BIOGEN ACCESS TOOLKIT
A Guide to Navigating Insurance and Biogen Support Services
HELPING PATIENTS NAVIGATE ACCESS FOR BIOGEN RELAPSING MS THERAPIES

This guide is meant to provide an overview of steps your office can take to assist with navigating insurance and enrolling eligible patients in support programs. The information contained in this guide is being provided for educational purposes only. Insurance coverage may vary by health plan, patient, and setting of care. Biogen does not guarantee coverage.

It is the sole responsibility of the healthcare professional (HCP) to ensure the accuracy of all statements used in seeking coverage for each individual patient. Each individual patient’s situation will vary and it is up to you and your patient to determine which product is appropriate and what steps are necessary in order to gain coverage for your patients.

BIOGEN PATIENT ACCESS JOURNEY

Send Start Form to Patient Services (PS) ➔ Benefits Investigation (BI) ➔ Submit Request for Prior Authorization (PA) and/or Medical Exception (ME)a ➔ PA/ME/Appeal Approvalb ➔ Product Procurement

Ongoing Support through Biogen Support Services

If the BI determines that a step therapy restriction or formulary exclusion applies, you may proactively include the necessary documentation to request a medical exception when you submit the request for PA.

The PA/ME request and/or appeal may not always be approved. Please refer to the decision rendered by the payer and/or contact the payer directly for additional guidance.
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Biogen can provide support at each step of the patient access journey to help appropriate patients start and stay on therapy

Biogen is committed to helping people living with relapsing MS. Biogen Support Services provides a variety of financial and insurance assistance options and other resources to help your patients start and stay on their prescribed Biogen therapy.

Contact Biogen Support Services at 1-800-456-2255, Monday through Friday, from 8:30 AM to 8 PM ET, to help your patients get support.
STEPS TO PRODUCT ACCESS

STEP 1: COMPLETE AND SUBMIT A BIOGEN PRODUCT START FORM

Each Biogen relapsing MS therapy has its own Start Form, which begins the process that helps your patients obtain their prescribed Biogen therapy. It also provides patients with an opportunity to expedite their enrollment in Biogen Support Services.

You can access a Biogen product Start Form in 1 of 2 ways:

1. Digital Start Forms can be accessed at each product’s website or completed through iAssist® or CoverMyMeds®
2. Paper Start Forms can be downloaded and printed from each product’s website

Check to ensure that your patient has completed all relevant sections of the Start Form

SECTION A
I. AUTHORIZATION TO SHARE HEALTH INFORMATION

The patient’s signature in Section A authorizes his or her confidential health information to be shared with Biogen. The patient or patient representative signs and dates this section. Biogen may use this information to offer support services, including financial assistance.

SECTION B
II. PATIENT SERVICES AND MARKETING/OTHER COMMUNICATIONS AUTHORIZATION

Your patient’s signature in Section B authorizes Biogen, Biogen Support Services, and companies working with Biogen to proactively contact your patient to provide support services. If your patients would like to receive a welcome call from Biogen with additional information about their therapy, as well as about Biogen’s financial support programs, please ensure that they sign Section B in addition to Section A.

SECTION C
III. OPT-IN FOR AUTOMATED MARKETING CALLS AND TEXT MESSAGES

Patients have the option to check the box in Section C to consent to receive autodialed and prerecorded calls and text messages from Biogen, Biogen Support Services, and companies working with Biogen.

Patients must sign Section A and Section B in order for a Biogen Case Manager to proactively contact them.

After all sections of the Start Form are completed and signed, it can be submitted in 1 of 3 ways:

1. Submit via E-Sign (DocuSign®) at each product’s website
2. Submit digital Start Form through iAssist or CoverMyMeds
3. Fax paper Start Form to Biogen Support Services at 1-855-474-3067

Upon receipt of the completed and signed Start Form, Biogen Support Services will send it to a specialty pharmacy (SP) accepted by the patient’s health plan.

CoverMyMeds® is a registered trademark of CoverMyMeds, LLC. DocuSign® is a registered trademark of DocuSign, Inc. iAssist® is a registered trademark of AssistRx.
STEPS TO PRODUCT ACCESS

STEP 2: A BI WILL BE CONDUCTED TO DETERMINE COVERAGE AND HEALTH PLAN REQUIREMENTS

A BI may be necessary to determine whether your patient has insurance coverage for their prescribed Biogen therapy. It provides information about whether a step edit or other restriction is in place, which SP can ship the drug, and the patient cost-sharing requirements.

If your office submitted a completed Biogen product Start Form to Biogen Support Services, the SP that received the Start Form will likely conduct the BI on your behalf. The SP may also be able to initiate the PA process, but will likely need additional information from your office. Make sure you and your patient respond to the SP in a timely manner to minimize delays in the PA process.

If your office is conducting its own BI, it is important to document the specific details for each exchange that you have with the health plan. You may be communicating with the health plan several times during the process.

STEP 3: SUBMIT REQUEST FOR PA AND/OR MEDICAL EXCEPTION

Health plans frequently require a PA before they will agree to cover a Biogen therapy for relapsing MS.

When the correct PA form is completed, there are 2 ways it can be submitted to the patient’s health plan:

1. Submit the PA directly to the health plan. PAs may be submitted electronically, via fax, or over the phone. Determine the health plan’s preferred method of submission
2. Submit an ePA using an online portal, such as iAssist® or CoverMyMeds®

If the BI determines that a step therapy restriction or formulary exclusion applies, you may proactively include the necessary documentation to request a medical exception to explain why the prescribed therapy is medically necessary when you submit the request for PA.

Keep track of the PA status for each patient. This step is important for many reasons, including if a patient needs financial assistance from Biogen Support Services in the future. If you submitted the PA electronically using an ePA platform such as CoverMyMeds, you can monitor the PA status within its portal.

ePA=electronic prior authorization.

Biogen works with multiple vendors in order to provide you with options to submit a Start Form or a PA request. Please contact your Biogen representative directly to confirm which options are currently available, as there may be more than those listed above.
STEPS TO PRODUCT ACCESS (CONT’D)

STEP 4: ADDRESS DENIAL OF PA OR MEDICAL EXCEPTION REQUEST (IF NECESSARY)

If the request for PA or medical exception is denied due to:

**NONCLINICAL REASONS**

Carefully review the documents that were submitted to the health plan to ensure that they were complete and accurate. If reasons for the denial are not provided, consider calling the health plan for details.

Resubmit the request, if necessary, with all of the required information.

**CLINICAL REASONS**

In the event that a health plan denies a request for PA, medical exception, or a reauthorization, you and your patient have the right to appeal the decision.

You and your patient may file an appeal with the patient’s health plan. Refer to the specific appeal rights and instructions within the denial letter.

STEP 5: FILE AN APPEAL (IF NECESSARY)

When filing an appeal on behalf of a patient, it’s important to follow the health plan’s guidelines and time frames. Be sure to contact the health plan with any questions and to obtain a written description of its appeals process. Appeal rights and instructions may also be included in the health plan’s denial letter. The appeals process may vary depending on the health plan.

If the health plan denies the appeal, you may request a peer-to-peer discussion with a medical director if you have not done so yet, and request a third-level appeal through a third party or state insurance department.

STEP 6: PRODUCT PROCUREMENT

Please remind the patient that they may be contacted by Biogen or the SP regarding their prescription. The patient should respond to the SP in a timely manner to avoid delays in procurement.

It is also important to note the PA expiration date for reauthorization in the patient’s records.

Encourage your patients to self-advocate throughout the access journey and make their voices heard.
MANAGING HEALTH PLAN RESTRICTIONS
BENEFITS INVESTIGATION

Completing a BI can help determine a health plan's coverage guidelines for Biogen relapsing MS therapies

Payers have different requirements for coverage, so it is important to complete a BI to determine important information such as coverage and PA requirements, patient financial responsibility, and product procurement options.

If your office submitted a completed Biogen product Start Form to Biogen Support Services, the in-network SP that received the Start Form will likely conduct the BI on your behalf and provide your office with a Summary of Benefits. The SP may also be able to help initiate the PA process, but will likely need additional information from your office.

Obtaining medical benefit and pharmacy benefit information

Biogen product Start Forms may ask for **medical and pharmacy benefit** information. It is important to complete the Biogen product Start Form with information for both benefits if it is required.

Before a patient leaves your office, check the insurance card information on file to determine if you also need to obtain the pharmacy benefit information from a different card. This will provide the SP with the information needed to verify the benefit in case the information is outdated or incorrect.

Completing your own BI

Your office can choose to contact the patient's health plan to conduct a BI. If you choose this option, it is important to document the specific details for each exchange that you have with the health plan. You may be communicating with the health plan several times during the process.

Requesting information on your patient's behalf

Some payers may require the patient to sign an Appointment of Representative (AOR) or Authorized Representative form in order for a provider to act on a patient's behalf in requesting information, generally regarding a denied claim/service and/or requesting an appeal. The appropriate form(s) may vary by health plan, so please ensure the proper plan requirements are met when requesting information and/or appeals by checking the health plan’s provider portal or website.

If a BI determines that a prescribed Biogen therapy is not covered, you will need to submit a request for a medical exception to the patient's health plan.
CHECKLIST: BENEFITS INVESTIGATION

- **COLLECT THE PATIENT’S MEDICAL AND PHARMACY BENEFIT INFORMATION WHEN YOU COMPLETE A BIOGEN PRODUCT START FORM.**
  - If the SP is conducting the BI, this will provide it with the information needed to verify the patient’s benefit design in case the information is outdated or incorrect

- **DETERMINE IF THE PATIENT’S SP OR YOUR OFFICE WILL BE CONDUCTING THE BI.**
  - If your office submitted a completed Biogen product Start Form to Biogen Support Services, the SP that received the Start Form will likely conduct the BI on your behalf
  - If your office conducts the BI, be sure to document the specific details for each exchange that you have with the health plan

- **REVIEW THE SUMMARY OF BENEFITS FROM THE SP OR THE BI FORM COMPLETED BY YOUR OFFICE TO ENSURE THAT ALL NECESSARY INFORMATION IS DETERMINED PRIOR TO SUBMITTING THE REQUEST FOR PA AND/OR A MEDICAL EXCEPTION. EXAMPLES INCLUDE:**
  - PA criteria and required documentation
  - Step therapy criteria
  - Process of appealing a denied request for PA or a medical exception
  - Claims submission requirements
  - Patient financial responsibility
  - Site of care requirements
  - Use of preferred SPs

- **INCLUDE THE SUMMARY OF BENEFITS OR BI FORM IN THE PATIENT’S FILE FOR FUTURE REFERENCE.**

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**CHECKLIST: BENEFITS INVESTIGATION**

- Managing Health Plan Restrictions
- The Appeals Process
- Biogen Support Services
- Steps to Product Access
REQUESTING PRIOR AUTHORIZATION

PA may be required before a health plan agrees to provide coverage for a relapsing MS therapy

PA (also known as preauthorization) is a process that requires HCPs to obtain approval from a patient’s health plan before it will cover the cost of a particular drug or service.

A health plan may require evidence that supports the prescriber’s decision and explains the potential consequences of the patient not receiving the prescribed drug or service during the PA process.

PAs are very common for drugs that treat relapsing MS because they enable health plans to monitor costs and facilitate appropriate use. Covered drugs that require PA may be listed in the plan’s formulary on its website.

Determine the health plan’s specific PA coverage criteria guidelines. They may include:

- Number of visits
- Number of relapses
- Authorization time limits
- Diagnosis limitations
- Required use of a specific SP
- Submission requirements
- Definition of failure on previous therapies

Identify specific documentation that may be required or serve as supporting evidence to accompany the PA request. This may include:

- Letter of Medical Necessity
- Chart notes
- Plan-specific PA form
- Relevant literature
- Magnetic resonance imaging (MRI) and other clinical data related to disease severity
- Prior use of disease-modifying therapy and/or documented failure of another therapy

Biogen can help you learn about the PA requirements for individual health plans in your area. Contact your Biogen representative directly.
OBTAIN THE PROPER FORM AND FILL IT OUT COMPLETELY.
Some health plans require specific forms. PAs can be denied simply because the form contains incorrect or incomplete information.

- A health plan may require you to provide a patient’s medical record (eg, test results) with appropriate chart notes, a Letter of Medical Necessity, and/or other documents.
- An SP is often able to initiate the PA process but may contact your office to collect additional information. Please respond as soon as possible to help minimize delays.

DETERMINE THE HEALTH PLAN’S PREFERENCE FOR PA SUBMISSION.
Find out if a health plan prefers to receive PAs and related documents via phone, fax, or email, through its website, or through an online portal.

- Keep copies of all documentation that you submit with the PA. There are many reasons that you may need to refer to them, such as if a patient requests financial assistance later on.

INQUIRE HOW MUCH TIME IT WILL TAKE FOR A DECISION.
Once a health plan receives the necessary forms and documentation, it is important to ask for a time frame in order to monitor the PA’s progress and confirm its approval.

- Follow up with the health plan if your office does not receive notification of its decision in a timely manner.

LOG ANY CALLS THAT YOUR OFFICE MAKES ABOUT A PA REQUEST.
Log the date and time of the call, the person you spoke with, and their direct telephone extension or email address.

RECORD THE APPROVAL CODE AND DATE.
When a PA approval is received, be sure to record the code and date.

MAINTAIN A SUMMARY SHEET OF THE REQUIREMENTS.
Document any unique PA requirements of common health plans in your area for your reference to help expedite future PA submissions.
REQUESTING A MEDICAL EXCEPTION

There are occasions when a physician may wish to prescribe a Biogen relapsing MS therapy even though it requires step therapy or is not covered by insurance

You may encounter a situation in which a health plan may not provide coverage for Biogen therapies unless other medications are tried first or excludes them from its formulary.

In these situations, the prescribing physician may choose to submit a request for a medical exception to bypass the health plan’s requirement due to the patient’s individual circumstances.

It is important to include all of the appropriate documentation in order to provide the support for the medical exception.

Supporting documentation that may strengthen your medical exception request

- Details from a patient’s medical record
- Expanded Disability Status Scale scores, MRI data, and relapse history
- If appropriate, general medical history listing comorbidities and any medication history, including contraindications
- Clinical evidence for treatment failure, such as inadequate response, adverse events, or side effects
- Prescribing Information
- Letters from consultants or other medical professionals that provide insight that impacts your treatment choice
- Clinical trials and literature that support your request for medical exception

If a request for medical exception is denied due to clinical reasons, the prescriber may contact the health plan directly to speak with a neurology specialist. This discussion may help the health plan understand your concerns regarding your patient taking the preferred formulary drugs and why you have submitted a request for a medical exception.
CHECK THE BI TO DETERMINE IF REQUESTING A MEDICAL EXCEPTION IS NECESSARY.
The information gathered during the BI may help determine if the prescribed Biogen therapy is subject to a step therapy restriction or is excluded from the health plan's formulary. If the patient's SP conducts the BI, it may notify you if submitting a request for a medical exception is required.

COMPLETE THE MEDICAL EXCEPTION REQUEST WITH A LETTER OF MEDICAL NECESSITY.
Confirm whether the health plan requires a specific form for medical exception requests or a separate letter from your office.
- Remember to carefully and accurately complete the medical exception request form. Requests for medical exception may be denied because the form contains inaccurate or incomplete information

PROPERLY SUBMIT THE MEDICAL EXCEPTION REQUEST.
Determine whether a health plan requires a medical exception request to be submitted via phone, fax, or email, or through a specific website. Also inquire about the appropriate contact for the request.
- Record the date, time, and method of submission

TRACK THE STATUS OF THE MEDICAL EXCEPTION REQUEST.
Some states have legislation that requires insurance carriers to respond to medical exception requests within a certain time frame.

Follow up with the health plan if your office does not receive notification of the decision in a timely manner.
COMPLETING A LETTER OF MEDICAL NECESSITY

An effective Letter of Medical Necessity is tailored to your patient’s needs

A request for medical exception may need to be completed using a form from the health plan and/or a separate Letter of Medical Necessity to justify the prescriber’s treatment choice. Biogen’s Sample Letters of Necessity (shown below) are based on different prescribing scenarios that you may want to populate and consider including with the request for medical exception.

Considerations when completing a Letter of Medical Necessity

- Be clear about your patient’s individual circumstances to justify why the prescribed therapy is the appropriate choice
- Provide background on your patient’s relapsing MS
- State any patient-specific reasons, such as efficacy, tolerability issues, route of administration, or comorbidities
- Explain why the health plan’s preferred treatments are not appropriate for your patient. Include information about adverse events that your patient has experienced or if they have already been treated with a similar therapy
- Submit additional information with the letter, as appropriate (eg, relevant chart notes, MRI data, supporting literature, etc)
- Be sure to note whether the prescribing physician specializes in MS

Click on the images below to download the Sample Letters of Medical Necessity.

[Sample Letter for a Treatment-Naive Patient Starting Therapy]
[Sample Letter for a Patient Transitioning to Another Therapy]
[Sample Letter to Request Continuation of a Patient’s Current Therapy]
[Sample Letter to Request a Site-of-Care Exception]
THE APPEALS PROCESS
THE APPEALS PROCESS

If a request for PA or a medical exception for Biogen relapsing MS therapy is denied, your office or your patient may consider submitting an appeal

Review the reason(s) for denial and contact the payer to ensure that you understand its appeals process. The most common reasons for denials include:

- Transposed, missing, or abbreviated policy numbers
- PA number missing from claim
- Patient’s payer mandates the use of an SP
- Clinical criteria not met

Standard Appeals Process for a Commercial Plan

Once the appeal is submitted, here’s how a standard commercial plan appeals process may go:

1. CONTRACT REVIEW

Components of the appeals process are designated in

- The physician’s contract with a payer
- The patient’s insurance policy

2. SPECIALIST REVIEW

A neurologist or other specialist familiar with relapsing MS therapies may review the request for medical necessity

3. MEDICAL DIRECTOR REVIEW

If the neurologist or other specialist does not agree with the reasoning included in the appeal, the prescribing physician may communicate directly with a health plan medical director to discuss the patient’s circumstances

4. THIRD-PARTY REVIEW

If the health plan denies the appeal, state insurance department resources may be used as a final means of arbitration

Contact the payer to check on the status of your request. Notify the patient of instances in which your office may need their involvement. Often, the patient can also submit an appeal to the payer.

It is important that you understand the appeals process for each payer and the time frame in which it must respond. Many states have specific time frames within which payers must respond to appeals (eg, 30 days).
THE APPEALS PROCESS (CONT’D)

Standard Appeals Process for Medicare\(^1,2\)

Once the appeal is submitted, here’s how a standard Medicare appeals process may go:

1. **REDETERMINATION**
   by Part D Plan Sponsor or Medicare Administrative Contractor

2. **RECONSIDERATION**
   by Independent Review Entity or Qualified Independent Contractor

3. **HEARING**
   by an Administrative Law Judge or Office of Medicare Hearings and Appeals

4. **REVIEW**
   by Medicare Appeals Council

5. **REVIEW**
   by Federal District Court

If you disagree with an unfavorable decision made by a lower appeal entity, you may appeal that decision at the next level.

While this is the standard process for Medicare Parts A, B, and D, some plan-specific requirements may exist. Always contact the patient’s plan for additional appeals guidance.


It is important that you understand the appeals process for each payer and the time frame in which it must respond. Many states have specific time frames within which payers must respond to appeals (eg, 30 days).
COMPLETING A LETTER OF APPEAL

A letter of appeal is a critical component of your request

Health plans may have their own appeal request forms. Be sure all information is complete and accurate. Forms are usually available on the health plan’s website. Biogen has developed a Sample Letter of Appeals that you can populate and consider including with the appeal request.

An effective letter of appeal may include the following elements:

- Patient information such as name, policy number, and case or claim reference number
- Reason for the denial as listed in the denial letter
- Patient’s history and current condition
- The reason(s) you disagree with the denial
- Explanation of the medical necessity
- Patient-specific reasons for choosing the prescribed therapy
- Product indication

Click on the image on the right to download the Sample Letter of Appeals.

Some payers may require the patient to sign an AOR or Authorized Representative form in order for a provider to act on a patient’s behalf in requesting information, generally regarding a denied claim/service and/or requesting an appeal. The appropriate form(s) may vary by health plan, so please ensure the proper plan requirements are met when requesting information and/or appeals by checking the health plan’s provider portal or website.
CHECKLIST: FILING AN APPEAL

**REVIEW THE REASON FOR THE DENIAL.**
Identify any incorrect or incomplete information in the request for PA or a medical exception, as this is the most common reason for a denied claim.

**VERIFY THE APPEALS PROCESS WITH THE HEALTH PLAN.**
It is important to determine the right course of action in the appeals process. Probe for the following:

- Does the plan require use of a specific form?
- Does the plan have a required or preferred method of submission (over the phone, in writing, etc)?
- If the appeal must be submitted in writing, to whom should it be directed?
- What information must be included in the appeal (eg, a copy of the original claim, Summary of Benefits, Letter of Medical Necessity)?
- How long does the appeals process usually take?
- How will the plan communicate the appeal decision?

**REVIEW THE APPEAL REQUEST FOR ACCURACY AND COMPLETENESS.**
Be sure to review patient ID numbers, codes, and additional requested information/documentation.

**PROMPTLY FILE THE APPEAL.**
Submit the proper documentation for the appeal within the health plan’s time limits.

**RECORD THE APPEAL DECISION.**
If the appeal is approved, document the PA number to include on the claim form.

In the event of an appeal denial, document the date the denial was received and the reason for denial. Determine if a third-level appeal will be requested.
BIOGEN SUPPORT SERVICES
BIOGEN SUPPORT SERVICES FOR YOUR PATIENTS

Biogen is here to help your patients get started on treatment and provide them with additional support throughout their time on a Biogen therapy.

BIOGEN CASE MANAGERS
When patients are prescribed a Biogen therapy, a Biogen Case Manager will contact them and provide support throughout their Biogen treatment journey. Support is also available in Spanish.

NURSE EDUCATORS
Patients who are prescribed a Biogen therapy have 24/7 access to registered nurses, many of whom are MS-certified. They are here to:
• Help your patients understand what to expect during treatment
• Give information about common side effects for their therapy
• Provide education about available resources

FINANCIAL & INSURANCE ASSISTANCE
When cost may be a concern for your patients, Biogen may be able to help them start and continue on a Biogen therapy. We will work with your patients based on their individual needs. Biogen Support Services offers a variety of different financial and insurance resources.

Your or your patients can call 1-800-456-2255 Monday-Friday from 8:30 AM to 8 PM ET.
Please contact your Biogen representative or Biogen Support Services if you have any questions.