile 5-micron blunt transfer filter needle 18-gauge x 1½ inch (included)
- One sterile 1 mL Luer lock syringe with a 0.05 mL dose mark (**not included**)
- One sterile injection needle 30-gauge x ½ inch (**not included**)
  Note that a 30-gauge injection needle is recommended to avoid increased injection forces that could be experienced with smaller diameter needles.
- Alcohol swab (**not included**).

2 To ensure all liquid settles at the bottom of the vial, place the vial upright on a flat surface (for about 1 minute) after removal from packaging (see **Figure G**). Gently tap the vial with your finger (see **Figure H**), as liquid may stick to the top of the vial.

Figure G

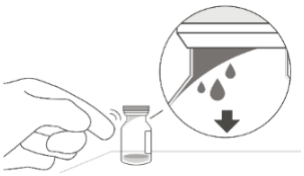


Figure H

3 Remove the flip-off cap from the vial (see **Figure I**) and wipe the vial septum with an alcohol swab (see **Figure J**).

Figure I

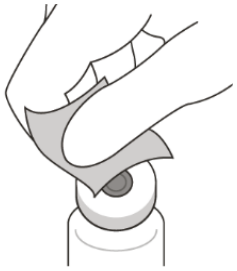


Figure J

4 Aseptically and firmly attach the included 18-gauge x 1½ inch transfer filter needle onto a 1 mL Luer lock syringe (see **Figure K**).

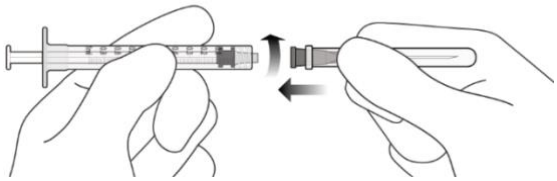


Figure K

5 Using aseptic technique, push the transfer filter needle into the center of the vial septum (see **Figure L**), push it all the way in, then tilt the vial slightly so that the needle touches the bottom edge of the vial (see **Figure M**).

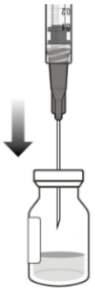


Figure L

Figure M

6 Hold the vial slightly inclined and **slowly** withdraw all the liquid from the vial (see **Figure N**). Keep the bevel of the transfer filter needle submerged in the liquid, to avoid introduction of air.

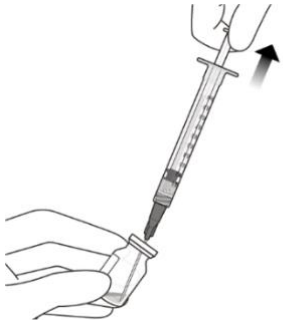


Figure N

7	Ensure that the plunger rod is drawn sufficiently back when emptying the vial, in order to completely empty the transfer filter needle (see **Figure N**).
8	Disconnect the transfer filter needle from the syringe and dispose of it in accordance with local regulations. **Do not use the transfer filter needle for the intravitreal injection.**
9	Aseptically and firmly attach a 30-gauge x ½ inch injection needle onto the Luer lock syringe (see **Figure O**).

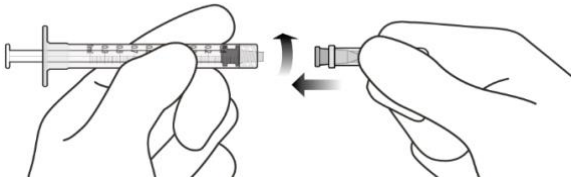


Figure O

10	Carefully remove the plastic needle shield from the needle by pulling it straight off.
11	To check for air bubbles, hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see **Figure P**).

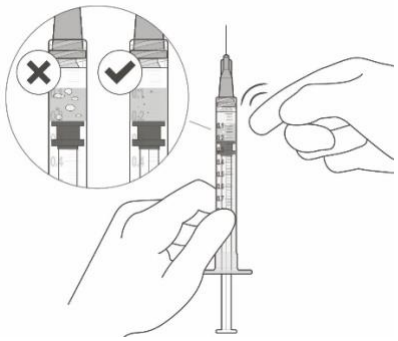


Figure P

12	Carefully expel the air from the syringe and needle, and **slowly** depress the plunger to align the rubber stopper tip to the 0.05 mL dose mark. The syringe is ready for the injection (see **Figure Q**). Ensure that the injection is given **immediately** after preparation of the dose.

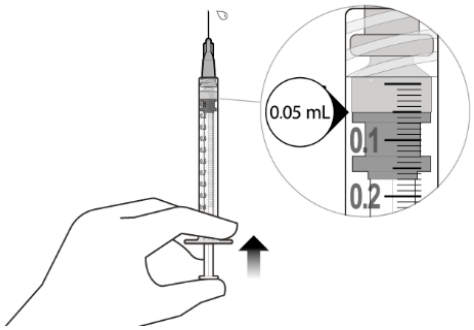


Figure Q

2.7 Injection Procedure

The intravitreal injection procedure must be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent), and the availability of sterile paracentesis equipment (if required). Adequate anesthesia and a broad-spectrum microbicide should be administered prior to the injection.

Inject **slowly** until the rubber stopper reaches the end of the syringe to deliver the volume of 0.05 mL.

Note for the prefilled syringe: **Do not** recap or detach the injection filter needle from the syringe.

Any unused drug product or waste material should be disposed of in accordance with local regulations.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available. Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., vision loss, eye pain, redness of the eye, photophobia, blurring of vision) without delay *[see Patient Counseling Information (17)]*.

Each syringe should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new syringe should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before VABYSMO is administered to the other eye.

3 DOSAGE FORMS AND STRENGTHS

VABYSMO is a clear to opalescent, colorless to brownish-yellow solution available as:

- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled glass syringe
- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose glass vial

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

VABYSMO is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation
VABYSMO is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity
VABYSMO is contraindicated in patients with known hypersensitivity to faricimab or any of the excipients in VABYSMO. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS
5.1 Endophthalmitis and Retinal Detachments
Intravitreal injections, including Vabysmo, have been associated with endophthalmitis and retinal detachments *[see Adverse Reactions (6.1)]*. Proper aseptic injection techniques must always be used when administering VABYSMO. Patients should be instructed to report any signs or symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management *[see Dosage and Administration (2.6) and Patient Counseling Information (17)]*.

5.2 Increase in Intraocular Pressure
Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injection, including with VABYSMO *[see Adverse Reactions (6.1)]*. IOP and the perfusion of the optic nerve head should be monitored and managed appropriately *[see Dosage and Administration (2.6)]*.

5.3 Thromboembolic Events
Although there was a low rate of arterial thromboembolic events (ATEs) observed in the VABYSMO clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

The incidence of reported ATEs in the nAMD studies during the first year was 1% (7 out of 664) in patients treated with VABYSMO compared with 1% (6 out of 662) in patients treated with aflibercept *[see Clinical Studies (14.1)]*.

The incidence of reported ATEs in the DME studies from baseline to week 100 was 5% (64 out of 1,262) in patients treated with VABYSMO compared with 5% (32 out of 625) in patients treated with aflibercept *[see Clinical Studies (14.2)]*.

The incidence of reported ATEs in the RVO studies during the first 6 months was 1.1% (7 out of 641) in patients treated with VABYSMO compared with 1.4% (9 out of 635) in patients treated with aflibercept *[see Clinical Studies (14.3)]*.

5.4 Retinal Vasculitis and/or Retinal Vascular Occlusion
Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of VABYSMO *[see Adverse Reactions (6.2)]*. Discontinue treatment with VABYSMO in patients who develop these events. Patients should be instructed to report any change in vision without delay.

6 ADVERSE REACTIONS
The following potentially serious adverse reactions are described elsewhere in the labeling:
- Hypersensitivity *[see Contraindications (4)]*
- Endophthalmitis and retinal detachments *[see Warnings and Precautions (5.1)]*

- Increase in intraocular pressure *[see Warnings and Precautions (5.2)]*
- Thromboembolic events *[see Warnings and Precautions (5.3)]*
- Retinal Vasculitis and/or Retinal Vascular Occlusion *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to VABYSMO in 2,567 patients, which constituted the safety population in six Phase 3 studies *[see Clinical Studies (14.1, 14.2, 14.3)]*.

Table 1: Common Adverse Reactions (≥ 1%)

Adverse Reactions	**VABYSMO**			**Active Control (aflibercept)**		
	AMD N=664	**DME N=1,262**	**RVO N=641**	**AMD N=662**	**DME N=625**	**RVO N=635**
Cataract	3%	15%	< 1%	2%	12%	1%
Conjunctival hemorrhage	7%	8%	3%	8%	7%	4%
Vitreous detachment	3%	5%	2%	3%	4%	2%
Vitreous floaters	3%	4%	2%	2%	3%	2%
Retinal pigment epithelial tear[a]	3%			1%		
Intraocular pressure increased	3%	4%	1%	2%	3%	3%
Eye pain	3%	3%	< 1%	3%	3%	< 1%
Intraocular inflammation[b]	2%	1%	1%	1%	1%	< 1%
Eye irritation	1%	< 1%	< 1%	< 1%	1%	< 1%
Lacrimation increased	1%	1%	0	1%	< 1%	< 1%
Ocular discomfort	1%	1%	< 1%	< 1%	< 1%	< 1%

[a] AMD only
[b] Including iridocyclitis, iritis, uveitis, vitritis

Less common adverse reactions reported in < 1% of the patients treated with VABYSMO were corneal abrasion, eye pruritus, ocular hyperemia, blurred vision, sensation of foreign body, endophthalmitis, conjunctival hyperaemia, visual acuity reduced, visual acuity reduced transiently, vitreous hemorrhage, retinal tear and rhegmatogenous retinal detachment.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of VABYSMO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Eye disorders: retinal vasculitis with or without retinal vascular occlusion.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of VABYSMO administration in pregnant women.

Administration of VABYSMO to pregnant monkeys throughout the period of organogenesis resulted in an increased incidence of abortions at intravenous (IV) doses 158 times the human exposure (based on C_{max}) of the maximum recommended human dose *[see Animal Data]*. Based on the mechanism of action of VEGF and Ang-2 inhibitors, there is a potential risk to female

reproductive capacity, and to embryo-fetal development. VABYSMO should not be used during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, and other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

Data

Animal Data

An embryo fetal developmental toxicity study was performed on pregnant cynomolgus monkeys. Pregnant animals received 5 weekly IV injections of VABYSMO starting on day 20 of gestation at 1 or 3 mg/kg. A non-dose dependent increase in pregnancy loss (abortions) was observed at both doses evaluated. Serum exposure (C_{max}) in pregnant monkeys at the low dose of 1 mg/kg was 158 times the human exposure at the maximum recommended intravitreal dose of 6 mg once every 4 weeks. A no observed adverse effect level (NOAEL) was not identified in this study.

8.2 Lactation

Risk Summary

There is no information regarding the presence of faricimab in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Many drugs are transferred in human milk with the potential for absorption and adverse reactions in the breastfed child.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VABYSMO and any potential adverse effects on the breastfed child from VABYSMO.

8.3 Females and Males of Reproductive Potential

Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment and for at least 3 months following the last dose of VABYSMO.

Infertility

No studies on the effects of faricimab on human fertility have been conducted and it is not known whether faricimab can affect reproduction capacity. Based on the mechanism of action, treatment with VABYSMO may pose a risk to reproductive capacity.

8.4 Pediatric Use

The safety and efficacy of VABYSMO in pediatric patients have not been established.

8.5 Geriatric Use

In the six clinical studies, approximately 58% (1,496/2,571) of patients randomized to treatment with VABYSMO were ≥ 65 years of age. No significant differences in efficacy or safety of faricimab were seen with increasing age in these studies. No dose adjustment is required in patients 65 years and above.

11 DESCRIPTION

Faricimab-svoa is a humanized bispecific immunoglobulin G1 (IgG1) antibody that binds both vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2). The fragment crystallizable (Fc) region of faricimab was engineered by selected point mutations to abolish binding interactions with Fcγ and FcRn receptors. Faricimab-svoa has a total molecular weight of approximately 149 kDa and is produced by recombinant DNA technology using mammalian Chinese Hamster Ovary (CHO) cell culture.

VABYSMO (faricimab-svoa) injection is a sterile, clear to opalescent, colorless to brownish-yellow solution in a single-dose prefilled glass syringe or glass vial for intravitreal administration. Each single-dose prefilled syringe or single-dose vial is designed to deliver 0.05 mL (50 microliters) of solution containing 6 mg faricimab-svoa, L-histidine (155 mcg), L-methionine (52.2 mcg), polysorbate 20 (20 mcg), sodium chloride (73.1 mcg), D-sucrose (2.74 mg) and Water for Injection, adjusted to pH 5.5 with acetic acid. The product does not contain an anti-microbial preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Faricimab is a humanized bispecific antibody that acts through inhibition of two pathways by binding to VEGF-A and Ang-2. By inhibiting VEGF-A, faricimab suppresses endothelial cell proliferation, neovascularization and vascular permeability. By inhibiting Ang-2, faricimab is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Ang-2 levels are increased in some patients with nAMD, DME, and RVO. The contribution of Ang-2 inhibition to the treatment effect and clinical response for nAMD, DME, and RVO has yet to be established.

12.2 Pharmacodynamics

Increased retinal thickness, assessed by optical coherence tomography (OCT), is associated with nAMD, DME and macular edema following RVO. Leakage of blood and fluid from choroidal neovascularization, assessed by fluorescein angiography, is associated with nAMD. Reductions in CST were observed across all treatment arms throughout the six Phase 3 studies in nAMD, DME, and RVO.

12.3 Pharmacokinetics

Absorption/Distribution

Maximum faricimab plasma concentrations (Cmax) are estimated to occur approximately 2 days post-dose. Mean (±SD) free faricimab (unbound to VEGF-A and Ang-2) plasma Cmax are estimated to be 0.23 (0.07) mcg/mL and 0.22 (0.07) mcg/mL in nAMD and in DME patients, respectively. After repeated intravitreal administrations, mean plasma free faricimab trough concentrations are predicted to be 0.002-0.003 mcg/mL for every 8 weeks (Q8W) dosing and 0.021-0.029 mcg/mL for every 4 weeks (Q4W) dosing. Although not directly measured in the vitreous, no accumulation of faricimab is expected in the vitreous and no accumulation has been observed in plasma when faricimab has been administered as repeat doses in the vitreous.

Metabolism/Elimination

Metabolism and elimination of faricimab has not been fully characterized. Faricimab is expected to be catabolized in lysosomes to small peptides and amino acids, which may be excreted renally, in a similar manner to the elimination of endogenous IgG. The estimated mean apparent systemic half-life of faricimab is approximately 7.5 days.

Specific Populations
The systemic pharmacokinetics of faricimab were not influenced by gender, race, or mild to severe renal impairment (i.e., estimated normalized creatinine clearance by Cockroft-Gault equation: 15 to 89 mL/min/1.73 m^2). The effect of severe renal impairment or any degree of hepatic impairment on the pharmacokinetics of VABYSMO is unknown. No special dosage modification is required for any of the populations that have been studied (e.g., elderly, gender, race).

Population pharmacokinetic analysis indicated that the pharmacokinetics of faricimab are comparable in nAMD, DME, and RVO patients.

12.6 Immunogenicity
The immunogenicity of VABYSMO was evaluated in plasma samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to VABYSMO in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to VABYSMO with the incidence of antibodies to other products may be misleading.

There is a potential for an immune response in patients treated with VABYSMO. In the nAMD, DME, and RVO studies, the pre-treatment incidence of anti-faricimab antibodies was approximately 0.8 to 1.8%. After initiation of dosing, the incidence of anti-faricimab antibodies was approximately 8% to 10.4% in patients treated with VABYSMO across studies. As with all therapeutic proteins, there is a potential for immunogenicity with VABYSMO.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
No carcinogenicity or mutagenicity data are available for VABYSMO injection in animals or humans.

Based on the anti-VEGF and Ang-2 mechanisms of action, treatment with VABYSMO may pose a risk to reproductive capacity *[see Females and Males of Reproductive Potential (8.3)]*.

14 CLINICAL STUDIES
14.1 Neovascular (wet) Age-Related Macular Degeneration (nAMD)
The safety and efficacy of VABYSMO were assessed in two randomized, multi-center, double-masked, active comparator-controlled, 2-year studies (TENAYA – NCT03823287 and LUCERNE – NCT03823300) in patients with nAMD.

A total of 1,329 newly diagnosed, treatment-naïve patients were enrolled in these studies, and 664 patients received at least one dose of VABYSMO. Patient ages ranged from 50 to 99 with a mean of 75.9 years. The studies were identically designed two year studies. Patients were randomized in a 1:1 ratio to one of two treatment arms: 1) aflibercept 2 mg administered fixed every 8 weeks (Q8W) after three initial monthly doses; and VABYSMO 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to determine whether to give a 6 mg (0.05 mL of 120 mg/mL solution) dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; (also referred to as Q16W dosing); 2) Weeks 24, 36 and 48 (also referred to as Q12W dosing); or 3) Weeks 20, 28, 36 and 44 (also referred to as Q8W dosing). However, the utility of these criteria to guide dosing intervals has not been established.

At week 48, after 4 initial monthly doses in the VABYSMO arm, 45% of patients received the Weeks 28 and 44 dosing, 33% of patients received the Weeks 24, 36 and 48 dosing, and the remaining 22% of patients received dosing every 8 weeks. These percentages are reflective of what happened within the conduct of these trials and indicate that some patients did well on two (2) doses spaced 16 weeks apart, or three (3) doses spaced 12 weeks apart, but the percentages may not be generalizable to a broader nAMD population for a variety of reasons. The inclusion/exclusion criteria limited enrollment to a select subset of treatment-naïve, newly diagnosed nAMD patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which was instrumental in determining dose frequency, is unvalidated. Stricter criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison, which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in Best Corrected Visual Acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and the VABYSMO arm. The lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, VABYSMO treated patients had a non-inferior mean change from baseline in BCVA compared to patients treated with aflibercept. Detailed results of both studies are shown in Table 2, Figure 1, and Figure 2 below. The clinical efficacy for the second year of the study has not been reviewed.

Table 2: Primary Endpoint Results[a] in the TENAYA and LUCERNE Studies

	TENAYA		**LUCERNE**	
	VABYSMO N = 334	**Aflibercept N = 337**	**VABYSMO N = 331**	**Aflibercept N = 327**
Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI)	5.8 (4.6, 7.1)	5.1 (3.9, 6.4)	6.6 (5.3, 7.8)	6.6 (5.3, 7.8)
Difference in LS mean (95% CI)	0.7 (-1.1, 2.5)		0.0 (-1.7, 1.8)	

[a] Average of weeks 40, 44 and 48
BCVA: Best Corrected Visual Acuity
ETDRS: Early Treatment Diabetic Retinopathy Study
CI: Confidence Interval
LS: Least Square

Figure 1: Mean Change in Visual Acuity from Baseline to Week 48 in TENAYA

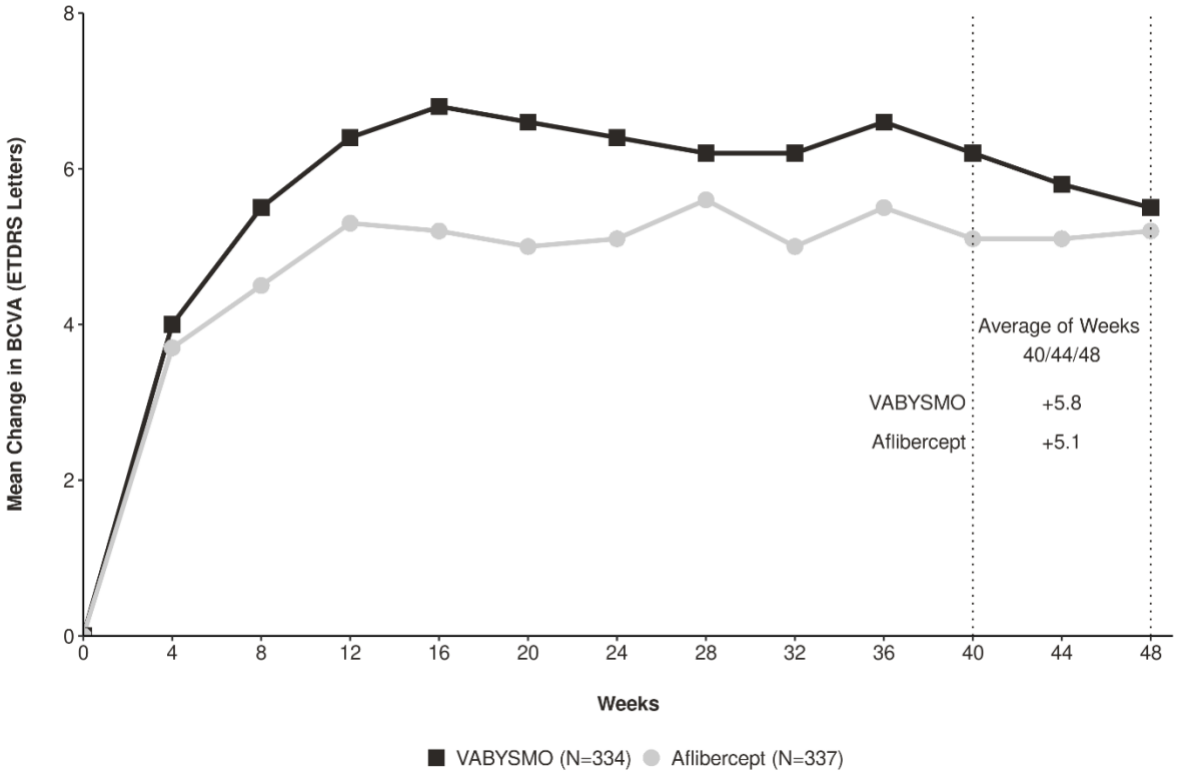
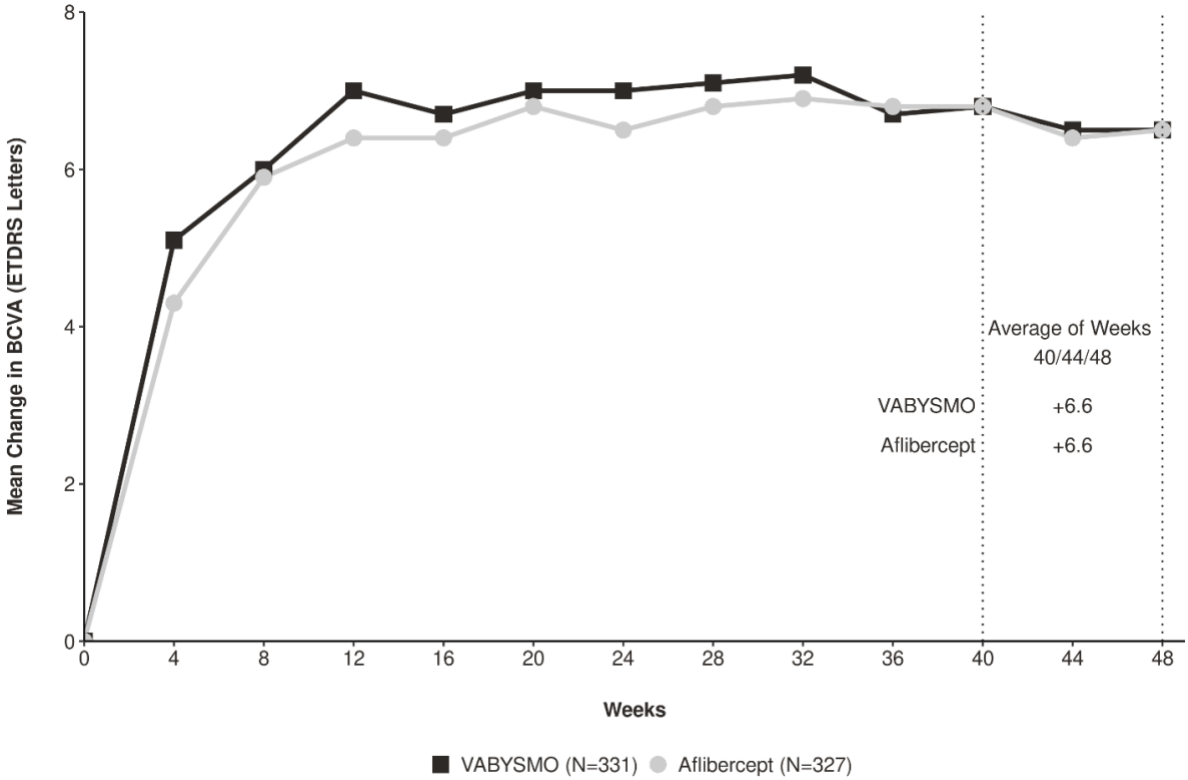


Figure 2: Mean Change in Visual Acuity from Baseline to Week 48 in LUCERNE



Treatment effects in evaluable subgroups (e.g., age, gender, race, baseline visual acuity) in each study were consistent with the results in the overall population.

14.2 Diabetic Macular Edema (DME)

The safety and efficacy of VABYSMO were assessed in two randomized, multi-center, double-masked, active comparator-controlled 2-year studies (YOSEMITE – NCT03622580 and RHINE – NCT03622593) in patients with DME.

A total of 1,891 diabetic patients were enrolled in the two studies with a total of 1,262 patients treated with at least one dose of VABYSMO. Patient ages ranged from 24 to 91 with a mean of 62.2 years. The overall population included both anti-VEGF naïve patients (78%) and patients who had been previously treated with a VEGF inhibitor prior to study participation (22%).

The studies were identically designed two year studies. Patients were randomized in a 1:1:1 ratio to one of three treatment regimens: 1) aflibercept Q8W, patients received fixed aflibercept 2 mg administered every 8 weeks (Q8W) after the first five monthly doses; 2) VABYSMO Q8W, patients received fixed VABYSMO 6 mg administered Q8W after the first six monthly doses; and 3) VABYSMO Variable, patients received VABYSMO 6 mg administered every 4 weeks for at least 4 doses and until the central subfield thickness (CST) of the macula measured by optical coherence tomography was less than approximately 325 microns, then the interval of dosing was modified by up to 4 week interval extensions or reductions of up to 8 week interval increments based on CST and visual acuity disease activity criteria at study drug dosing visits.

After 4 initial monthly doses, the patients in the VABYSMO Variable arm received between a minimum of 1 and a maximum of 21 total injections (median of 7 injections) through Week 96 inclusive. At Week 56, 32% of patients had completed at least one Q12W interval followed by one full Q16W interval. Seventeen percent (17%) of patients were treated on Q8W and/or Q4W dosing intervals through Week 56 (7% only on Q4W). These percentages are reflective of what happened within the conduct of these trials, but the percentages may not be generalizable to a broader DME population.

The inclusion/exclusion criteria limited enrollment to a select subset of DME patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which were instrumental in determining dose frequency, are unvalidated. Different criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in BCVA at year 1 (average of the Week 48, 52, and 56 visits), measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and VABYSMO arms. The lower bound of the 97.5% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, VABYSMO Q8W and VABYSMO Variable treated patients had a non-inferior mean change from baseline in BCVA to the patients treated with aflibercept Q8W at the year 1 primary endpoint. Detailed results of both studies are shown in Table 3, Figure 3, and Figure 4 below.

Table 3: Efficacy Results at Year 1[a] and at Year 2[b] in the YOSEMITE and RHINE Studies

	YOSEMITE						RHINE					
	Year 1			Year 2			Year 1			Year 2		
	VABYSMO Q8W N = 315	VABYSMO Variable N = 313	Aflibercept Q8W N = 312	VABYSMO Q8W N = 262	VABYSMO Variable N = 270	Aflibercept Q8W N = 259	VABYSMO Q8W N = 317	VABYSMO Variable N = 319	Aflibercept Q8W N = 315	VABYSMO Q8W N = 259	VABYSMO Variable N = 282	Aflibercept Q8W N = 254
Mean change in BCVA as measured by ETDRS letter score from baseline (97.5% CI year 1 and 95% CI year 2)	10.7 (9.4, 12.0)	11.6 (10.3, 12.9)	10.9 (9.6, 12.2)	10.7 (9.4, 12.1)	10.7 (9.4, 12.1)	11.4 (10.0, 12.7)	11.8 (10.6, 13.0)	10.8 (9.6, 11.9)	10.3 (9.1, 11.4)	10.9 (9.5, 12.3)	10.1 (8.7, 11.5)	9.4 (7.9, 10.8)
Difference in LS mean (97.5% CI year 1 and 95% CI year 2)	-0.2 (-2.0, 1.6)	0.7 (-1.1, 2.5)		-0.7[c]	-0.7[c]		1.5 (-0.1, 3.2)	0.5 (-1.1, 2.1)		1.5[c]	0.7[c]	

[a]Average of Weeks 48, 52, 56
[b]Average of Weeks 92, 96, 100
[c]A non-inferiority margin was not available for year 2
BCVA: Best Corrected Visual Acuity
ETDRS: Early Treatment Diabetic Retinopathy Study
CI: Confidence Interval
LS: Least Square

Figure 3: Mean Change in Visual Acuity from Baseline to Year 2 (Week 100) in YOSEMITE

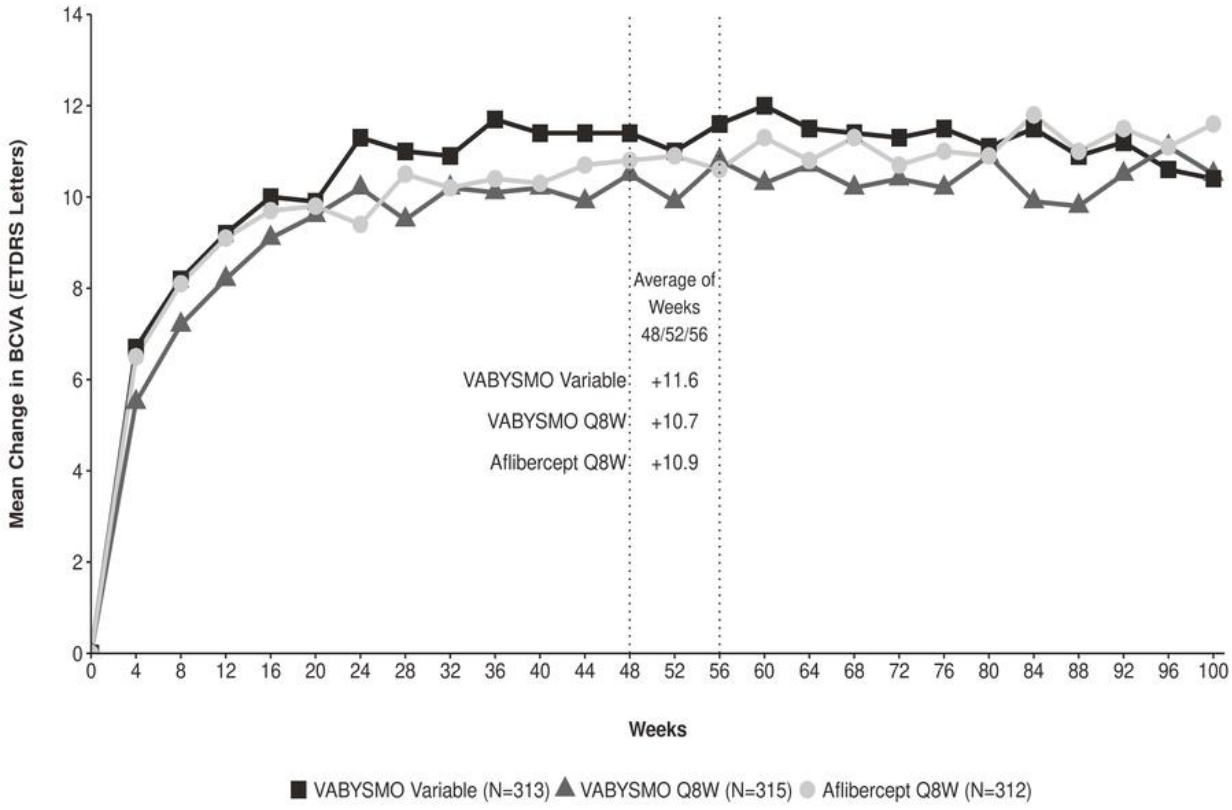
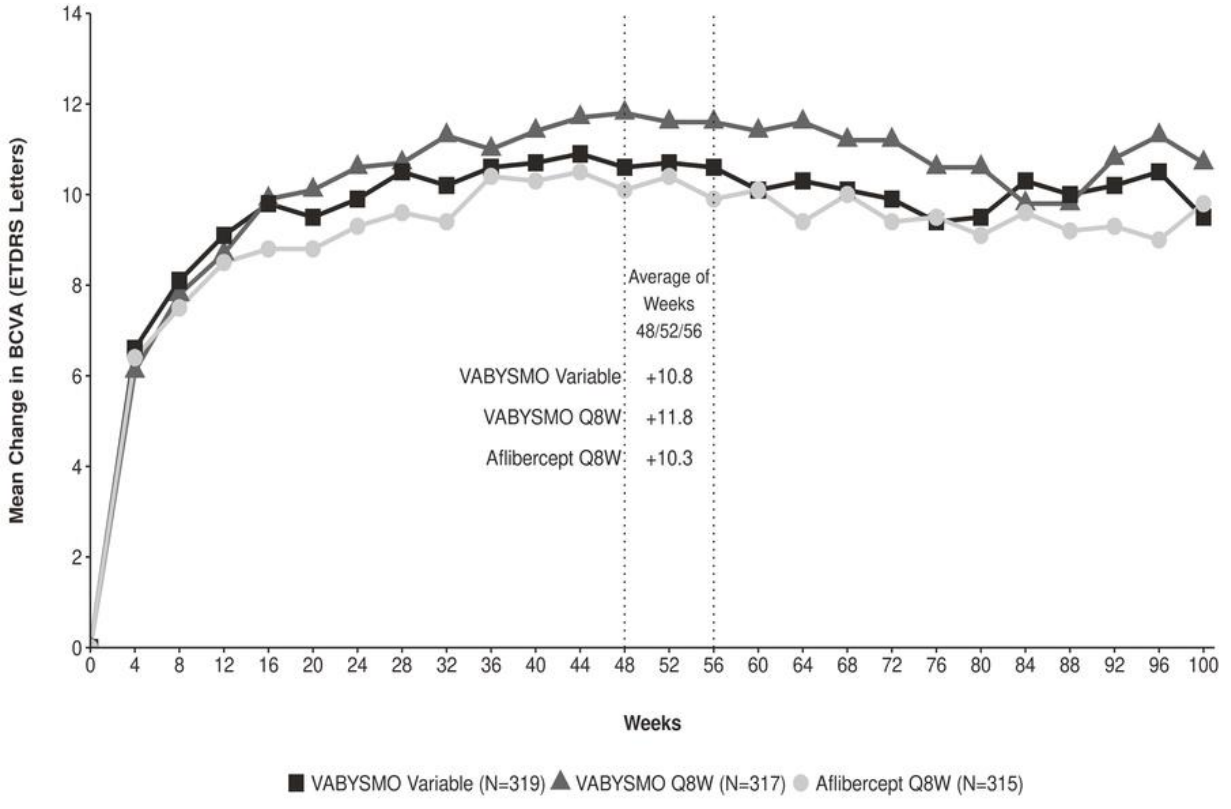


Figure 4: Mean Change in Visual Acuity from Baseline to Year 2 (Week 100) in RHINE



Treatment effects in the subgroup of patients who were anti-VEGF naïve prior to study participation were similar to those observed in the overall population. Treatment effects in evaluable subgroups (e.g., by age, gender, race, baseline HbA1c, baseline visual acuity) in each study were generally consistent with the results in the overall population.

14.3 Macular Edema Following Retinal Vein Occlusion (RVO)

The safety and efficacy of VABYSMO were assessed in two randomized, multicenter, double-masked, studies (BALATON – NCT04740905 in patients with macular edema following branch retinal vein occlusion, and COMINO – NCT04740931 in patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion). Active comparator-controlled data are available through month 6.

A total of 1,282 newly diagnosed, treatment-naïve patients were enrolled in these studies, of which 641 patients received at least one dose of VABYSMO through 6 months. Patient ages ranged from 28 to 93 with a mean of 64 years, and 22 to 100 with a mean of 65 years in BALATON and COMINO, respectively.

In both studies, patients were randomized in a 1:1 ratio to either 6 mg VABYSMO administered every 4 weeks, or the control arm receiving aflibercept 2 mg injections every 4 weeks for a total of 6 injections.

In both studies, the VABYSMO 6 mg Q4W arm demonstrated non-inferiority to the comparator control (aflibercept) arm for the primary endpoint, which was defined as the change from baseline in BCVA at week 24, measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and VABYSMO arms, where the lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority.

Detailed results for both BALATON and COMINO studies are shown in Table 4, Figure 5, and Figure 6 below.

Table 4: Primary Endpoint Results at Week 24 in the BALATON and COMINO Studies

	BALATON		**COMINO**	
	VABYSMO N = 276	**Aflibercept N = 277**	**VABYSMO N = 366**	**Aflibercept N = 363**
Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI)	16.9 (15.7, 18.1)	17.5 (16.3, 18.6)	16.9 (15.4, 18.3)	17.3 (15.9, 18.8)
Difference in LS mean (95% CI)	-0.6 (-2.2, 1.1)		-0.4 (-2.5, 1.6)	

BCVA: Best Corrected Visual Acuity
ETDRS: Early Treatment Diabetic Retinopathy Study
CI: Confidence Interval
LS: Least Square

Figure 5: Mean Change in Visual Acuity from Baseline to Week 24 in BALATON

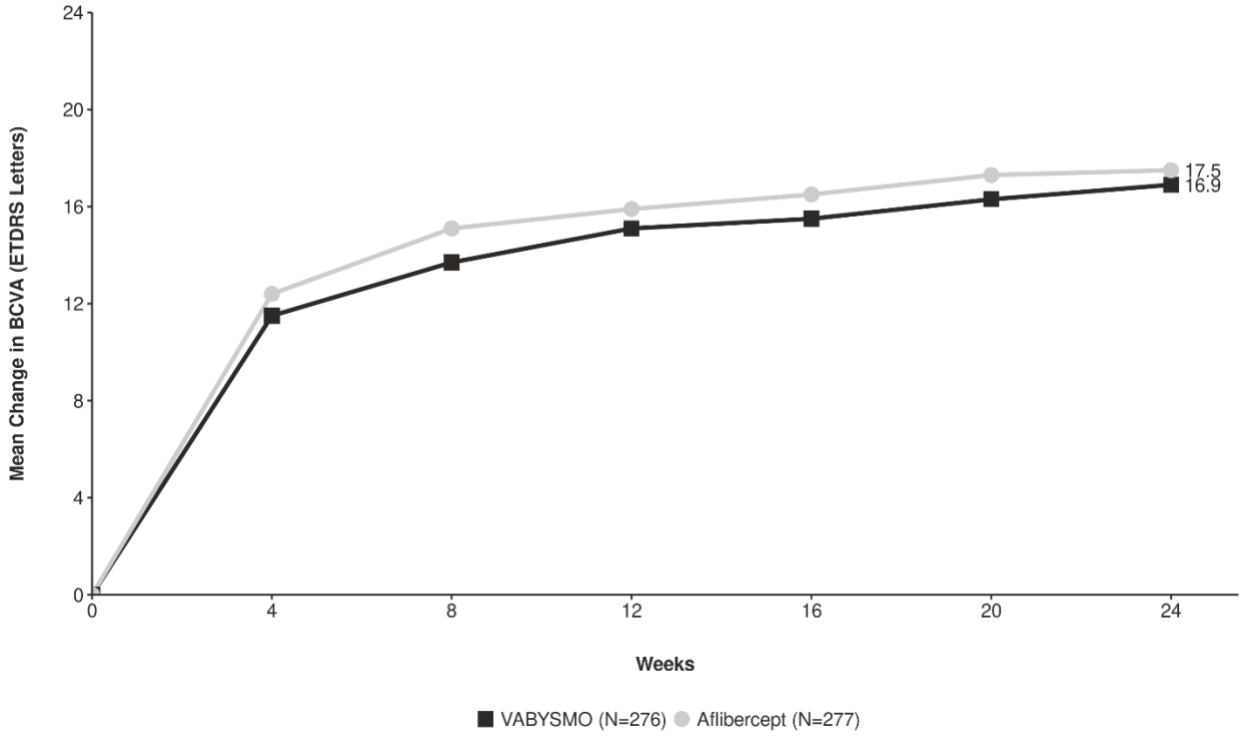
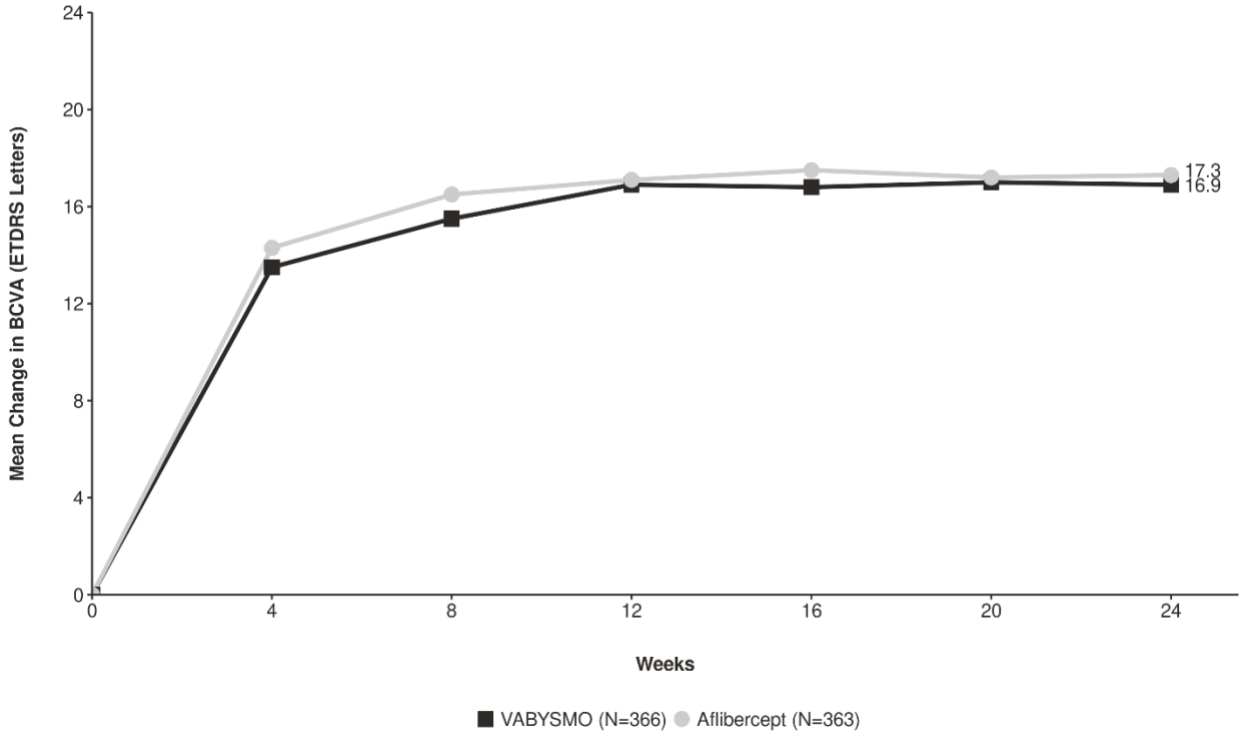


Figure 6: Mean Change in Visual Acuity from Baseline to Week 24 in COMINO



16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

VABYSMO (faricimab-svoa) injection is supplied as a clear to opalescent, colorless to brownish-yellow solution as 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled syringe or single-dose vial. Each prefilled syringe or vial is for treatment of a single eye.

VABYSMO is supplied in the following presentations:

NDC NUMBER	CARTON TYPE	CARTON CONTENTS
50242-096-06	Prefilled Syringe	one 6 mg (0.05 mL of 120 mg/mL solution) single-dose prefilled glass syringe, in a sealed tray one sterile injection filter needle (30-gauge x ½ inch, 0.30 mm x 12.7 mm, Extra Thin Wall) one Prescribing Information
50242-096-01	Vial	one 6 mg (0.05 mL of 120 mg/mL solution) single-dose glass vial one sterile 5-micron blunt transfer filter needle (18-gauge x 1½ inch, 1.2 mm x 40 mm) one Prescribing Information

16.2 Storage and Handling

Store VABYSMO in the refrigerator between 2°C to 8°C (36°F to 46°F). Do not freeze. Do not shake. Keep the sealed tray containing the prefilled syringe or the vial in the original carton to protect from light.

Prior to use, the unopened prefilled syringe or glass vial of VABYSMO may be kept at room temperature, 20°C to 25°C (68°F to 77°F), for up to 24 hours. Ensure that the injection is given immediately after preparation of the dose.

17 PATIENT COUNSELING INFORMATION

Advise patients that in the days following VABYSMO administration, patients are at risk of developing endophthalmitis, retinal detachment, intraocular inflammation and retinal vasculitis with or without retinal vascular occlusion. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist *[see Warnings and Precautions (5)]*.

Patients may experience temporary visual disturbances after an intravitreal injection with VABYSMO and the associated eye examinations *[see Adverse Reactions (6)]*. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

VABYSMO® [faricimab-svoa]
Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990
U.S. License No.: 1048