MAYZENT®
(siponimod) tablets
0.25 mg • 2 mg

# AUTHORIZATION AND APPEALS KIT

## To support patient access to prescribed therapy

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

**Please see Important Safety Information on pages 20-21 and click links for the full Prescribing Information, including Medication Guide.**

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# CONTENTS



**Alongside MS** is available to help your patients with benefits verification and financial assistance options. A dedicated Alongside MS coordinator can also answer questions you or your patients may have about PAs, appeals, and formulary exception requests.

**Contact a coordinator at our 24-hour hotline at 1-877-MAYZENT (1-877-629-9368).**

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

HCP=health care professional; MS=multiple sclerosis; PA=prior authorization.

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# HOW TO USE THIS KIT

Each health plan manages access to MAYZENT® (siponimod) differently. Even if you decide that prescribing MAYZENT to patients with active SPMS is the right clinical decision, you may run into health plan restrictions, such as PAs, step edits, or no formulary coverage at all.

This kit walks you through some common insurance restrictions and includes sample template letters if the health plan's formulary requires further documentation to support your clinical decision.

## TREATMENT CHOICE

Based on the patient's medical circumstances, MAYZENT is the treatment of choice for your patient.

## COVERAGE ASSESSMENT

Does the patient's health plan provide coverage for MAYZENT?

Your practice should contact the health plan to understand your patient's specific coverage criteria. Another option is for you to enroll the patient in Alongside MS™. A dedicated Alongside MS coordinator will then call the health plan to identify your patient's specific coverage criteria for MAYZENT.

## TYPICAL DRUG COVERAGE POLICIES

### REQUIRED

A PA is needed to confirm certain criteria have been met.

**Submit a PA form requesting MAYZENT.**

OR

### NOT COVERED

Coverage may not be granted because:

- MAYZENT is excluded from the health plan's formulary
- NDC blocks are in place

In these instances, submit 1 of the following:

**Letter of Medical Necessity**

**Formulary Exception Request Letter**

OR

### APPROVED

MAYZENT is a preferred treatment on the health plan's formulary and is covered for the patient.

**No further action is needed on your part.**

## PATIENT APPEAL

If the PA or formulary exception request is denied, submit the following:

**Letter of Appeal**

**Letter of Medical Necessity**

**Note:** There can be multiple levels of appeal. Each of the appeal letters can be adapted for higher-level appeals.

NDC=National Drug Code; SPMS=secondary progressive multiple sclerosis.

# INDICATION

MAYZENT® (siponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

# IMPORTANT SAFETY INFORMATION

**Contraindications**

- Patients with a CYP2C9*3/*3 genotype
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, unless patient has a functioning pacemaker

# SAMPLE PROFILE OF A PATIENT WITH ACTIVE SPMS

## THE COMPOSITE EDSS SCORE FOR THIS PATIENT (NOT AN ACTUAL PATIENT) HAS INCREASED FROM 4.0 TO 5.0 WITHIN THE LAST YEAR

***SUE SMITH,*** *Early 40s*

**Disease duration:**

- 12 years

**Recent relapse history:**

- Infrequent: 1 relapse within the last 24 months

**8 domains comprising EDSS as follows:**

- **Ambulation:** Persistent left-side weakness evidenced by slight foot drag
- **Bowel/Bladder:** Urinary incontinence from 2 times a month to 4 times a week
- **Cerebral:** Increasing fatigue in daily activities
- **Visual:** No change
- **Brain Stem:** No change
- **Pyramidal:** No change
- **Cerebellar:** No change
- **Sensory:** No change

## TRANSITIONER TO ACTIVE SPMS

Sue Smith is married with 2 kids, is in her early 40s, and owns a small business that provides back-office support for Internet retailers. When she was diagnosed with MS 12 years ago, her MS specialist started her on glatiramer acetate. After 9 years on glatiramer acetate, she was switched to dimethyl fumarate due to poor control of her MS symptoms. She has been on dimethyl fumarate for the past 3 years.

Lately, Sue has been sending employees in her place for client meetings because she is having difficulty keeping up with her work schedule. Sue is also experiencing greater fatigue and is avoiding going out in public due to embarrassment from urinary urgency/incontinence. Recently, Sue has noticed that she has to stop and rest frequently when walking, due to a recent development of a slight foot drag.

EDSS=Expanded Disability Status Scale.

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# PRIOR AUTHORIZATION CHECKLIST

HCPs must prove to the health plan that the health plan's specific PA requirements have been met, or, if a step edit is being passed over, why MAYZENT® (siponimod) is the treatment of choice for the patient.

For plans requiring a PA request for MAYZENT (consider using Alongside MS™ or CoverMyMeds® for support with PAs and appeals):

- Complete a PA request utilizing the health plan's PA form
- If a PA is denied, submit a Letter of Appeal (samples shown on pages 10 and 11)

## RELY ON ALONGSIDE MS FOR SUPPORT

- If you have questions about the health plan's PA form or the process, Alongside MS is available to help
- Speak to a dedicated Alongside MS coordinator at 1-877-MAYZENT (1-877-629-9368)
- If you prefer to submit the PA electronically, consider submitting the form through CoverMyMeds

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

# PRIOR AUTHORIZATION CHECKLIST (cont)

## CHECKLIST FOR A COMPLETE PA SUBMISSION

- ☐ **Include the patient's name, policy number, date of birth, and dates of service**
- ☐ **Provide the patient's diagnosis and corresponding ICD-10 code**
- ☐ **List previous therapies**
- ☐ **Make sure that you address all PA requirements of the health plan, if applicable**
- ☐ **Be sure that the patient has satisfied any requirements, if applicable**

Some examples of PA and step therapy requirements for active SPMS are:

- History of failure following a trial for a specified amount of time or history of intolerance or contraindication to at least one other MS therapy (including, but not limited to, IFN, glatiramer acetate, other S1P receptor modulators, or any other DMTs). Failure may be defined as:
  - Continued disability progression regardless of acute neurological events (eg, relapses and/or disease activity)
  - EDSS >3
  - Continued worsening of MS symptoms despite reducing frequency of relapses

***Remember, incomplete forms may result in further delays.***

If the health plan denies your request for coverage, do not worry. Your office can submit an appeal on behalf of the patient. Recommendations on how to compose a Letter of Appeal are provided on pages 8 to 11.

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

DMT=disease-modifying therapy; IFN=interferon.

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# SAMPLE LETTERS OF APPEAL

If a patient is denied coverage, HCPs are required to explain their clinical rationale for prescribing MAYZENT® (siponimod) in a Letter of Appeal. This letter addresses each specific reason given for the denial. The health plan is likely to have a preferred formulary for the management of MS, so the appeal will also need to demonstrate why the health plan's formulary is not the most appropriate treatment for this patient.

We have included 2 sample Letters of Appeal, which address whether the patient is actively on MS treatment or not. No matter the patient's treatment status, each letter should be submitted with a copy of the patient's relevant medical records and a Letter of Medical Necessity (samples shown on pages 14 and 15).

You can submit a Letter of Appeal on your own or submit an appeal through Alongside MS™ or electronically via CoverMyMeds.

Note that there can be multiple levels of appeal. You should refer to the health plan's specific appeal guidelines. Many health plans will allow up to 3 levels of appeal of PA denials. The third level of appeal may include a review by an independent, noninsurance-affiliated external review board or hearing.

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

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# SAMPLE LETTERS OF APPEAL (cont)

## CHECKLIST FOR WRITING A LETTER OF APPEAL

- ☐ **Include the patient's name, policy number, date of birth, case ID number, and dates of service**
- ☐ **Acknowledge that you are familiar with the company's policy on claims denial and include the reason(s) for the denial**
- ☐ **Include the patient's medical records**
- ☐ **Include the ICD-10 code**
- ☐ **Provide clinical support for prescribing MAYZENT® (siponimod). This may include failure with previous MS therapies, with failure defined as:**
  - Continued disability progression regardless of acute neurological events (eg, relapses and/or disease activity)
  - EDSS >3
  - Continued worsening of MS symptoms despite reducing frequency of relapses
- ☐ **Provide copies of relevant medical records (health plans may want to see if infections, allergies, or comorbidities are present)**
- ☐ **List previous therapies (eg, IFN, glatiramer acetate, S1P receptor modulators, or others)**
  - Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ **Explain why other agents/treatments are inappropriate for this patient**
- ☐ **Include a Letter of Medical Necessity**
- ☐ **Include FDA approval letter for MAYZENT**

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

FDA=Food and Drug Administration.

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## SAMPLE LETTER OF APPEAL (FOR PATIENTS NOT ACTIVELY ON MS TREATMENT)

Address the letter to the PA department or contact person from the denial letter.

[Date]
[Health plan name]
ATTN: [Department]
[Medical/pharmacy director name (if available)]
[Health plan address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Dates of service]

Re: Appeal of Denial of MAYZENT® (siponimod) tablets 0.25 mg - 2 mg

Dear [Medical/pharmacy director name],

Acknowledge the health plan's reason for denial up front.

I am writing to request reconsideration of your denial of coverage for MAYZENT, which I have prescribed for the patient referenced above. I have read and acknowledged your policy for responsible management of drugs for multiple sclerosis (MS), including [active secondary progressive multiple sclerosis (SPMS)]. Your reason(s) for the denial [is/are] [reason(s) for the denial].

Based on the patient's condition and medical history, as well as my experience treating patients with [active SPMS] [ICD-10 code], I believe treatment with MAYZENT is warranted, appropriate, and medically necessary in this case. Please see my clinical reasoning below for prescribing MAYZENT to my patient.

**Patient's diagnosis and medical history in support of the appeal**
[Patient's name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [active SPMS] as of [date]. [He/She] has been in my care since [date].

[Include relevant medical information to support your reason for treatment with MAYZENT. An example may include evidence that the patient's relapsing MS symptoms and disabilities have been progressing despite his/her MS therapies. Additional information needed may include:

- Supporting information as requested by the plan in their denial letter
- Clinical attributes of MAYZENT and relevance to the patient]

Explain why each therapy was discontinued and give the duration of therapy for each agent.

History of previous therapies for MS/SPMS_____

Reasons for discontinuation of previous therapies_____

Duration of previous therapies_____

**Summary**
This is my [level of request] prior authorization appeal. A copy of the [level of denial] denial letter is included along with medical notes in response to the denial. In my professional opinion, and considering [patient's name]'s history and condition, I believe treatment with MAYZENT is appropriate and medically necessary. If you have any further questions about this matter, please contact me at [physician's phone number] or via e-mail at [physician's e-mail]. Thank you for your time and consideration.

If this is the second- or third-level appeal, it may be helpful to include the original denial letter as well as specific medical notes in response to the denial. Give the physician's contact information in case there are any questions that need to be answered.

Sincerely,

[Physician's signature]

Enclosures

[List and attach additional documents, which may include a denial letter, Letter of Medical Necessity, prescribing information, clinical notes/medical records, FDA approval letter, or clinical practice guidelines.]

## SAMPLE LETTER OF APPEAL (FOR PATIENTS CURRENTLY ON MS TREATMENTS)

[Date]
[Health plan name]
ATTN: [Department]
[Medical/pharmacy director name (if available)]
[Health plan address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Dates of service]

Re: Appeal of Denial of MAYZENT® (siponimod) tablets 0.25 mg - 2 mg

Dear [Medical/pharmacy director name],

I am writing to request reconsideration of your denial of coverage for MAYZENT, which I have prescribed for the patient referenced above. I have read and acknowledged your policy for responsible management of drugs for multiple sclerosis (MS), including [active secondary progressive multiple sclerosis (SPMS)]. Your reason(s) for the denial [is/are] [reason(s) for the denial].

**The key difference** in this sample letter is to call out the patient's current treatment and your decision to initiate MAYZENT® (siponimod) for the treatment of active SPMS instead. Be clear in this directive and follow up with your clinical rationale below.

Based on the patient's condition and medical history, as well as my experience treating patients with [active SPMS] [ICD-10 code], I believe the appropriate and medically necessary decision for [patient's name] at this time is to discontinue [current drug name] and initiate treatment with MAYZENT. Please see my clinical reasoning below for prescribing MAYZENT to my patient.

**Patient's diagnosis and medical history in support of the appeal**
[Patient's name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [active SPMS] as of [date]. [He/She] has been in my care since [date].

[Include relevant medical information to support your reason for treatment with MAYZENT. An example may include evidence that the patient's relapsing MS symptoms and disabilities have been progressing despite his/her MS therapies. Additional information needed may include:

- Supporting information as requested by the plan in their denial letter
- Clinical attributes of MAYZENT and relevance to the patient]

History of previous therapies for RMS/SPMS_____

Reasons for discontinuation of previous therapies_____

Duration of previous therapies_____

**Summary**
This is my [level of request] prior authorization appeal. A copy of the [level of denial] denial letter is included along with medical notes in response to the denial. In my professional opinion, and considering [patient's name]'s history and condition, I believe treatment with MAYZENT is appropriate and medically necessary. If you have any further questions about this matter, please contact me at [physician's phone number] or via e-mail at [physician's e-mail]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Enclosures

[List and attach additional documents, which may include a denial letter, Letter of Medical Necessity, prescribing information, clinical notes/medical records, FDA approval letter, or clinical practice guidelines.]

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# SAMPLE LETTERS OF MEDICAL NECESSITY

In cases where PA appeals may be exhausted or where MAYZENT® (siponimod) is not covered or has an NDC block, HCPs may need to prepare a Letter of Medical Necessity to document the medical need for MAYZENT based on the patient's specific medical history and diagnosis.

This is your opportunity to communicate your clinical decision to prescribe MAYZENT in the context of the patient's specific record. There are 2 sample letters included, depending on whether your patient is actively on MS treatment or not.

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

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# SAMPLE LETTERS OF MEDICAL NECESSITY (cont)

## CHECKLIST FOR WRITING A LETTER OF MEDICAL NECESSITY

- ☐ **Include the patient's name, policy number, and date of birth**
- ☐ **Include the ICD-10 code**
- ☐ **Clearly state the rationale for treatment with MAYZENT® (siponimod) and why it is appropriate for your patient**
- ☐ **This may include failure with previous MS therapies, with failure defined as:**
  - Continued disability progression regardless of acute neurological events (eg, relapses and/or disease activity)
  - EDSS >3
  - Continued worsening of MS symptoms despite reducing frequency of relapses
- ☐ **List previous therapies**
  - Give the reasons each therapy was discontinued and the duration of therapy for each agent
- ☐ **Explain why formulary-preferred agents are not appropriate if they have not already been listed as previous therapies**
- ☐ **Provide clinical support for your recommendation**
  - This can be clinical trial data from the MAYZENT prescribing information or the FDA approval letter
- ☐ **To close the letter, summarize your recommendation and provide a phone number should any additional information be required**

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

## SAMPLE LETTER OF MEDICAL NECESSITY (FOR PATIENTS NOT ACTIVELY ON MS TREATMENT)

[Date]
[Health plan name]
ATTN: [Department]
[Medical/pharmacy director name (if available)]
[Health plan address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Dates of service]

Re: Letter of Medical Necessity for MAYZENT® (siponimod) tablets 0.25 mg - 2 mg

Dear [Medical/pharmacy director name],

I am writing this letter on behalf of [patient's name] to request coverage for MAYZENT for the treatment of [active secondary progressive multiple sclerosis (SPMS)], [ICD-10 code]. I have reviewed your drug coverage policy and believe that MAYZENT is the appropriate treatment for the patient at this time. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

**Patient's diagnosis and medical history**

[Patient's name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [active SPMS] as of [date]. [He/She] has been in my care since [date].

My rationale for prescribing MAYZENT is [Include relevant medical information to support your rationale for treatment with MAYZENT. An example may include evidence that the patient's relapsing multiple sclerosis (MS) symptoms and disabilities have been progressing despite his/her MS therapies. Additional information needed may include:

- A qualitative description of clinically evident progressive disability
- Disease activity, including relapses and/or magnetic resonance imaging brain lesions
- A brief description of MRI test results, as appropriate
- Changes in MS quality of life assessment
- Underlying health issues
- Intolerable side effects
- MS treatments that the patient has tried and failed]

It may be helpful to include the FDA approval letter and data from the MAYZENT® (siponimod) pivotal trial to support your decision.

**Treatment plan**

In my clinical opinion, [patient's name] should receive MAYZENT for the following reasons: [Include a summary of reasons the preferred drugs on formulary are not appropriate for this patient and why MAYZENT is clinically indicated for this patient]. I have included the FDA approval letter for MAYZENT as well as supporting clinical data.

**Summary**

I believe MAYZENT is appropriate and medically necessary for this patient. If you have any further questions about this matter, please contact me at [physician's phone number] or via e-mail at [physician's e-mail]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Enclosures

[List and attach medical records, laboratory work, imaging results, prescribing information, and FDA approval letter.]

## SAMPLE LETTER OF MEDICAL NECESSITY (FOR PATIENTS CURRENTLY ON MS TREATMENT)

[Date]
[Health plan name]
ATTN: [Department]
[Medical/pharmacy director name (if available)]
[Health plan address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Dates of service]

Re: Letter of Medical Necessity for MAYZENT® (siponimod) tablets 0.25 mg - 2 mg

Dear [Medical/pharmacy director name],

I am writing this letter on behalf of [patient's name] to request coverage for MAYZENT for the treatment of [active secondary progressive multiple sclerosis (SPMS)], [ICD-10 code]. I have reviewed your drug coverage policy and believe that the appropriate treatment decision at this time is to discontinue [current drug name] and initiate treatment with MAYZENT. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

**The key difference** in this sample letter is to call out the patient's current treatment and your decision to initiate MAYZENT® (siponimod) for the treatment of active SPMS instead. Be clear in this directive and follow up with your clinical rationale below.

**Patient's diagnosis and medical history**

[Patient's name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [active SPMS] as of [date]. [He/She] has been in my care since [date].

My rationale for prescribing MAYZENT is: [Include relevant medical information to support your rationale for treatment with MAYZENT. An example may include evidence that the patient's relapsing multiple sclerosis (MS) symptoms and disabilities have been progressing despite his/her MS therapies. Additional information needed may include:

- A qualitative description of clinically evident progressive disability
- Breakthrough disease activity, including relapses and/or magnetic resonance imaging brain lesions
- A brief description of MRI test results, as appropriate
- Changes in MS quality of life assessment
- Underlying health issues
- Intolerable side effects
- MS treatments that the patient has tried and failed]

**Treatment plan**

In my clinical opinion, [patient's name] should receive MAYZENT for the following reasons: [Include a summary of reasons the preferred drugs on formulary are not appropriate and why MAYZENT is clinically indicated for this patient]. I have included the FDA approval letter for MAYZENT as well as supporting clinical data.

**Summary**

I believe MAYZENT is appropriate and medically necessary for this patient. If you have any further questions about this matter, please contact me at [physician's phone number] or via e-mail at [physician's e-mail]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Enclosures

[List and attach medical records, laboratory work, imaging results, prescribing information, and FDA approval letter.]

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# SAMPLE FORMULARY EXCEPTION REQUEST LETTER

For health plans that list MAYZENT® (siponimod) as nonformulary or not covered/NDC block, you may be asked to submit one of the following, depending on the health plan's requirements:

- Formulary Exception Request Letter
- Letter of Medical Necessity (samples shown on pages 14 and 15)

While the health plan may provide a form on its website that can be used to apply for an exception, you can refer to the sample provided in this kit to see the type of information that is typically required.

For a complete submission, it is recommended that a copy of the patient's relevant medical records accompany this letter and the Letter of Medical Necessity.

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

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# SAMPLE FORMULARY EXCEPTION REQUEST LETTER (cont)

## CHECKLIST FOR WRITING A FORMULARY EXCEPTION REQUEST LETTER

- ☐ **Include the patient's name, policy number, and date of birth**
- ☐ **Include the patient's diagnosis with active SPMS**
- ☐ **List previous therapies (IFN or non-IFN treatments for MS)**
- ☐ **Provide the reason for your choice to prescribe MAYZENT® (siponimod), such as failure with previous MS therapies, with failure defined as:**
  - Continued disability progression regardless of acute neurological events (eg, relapses and/or disease activity)
  - EDSS >3
  - Continued worsening of MS symptoms despite reducing frequency of relapses
- ☐ **Include the patient's relevant medical records**
- ☐ **Provide a copy of the denial letter and medical notes if this is a second- or third-level appeal**
- ☐ **Include a Letter of Medical Necessity (samples shown on pages 14 and 15)**

For Medicare or Medicaid beneficiaries, completion and submission of a CMS Coverage Determination Form may be required. A Formulary Exception Request Letter would accompany the CMS Coverage Determination Form when it is submitted.

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

CMS=Centers for Medicare & Medicaid Services.

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## SAMPLE FORMULARY EXCEPTION REQUEST LETTER

[Date]
[Health plan name]
ATTN: [Department]
[Medical/pharmacy director name (if available)]
[Health plan address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Policy number]

Re: Request for Formulary Exception for MAYZENT® (siponimod) tablets 0.25 mg - 2 mg

To [Medical/pharmacy director name],

I am writing this letter on behalf of [patient's name] to request coverage for MAYZENT. Currently, MAYZENT is not listed on your formulary for [active secondary progressive multiple sclerosis (SPMS)], [insert ICD-10 code].

I am requesting an exception to your formulary so the prescription for MAYZENT can be filled.

[Patient's name] has been previously treated with other multiple sclerosis (MS) medications prior to this one, including [list previous therapies]. The main reasons for requesting this exception are [insert main medical necessity points, which may include worsening of patient's relapsing MS symptoms and disabilities that have been progressing despite his/her MS therapies]. These reasons are supported by the information attached.

Considering [patient's name]'s history and condition, I believe treatment with MAYZENT is appropriate and medically necessary. I can be contacted at [physician's phone number] or via e-mail at [physician's e-mail] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of MAYZENT in the treatment of the patient's [active SPMS]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Enclosures

[List and attach additional documents, which may include a denial letter, Letter of Medical Necessity, prescribing information, clinical notes/medical records, FDA approval letter, or clinical practice guidelines.]

State your request for exception with clear intent. Use the rest of the letter to support your clinical rationale for prescribing MAYZENT® (siponimod) for active SPMS

Medical records should include documentation from the date MAYZENT was first prescribed to the patient. The records should include diagnosis severity indicators if the patient is already taking MAYZENT.
It may also be useful to include the FDA approval letter and data from the MAYZENT pivotal trial to support your decision.

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# ALONGSIDE MS™ OFFERINGS

## SIMPLIFYING PATIENT SUPPORT

Alongside MS was designed to give patients access to support by taking a multidimensional approach to deliver what patients need, every step of the way, including:

- **Financial assistance and coverage support.** We check with the patients' insurance plans to confirm coverage, and offer a $0 co-pay*, if they qualify. We also provide informational support with PAs and appeals, so they can focus on treatment
- **Assessment support.** We help schedule, coordinate, and in some cases, cover the cost for all necessary assessments†
- **One-on-one support.** Patients can rely on their dedicated Alongside MS coordinator for guidance, answers, and personalized reminders when starting treatment and along the way‡

## GETTING PATIENTS STARTED ON MAYZENT® (siponimod)

Starting patients on MAYZENT begins as soon as you submit the Start Form, which initiates a 3-step onboarding process:

| Access and financial eligibility | Assessments | Delivery and initiation |
|---|---|---|
| We will contact the patient's insurance company to determine coverage, and assess their eligibility for financial assistance | We will help schedule assessments§ and cover the cost for those who qualify† | We will arrange delivery of the patient's Starter Pack, as well as their monthly maintenance dose, if eligible‖ |

*Limitations apply. Up to a $18,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions for details at www.mayzent.com.

†Free for commercially insured patients and those without insurance who are starting or restarting MAYZENT. Covered medical assessments include recommended blood tests, macular edema screening, electrocardiogram (ECG) and first dose observation (FDO), as prescribed, provided via a program-sponsored medical facility or at home. Macular Edema screening is available in select areas only. Health care professionals overseeing FDO will evaluate pre-existing conditions or concomitant medications that may preclude the patients from completing their FDO. This offer is not valid for medical assessments (i) performed in RI; (ii) for which payment may be made in whole or in part under federal or state healthcare programs, including but not limited to Medicare or Medicaid or (iii) where prohibited by law. There is a cash-pay option for residents of RI choosing to use a program-sponsored medical facility. No purchase required. This program is subject to termination or modification at any time. Medicare is accepted at some program-sponsored facilities.

‡Information provided by Alongside MS is for educational purposes only and is not intended to replace discussions with a healthcare provider. All medical decisions regarding patient care must be made with the patient's healthcare provider.

§Scheduling support is available for patients using a Program-sponsored facility.

‖See the MAYZENT Start Form for eligibility requirements and additional information.

**For any questions about our patient services, call us at our 24-hour hotline at 1-877-MAYZENT (1-877-629-9368).**

**Access help is always available.** You can access the sample letters of all resources described in this kit from the MAYZENT HCP website under Coverage Resources.

**Please see Important Safety Information on pages 20-21 and click links for the full Prescribing Information, including Medication Guide.**

# INDICATION AND IMPORTANT SAFETY INFORMATION

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## INDICATION

MAYZENT® (siponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

## IMPORTANT SAFETY INFORMATION

### Contraindications

- Patients with a CYP2C9*3/*3 genotype
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, unless patient has a functioning pacemaker

**Infections:** MAYZENT may increase risk of infections with some that are serious in nature. Life-threatening and rare fatal infections have occurred.

Before starting MAYZENT, review a recent complete blood count (CBC) (ie, within 6 months or after discontinuation of prior therapy). Delay initiation of treatment in patients with severe active infections until resolved. Employ effective treatments and monitor patients with symptoms of infection while on therapy. Consider discontinuing treatment if patient develops a serious infection.

Cases of fatal cryptococcal meningitis (CM) were reported in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator. Rare cases of CM have occurred with MAYZENT. If CM is suspected, MAYZENT should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

No cases of progressive multifocal leukoencephalopathy (PML) were reported in MAYZENT clinical trials; however, they have been observed in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator and other multiple sclerosis (MS) therapies. If PML is suspected, MAYZENT should be discontinued.

Cases of herpes viral infection, including one case of reactivation of varicella zoster virus leading to varicella zoster meningitis, have been reported. Patients without a confirmed history of varicella zoster virus (VZV) or without vaccination should be tested for antibodies before starting MAYZENT. If VZV antibodies are not present or detected, then VZV immunization is recommended and MAYZENT should be initiated 4 weeks after vaccination.

Use of live vaccines should be avoided while taking MAYZENT and for 4 weeks after stopping treatment.

Caution should be used when combining treatment (ie, anti-neoplastic, immune-modulating, or immunosuppressive therapies) due to additive immune system effects.

**Macular Edema:** In most cases, macular edema occurred within 4 months of therapy. Patients with history of uveitis or diabetes are at an increased risk. Before starting treatment, an ophthalmic evaluation of the fundus, including the macula, is recommended and at any time if there is a change in vision. The use of MAYZENT in patients with macular edema has not been evaluated; the potential risks and benefits to the individual patient should be considered.

**Bradyarrhythmia and Atrioventricular Conduction Delays:** Prior to initiation of MAYZENT, an ECG should be obtained to determine if preexisting cardiac conduction abnormalities are present. In all patients, a dose titration is recommended for initiation of MAYZENT treatment to help reduce cardiac effects.

MAYZENT was not studied in patients who had:

- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, or decompensated heart failure requiring hospitalization
- New York Heart Association Class II-IV heart failure
- Cardiac conduction or rhythm disorders, including complete left bundle branch block, sinus arrest or sino-atrial block, symptomatic bradycardia, sick sinus syndrome, Mobitz type II second-degree AV-block or higher-grade AV-block (either history or observed at screening), unless patient has a functioning pacemaker
- Significant QT prolongation (QTc greater than 500 msec)
- Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic drugs

Reinitiation of treatment (initial dose titration, monitoring effects on heart rate and AV conduction [ie, ECG]) should apply if ≥4 consecutive daily doses are missed.

**Respiratory Effects:** MAYZENT may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy if clinically warranted.

**Liver Injury:** Elevation of transaminases may occur in patients taking MAYZENT. Before starting treatment, obtain liver transaminase and bilirubin levels. Closely monitor patients with severe hepatic impairment. Patients who develop symptoms suggestive of hepatic dysfunction should have liver enzymes checked, and MAYZENT should be discontinued if significant liver injury is confirmed.

**Increased Blood Pressure:** Increase in systolic and diastolic pressure was observed about 1 month after initiation of treatment and persisted with continued treatment. During therapy, blood pressure should be monitored and managed appropriately.

**Please see additional Important Safety Information on page 21 and click links for the full Prescribing Information, including Medication Guide.**

MAYZENT®
(siponimod) tablets
0.25 mg • 2 mg

# IMPORTANT SAFETY INFORMATION (cont)

**Fetal Risk:** Based on animal studies, MAYZENT® (siponimod) may cause fetal harm. Women of childbearing potential should use effective contraception to avoid pregnancy during and for 10 days after stopping MAYZENT therapy.

**Posterior Reversible Encephalopathy Syndrome (PRES):** Rare cases of PRES have been reported in patients receiving a sphingosine 1-phosphate (S1P) receptor modulator. Such events have not been reported for patients treated with MAYZENT in clinical trials. If patients develop any unexpected neurological or psychiatric symptoms, a prompt evaluation should be considered. If PRES is suspected, MAYZENT should be discontinued.

**Unintended Additive Immunosuppressive Effects From Prior Treatment or After Stopping MAYZENT:** When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects.

Initiating treatment with MAYZENT after treatment with alemtuzumab is not recommended.

After stopping MAYZENT therapy, siponimod remains in the blood for up to 10 days. Starting other therapies during this interval will result in concomitant exposure to siponimod.

Lymphocyte counts returned to the normal range in 90% of patients within 10 days of stopping therapy. However, residual pharmacodynamic effects, such as lowering effects on peripheral lymphocyte count, may persist for up to 3-4 weeks after the last dose. Use of immunosuppressants within this period may lead to an additive effect on the immune system, and therefore, caution should be applied 3-4 weeks after the last dose of MAYZENT.

**Severe Increase in Disability After Stopping MAYZENT:** Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of an S1P receptor modulator. The possibility of severe exacerbation of disease should be considered after stopping MAYZENT treatment, thus patients should be monitored upon discontinuation.

**Most Common Adverse Reactions:** Most common adverse reactions (>10%) are headache, hypertension, and transaminase increases.

**Please click links for the full Prescribing Information, including Medication Guide.**

**Reference: 1.** Mayzent [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2019.



NOVARTIS



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