



Not an actual patient.

Prior Authorization and Appeals Guide

Information and sample letters to help you navigate coverage for your patients on RHAPSIDO® (remibrutinib)



Phone:
87-RHAPSIDO (877-427-7436)



Online:
www.rhapsido-hcp.com



Fax:
866-433-2300



Portal:
www.covermyeds.health

For questions or support, reach out to your dedicated Access and Reimbursement Team or contact Novartis Patient Support.

Please see pages 12-13 for Important Safety Information.
Please see full [Prescribing Information](#), including [Patient Information](#).

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patients.



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This guide intends to be a resource for you to use if your patient is faced with common insurance restrictions like a prior authorization (PA), step edit, or a plan not having a policy in place for RHAPSIDO®. Whether using an electronic PA form or submitting requests manually, the tips, checklists, and sample letters included in this guide are designed to help you and your patients gather relevant documentation for complete communications with your patient's health plan.

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 ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

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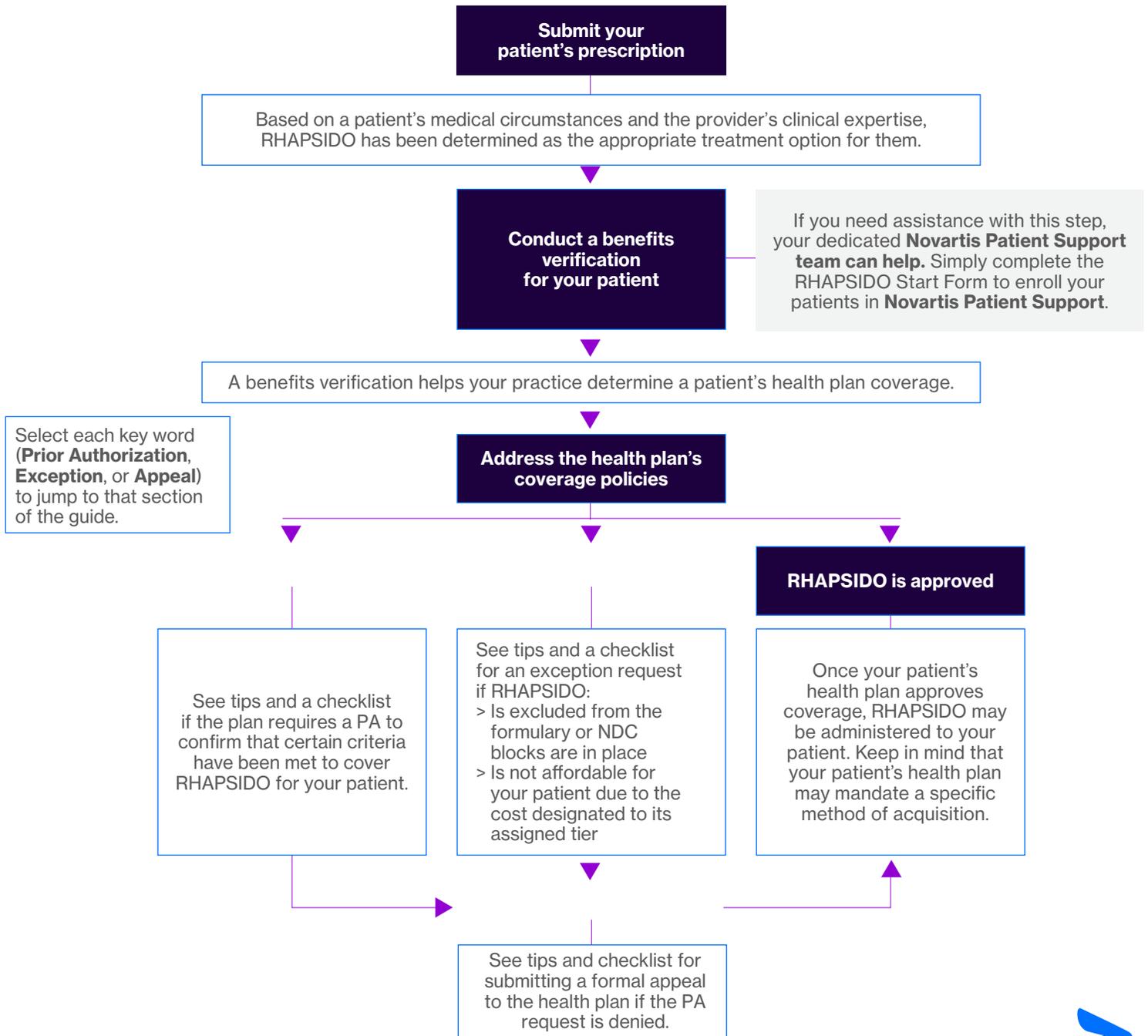
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Overview of the Reimbursement Process

Various health insurance providers may manage access to RHAPSIDO® differently. Use this page to review the coverage process and identify which steps apply to your patient.



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Tips for Completing a PA Request

If a patient's health plan requires a PA for RHAPSIDO®, review the specific forms and information required by the health plan to ensure that the PA request is as complete as possible.

Tips



- ▶ **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for RHAPSIDO



- ▶ **Ensure** that you understand and satisfy all plan-specific requirements
 - The patient's health plan may have a unique PA form that can be located on their website or by contacting their customer service
 - In certain states, a standardized PA form may be required for submission to a health plan along with clinical documentation
 - Some health plans encourage the use of electronic PA submission platforms such as CoverMyMeds®:
 - Quickly enroll patients and track their progress

Start a request

Visit www.covermyeds.health

Log in to your account

Select "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests.

CoverMyMeds: Automating part of the prior authorization (PA) process

CoverMyMeds' nationwide pharmacy integrations support the start of a PA request that is sent to the provider for completion—which may help patients access their medications faster.*

*Compared to phone and fax.



- ▶ **Consider** including a personalized letter with PA documentation; your patient's health plan may require you to submit a Letter of Medical Necessity to explain your rationale supporting your patient's clinical need for RHAPSIDO



[Click here](#) to view sample **Letter(s) of Medical Necessity** for your office:

A PA may be denied for RHAPSIDO based on various reasons. Common causes of a PA denial are shown below.

Medical Necessity

Health plans may deny access if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.

Administrative Errors

An incorrect billing code, spelling errors, insufficient information, or other administrative inaccuracies can result in a denied PA request.

Step Therapy

Depending on a health plan's formulary, patients are often required to receive a less expensive drug before a more expensive treatment can be prescribed.

Health plans take time to formulate their PA policies and coverage decisions. If a drug is not listed on formulary or is NDC blocked, you may be able to submit an exception for these scenarios.

See the following page for a helpful PA request checklist.

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Preparing a PA Submission

Submission checklist

Consider the following points when preparing to submit a PA for your patient. The checklist below is provided to help ensure your PA Request Letter is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The list below is intended to provide examples of what information is usually required.

▶ **Fill out the plan- and/or state-specific PA form**

- Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements for RHAPSIDO®

▶ **Check that the following information is accurate and complete:**

- Patient and insurance information (name, address, DOB, insurance information, etc)
- Prescriber information (name, address, specialty, office contact, NPI, etc)

▶ **Document the treatment strength, frequency, quantity, and estimated length of therapy, including the appropriate NDC code**

▶ **Attach relevant clinical documentation supporting treatment with RHAPSIDO, such as:**

- Relevant medical records and clinical notes that support treatment with RHAPSIDO
 - Documentation of chronic spontaneous urticaria (CSU) including appropriate ICD-10-CM code and date of diagnosis
- Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
- Appropriate clinical information from the Prescribing Information for RHAPSIDO
 - Additional clinical data that may support the prescriber's recommendation
- Disease-specific criteria, including information such as the following:
 - Laboratory testing
 - Disease-specific scores including urticaria activity score (UAS7), itch severity score (ISS7), hive severity score (HSS7)
 - List of previous therapies used, duration of therapy, and reason for discontinuation
 - If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)

 [Click here](#) to download a customizable PA letter for your office in Word doc format.

 [Click here](#) for a list of ICD-10 codes.



- ▶ **Reach out** to your dedicated Novartis Access and Reimbursement Team Member—they can help you understand plan requirements and coverage criteria



- ▶ **For support** throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by 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.

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Submitting an Exception

If the patient's health plan has placed restrictions on RHAPSIDO®, such as formulary exclusion or step therapy requirements, you will need to submit an exception request to ensure coverage.



Formulary Exception Request

Use this type of exception request to support patients seeking approval for RHAPSIDO or to remove any applicable National Drug Code (NDC) blocks if RHAPSIDO is excluded from the formulary of your patient's health plan.



Step Therapy Exception Request

Use this type of exception request to support patients seeking approval for RHAPSIDO without having to try other health plan preferred alternatives first.

Tips



► **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for RHAPSIDO



► **Check** to see if the patient's health plan has its own **Exception Request Form**—it can be located on their website or by contacting their customer service



► **You may also submit** a **Formulary Exception Request** or **Step Therapy Exception Request** if your patient's health plan previously approved RHAPSIDO but has since changed its formulary to exclude or move RHAPSIDO to a higher tier without grandfathering in current patients



► **Consider** asking your patient to write their own exception request letter that is signed by the physician



► [Click here](#) to view a checklist with helpful tips for your patient when writing to their health plan



► If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform

See the following page for a helpful exception request checklist.

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by 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.

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Exception Request Checklist

Consider the following points when preparing to submit an exception request. The checklist below is provided to help ensure your exception request is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

▶ **Fill out the health plan's exception request form, if required**

- Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements

▶ **Complete a Letter of Medical Necessity with relevant patient information and clinical support, which can include information such as:**

- Patient's name, date of birth, health plan information (policy number)
- A statement of the exception you are requesting for the patient and the reason for the request
- Diagnosis and corresponding ICD-10 code(s)
 - [Click here](#) for a list of ICD-10 codes
- Rationale for choosing RHAPSIDO®
- Summary of the patient's current condition and relevant treatment history
- If appropriate, a statement of the patient's financial hardship

▶ **Attach relevant clinical documentation supporting treatment with RHAPSIDO, such as:**

- Relevant medical records and clinical notes that support treatment with RHAPSIDO
 - Documentation of chronic spontaneous urticaria (CSU) including appropriate ICD-10-CM code and date of diagnosis
- Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
- Appropriate clinical information from the Prescribing Information for RHAPSIDO
 - Additional clinical data that may support the prescriber's recommendation
- Disease-specific criteria, including information such as the following:
 - Laboratory testing
 - Disease-specific scores including urticaria activity score (UAS7), itch severity score (ISS7), hive severity score (HSS7)
 - List of previous therapies used, duration of therapy, and reason for discontinuation
 - If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)

 [Click here](#) to view sample **Letter(s) of Medical Necessity** for your office.



- ▶ **Reach out** to your dedicated Novartis Access and Reimbursement Team Member—they can help you identify and understand plan requirements and coverage criteria



- ▶ **For support** throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

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Submitting an Appeal

If the patient's PA or exception request for RHAPSIDO® has been denied, you can consider an appeal. Your patient's health plan will provide a written explanation and include information about how to request an appeal. Review the health plan's guidelines on the appeals process to ensure the appeal is as complete as possible.

Tips



▶ **Conduct a benefits verification** of your patient's health plan to help determine the specific coverage criteria for RHAPSIDO



▶ **Promptly submit the appeal** upon receipt of the denial before the health plan's deadline



▶ **Clearly address the plan's specific reason(s)** for denial when writing the appeal letter



▶ **Review the appeals process** for your patient's health plan



▶ **Always refer to the health plan's website** to locate their appeal form or information for submitting your own document

- 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, non-insurance-affiliated external review board or hearing
- Your patient's appeals rights and the appeals process are covered in health plan documents and on each Explanation of Benefits (EOB) form



▶ If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by 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.

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Appeal Submission Checklist

Consider the following points when preparing to submit an appeal. The checklist below is provided to help ensure your appeal submission is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

▶ **Fill out an Appeal Form in response to the denial, if required by the health plan**

- Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
- Make sure that you review and attach the denial letter

▶ **Complete an Appeal Letter with relevant patient information and clinical support, such as:**

- Patient's name, date of birth, health plan information (policy number)
- Denial date and denial reference number
- Summary of patient's diagnosis and corresponding ICD-10 code(s)
 - [Click here](#) for a list of ICD-10 codes
- Summary of patient's treatment history
- Detail why each of the health plan's suggested alternative therapies are not appropriate for your patient
- If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)
- Rationale for choosing RHAPSIDO®

▶ **Attach relevant clinical documentation supporting treatment with RHAPSIDO, such as:**

- Relevant medical records and clinical notes that support treatment with RHAPSIDO
 - Documentation of chronic spontaneous urticaria (CSU) including appropriate ICD-10-CM code and date of diagnosis
- Visual documentation of the patient's condition (ie, photos and/or diagnostic images)
- Appropriate clinical information from the Prescribing Information for RHAPSIDO
 - Additional clinical data that may support the prescriber's recommendation
- Disease-specific criteria, including information such as the following:
 - Laboratory testing
 - Disease-specific scores including urticaria activity score (UAS7), itch severity score (ISS7), hive severity score (HSS7)
 - List of previous therapies used, duration of therapy, and reason for discontinuation
 - If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)



- ▶ **Reach out** to your dedicated Novartis Access and Reimbursement Team Member—they can help you identify and understand plan requirements and coverage criteria



- ▶ **For support** throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

 [Click here](#) to view sample **Letter(s) of Appeal** for your office.

Please see pages 12-13 for Important Safety Information.
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Sample Letters

The sample letter links below are available for you to reference when crafting your own letter to the patient's health plan. The sample letters are intended to provide examples of the types of information that are often required.

Click the links below to view sample letters for your office:



Sample Letters

[Sample PA Request Letter](#)

[Sample Letter of Medical Necessity](#)

[Sample Appeal Letter](#)



Example of Letter of Medical Necessity

Click the links below to view patient resources for your office:



Patient Resources

[Patient Letter Checklist](#)



Example of Patient Letter Checklist

Please see pages 12-13 for Important Safety Information.
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Glossary

- ▶ **Appeal:** A request to a patient's health plan to reconsider their decision to deny coverage
- ▶ **Co-payment:** A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—like doctor visits, prescription medications, and other health care services
- ▶ **Exception:** A coverage request made to a patient's health plan to remove a plan restriction placed on a treatment
- ▶ **Explanation of benefits (EOB):** A statement from the health plan sent to members to track the use of medications and/or health care services, and the associated costs and payments
- ▶ **Formulary:** A list of prescription medications covered by an insurer/health plan
- ▶ **National Drug Code (NDC):** Universal product identifier with a unique set of numbers used for human drugs in the US
- ▶ **Preferred drug:** A medication designated as a valuable, cost-effective treatment option. In a multi-tier plan, preferred drugs are assigned to a lower tier than non-preferred drugs
- ▶ **Prior authorization (PA):** Also called preauthorization, an administrative tool used by health plans to determine if they will cover a prescribed procedure, service, or medication based on the patient's medical necessity
- ▶ **Step therapy:** A health plan policy requiring patients to follow a stepwise approach to trying (and failing) a medication before the plan will cover any alternative medications
- ▶ **Tiers:** Most health plans' formularies are divided into different categories, called tiers, with increasingly scaled co-payments. Tiers are commonly based on brand or generic medications, preferred or non-preferred medications, and traditional or specialty medications

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RHAPSIDO® (remibrutinib) Indication and Important Safety Information

Indication

RHAPSIDO® (remibrutinib) is indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: RHAPSIDO is not indicated for other forms of urticaria.

Important Safety Information

Warnings and Precautions

- Risk of Bleeding: Mucocutaneous-related bleeding occurred in 9% of patients who received RHAPSIDO. Interrupt treatment with RHAPSIDO if bleeding is observed and resume if the benefit is expected to outweigh the risk. Interrupt treatment with RHAPSIDO for 3 to 7 days pre- and post-surgery or invasive procedures. Use of antithrombotic agents concomitantly with RHAPSIDO may further increase the risk of bleeding. Consider the benefits and risks of antithrombotic agents when used with RHAPSIDO. Monitor for signs and symptoms of bleeding
- The use of live and live-attenuated vaccines should be avoided in patients receiving RHAPSIDO

Adverse Reactions

- The most common adverse reactions (incidence \geq 3%) were nasopharyngitis, bleeding, headache, nausea, and abdominal pain

Drug Interactions

- Remibrutinib is a CYP3A4 substrate and a P-glycoprotein (P-gp) inhibitor
- Avoid use of RHAPSIDO with strong or moderate CYP3A4 inhibitors. Concomitant use with a strong or moderate CYP3A4 inhibitor increases remibrutinib exposure, which may increase the risk of RHAPSIDO adverse reactions
- Avoid use of RHAPSIDO with strong or moderate CYP3A4 inducers. Concomitant use with a strong or moderate CYP3A4 inducer decreases remibrutinib exposure, which may decrease the efficacy of RHAPSIDO
- Monitor more frequently for adverse reactions when using RHAPSIDO with P-gp substrates where minimal concentration changes may lead to serious adverse reactions (eg, digoxin). Remibrutinib increases exposure of P-gp substrates, which may increase the risk of adverse reactions related to P-gp substrates
- No data are available on concomitant use of RHAPSIDO with anticoagulants. The concomitant use of RHAPSIDO and anticoagulants was not allowed in clinical studies. Use of the antiplatelet agents, acetyl salicylic acid at doses up to 100 mg daily or clopidogrel up to 75 mg daily, was allowed in the RHAPSIDO clinical studies

Please see full [Prescribing Information](#), including [Patient Information](#).

RHAPSIDO® (remibrutinib) Indication and Important Safety Information

Important Safety Information (cont)

Use In Specific Populations

- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to RHAPSIDO during pregnancy
- Avoid use of RHAPSIDO in patients with mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, and C). RHAPSIDO exposure is increased in these patients relative to patients with normal hepatic function

Please see full [Prescribing Information](#), including [Patient Information](#).

NOTE: This Sample Letter of Medical Necessity is a template to help you write your own letter to health plans. Bracketed copy in blue font color is to be updated reflecting relevant information for you, your practice, and your patient.

RHAPSIDO® (remibrutinib) Sample Letter of Medical Necessity for the treatment of chronic spontaneous urticaria (CSU)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, RHAPSIDO is required for the treatment of this patient for [diagnosis and ICD-10 code]. [If you are writing this letter for a formulary or tiering exception request, provide a statement of the exception you are requesting and the reason for the request.] The following information supports my recommendation for treatment with RHAPSIDO:

Summary of Patient's Medical History and Diagnosis

[Include a summary of the patient's diagnosis and their current condition: Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:

- Patient's chronic spontaneous urticaria (CSU) diagnosis and date of diagnosis
- Documentation that other diagnoses have been excluded
- Laboratory testing
- Disease-specific scores including urticaria activity score (UAS7), itch severity score (ISS7), and hive severity score (HSS7)
- Persistent or troublesome disease aspects/symptoms (if applicable)
- Description of impact on patient's quality of life
- Visual documentation of patient's condition
- If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)]

Treatment History

[Include a summary of your patient's treatment history:

- Provide a comprehensive list of previous therapies used, duration of therapy, and reason for discontinuation
- Specify which treatments the patient has tried and failed
- Confirm that the patient has not received adequate results from any previous treatment]

Rationale for Treatment

[Provide your rationale for choosing RHAPSIDO:

- Include clinical support for prescribing RHAPSIDO (This may be clinical trial data found in the RHAPSIDO Prescribing Information)
- Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- Explain why the health plan's preferred therapies are not appropriate for your patient
- If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)
- If your patient is already taking RHAPSIDO, describe their response to RHAPSIDO and explain why it is not in the best interest of your patient to switch therapies
- Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with RHAPSIDO
- If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name's] current condition and treatment history, I believe RHAPSIDO is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of RHAPSIDO for this patient. The coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP name and signature]
[Specialty, name of practice, phone number]

Encl: [Medical records, RHAPSIDO Prescribing Information]

NOTE: This Sample Letter of Appeal is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

RHAPSIDO® (remibrutinib) Sample Letter of Appeal for the treatment of chronic spontaneous urticaria (CSU)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I prescribed RHAPSIDO for this patient to treat [diagnosis and ICD-10 code] and submitted a [Prior Authorization/Formulary Exception Request/Tiering Exception Request] on [date of submission]. The request was denied on [date of denial and reference number] and the reason given was [reason from the health plan's denial letter]. I request a formal appeal of your denial for RHAPSIDO, based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that RHAPSIDO is the appropriate therapy for [Patient's name]. The following information supports my recommendation for treatment with RHAPSIDO:

Summary of Patient's Medical History and Diagnosis

[Include a summary of the patient's diagnosis and current condition: Be sure to attach relevant medical records that support this information.]

The following topics are examples of information you may want to include:

- Patient's chronic spontaneous urticaria (CSU) diagnosis and date of diagnosis
- Documentation that other diagnoses have been excluded
- Laboratory testing
- Disease-specific scores including urticaria activity score (UAS7), itch severity score (ISS7), and hive severity score (HSS7)
- Persistent, troublesome disease/condition aspects or symptoms (if applicable)
- Description of impact on patient's quality of life
- Visual documentation of patient's condition
- If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)]

Treatment History

[Include a summary of your patient's treatment history:]

- Provide a comprehensive list of previous therapies used, duration of therapy, and reason for discontinuation
- Specify which treatments the patient has tried and failed
- Confirm that the patient has not received adequate results from any previous treatment]

Rationale for Treatment

[Provide your rationale for choosing RHAPSIDO:]

- Include clinical support for prescribing RHAPSIDO (*This may be clinical trial data found in the RHAPSIDO Prescribing Information*)
- Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)
- If your patient is already taking RHAPSIDO, describe their response to RHAPSIDO and explain why it is not in the best interest of your patient to switch therapies
- Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with RHAPSIDO]

Given [Patient's name's] current condition and treatment history, I believe RHAPSIDO is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient and would appreciate your prompt reconsideration of this denial.

I have included a copy of the denial letter along with relevant medical notes in response to the denial. Please feel free to contact me, [HCP's name, NPI number], by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of RHAPSIDO for this patient. The appeal decision may be faxed to [fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: Denial letter, Medical records, RHAPSIDO Prescribing Information

NOTE: This Sample Prior Authorization Request Letter is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

RHAPSIDO® (remibrutinib) Sample Prior Authorization Request Letter for the treatment of chronic spontaneous urticaria (CSU)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name] and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I am writing to request prior authorization of RHAPSIDO [dose/frequency] for the treatment of this patient for [diagnosis and ICD-10 code(s)]. As per the requirements of the plan, I have tried [required step-therapies] for my patient before prescribing RHAPSIDO. Included please find a statement explaining why these preferred therapies are not appropriate for my patient. The following information supports my recommendation for treatment with RHAPSIDO:

I have attached relevant medical records, including the patient's diagnosis, test results, and treatment history.

[Include a summary of the patient's treatment history:

- Provide a comprehensive list of previous therapies, duration of therapy, and reason for discontinuation
- Specify which treatments the patient has tried and failed, and confirm that the patient has not received adequate results from any previous treatments
- Include clinical support for prescribing RHAPSIDO (This may be clinical trial data found in the RHAPSIDO Prescribing Information)
- Detail any comorbidities that could serve as contraindications to certain other treatments
- If your patient has not had success with alternative injectable therapies because of a fear of injections, be sure to include the ICD-10 code: F40.231 (fear of injections and transfusions)]

Given [Patient's name's] current condition and treatment history, I believe RHAPSIDO should be authorized to treat [diagnosis] for this patient. Please do not hesitate to contact me by calling [office phone number] if you require additional information or would like to discuss this case further.

The prior authorization decision may be faxed to [fax number] or mailed to [HCP business office address]. Thank you for your prompt attention to this matter.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: Medical records, RHAPSIDO Prescribing Information