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PRIOR AUTHORIZATION RESOURCE GUIDE

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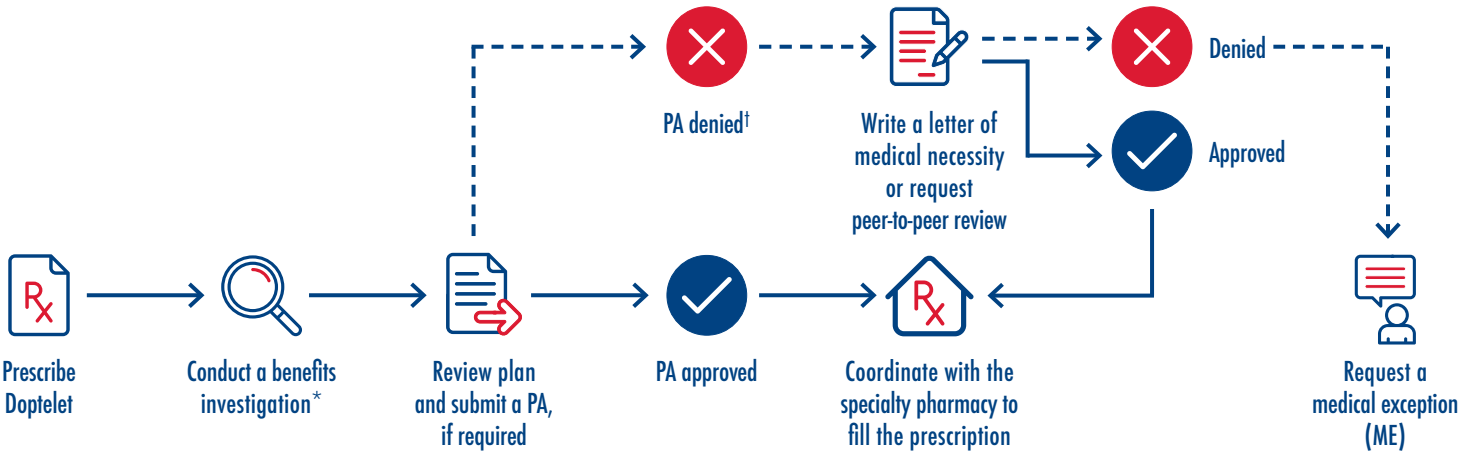
PRIOR AUTHORIZATION PROCESS OVERVIEW

Your patient's health plan may require a prior authorization (PA) to be submitted before Doptelet® (avatrombopag) can be administered. PAs allow payers to monitor costs and to ensure that medications are necessary and appropriate for patients to whom they are prescribed.



Please see page 6 for details about the ME process.

LENGTH OF TIME FOR A PA RESPONSE

Type of Plan	Response Time
Commercial	• PA timelines vary by each payer.[1] • ME timelines vary by payer, but the federal law requires a response to expedited requests within 24 hours.[2]
Medicare	• Part C and D plans must decide within 72 hours.[3] • If the PA is an expedited request, the decision can be made within 24 hours.[3]
Medicaid	• Since PA processes are established, defined, and administered at the state level, turnaround times vary but must fall within the state requirements.[1,4,5]

Doptelet Connect™ offers access and reimbursement support to help patients access Doptelet. Doptelet Connect provides information regarding patient healthcare coverage options and financial assistance information that may be available to help patients with financial needs.

For more information, call 1-833-368-2663. If a patient is enrolled, Doptelet Connect can provide you with the appropriate PA forms and follow up on the submission status. The healthcare provider office must complete and submit the PA request, but Doptelet Connect can provide support at every step in the process.

*If Doptelet is not on formulary, an ME may be requested.
†If a PA is denied, an ME request may be submitted in support.

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HOW TO COMPLETE A PRIOR AUTHORIZATION

STEP 1: Complete a benefits investigation

A benefits investigation verifies a patient's health plan coverage and restrictions and patient cost-sharing responsibilities for Doptelet® (avatrombopag). If the health plan requires a PA, continue to follow the steps below. If it is determined that Doptelet is not covered, see page 6 for information about submitting an ME instead.

STEP 2: Complete the PA request

Accurate, complete forms and documentation ensure an efficient and timely approval process.

- Call the payer or check its website to determine PA submission requirements. Remember, different payers within a geographic area may have different criteria for the same drug.

6

COMMON PA CRITERIA INCLUDE

- Diagnosis code
- Platelet count
- Age
- Previous therapies, including step edits (step edits require that 1 or more treatment options are tried before a drug will be reimbursed)
- A scheduled procedure date (patients with chronic liver disease only)
- Other clinical information, such as whether the patient is new to therapy or has any drug allergies, and supporting documentation (eg, physical findings and/or lab test results)

- Determine whether the plan is **fully insured** or **self-insured**.
  - *Fully insured plans* provide a standard package of benefits. *Self-insured plans* provide a customized package of benefits that are specific to 1 employer and may carve out pharmacy benefits to a separate pharmacy benefit manager.[6,7]

Follow the plan's instructions for accurately submitting the appropriate PA form. Your PA can be denied due to inaccurate or incomplete information.

HOW TO COMPLETE A PRIOR AUTHORIZATION *(cont'd)*

STEP 2 (cont'd): Complete the PA request

- Submit the PA request according to the payer's preferred method. Options for submitting the PA request may include
  - Completing the payer's Doptelet® (avatrombopag)-specific PA form, if one exists
  - Completing an electronic form through a proprietary health plan portal or an electronic authorization platform

- To obtain PA approval, you may need to submit additional supplemental documentation
  - The payer's drug-specific PA form, if one exists
  - The patient's insurance information or a copy of the patient's insurance card
  - A letter of medical necessity *(please see a sample letter on the next page)*
  - Peer-reviewed literature
  - Doptelet Prescribing Information

- It may also be necessary to speak to a heath plan representative on the phone before submitting a PA.

STEP 3: Track the status of the PA request and follow up as needed

- Keep a copy of everything submitted to the payer and a log of PA submissions and denials for each patient, including reference numbers.
- Keep track of dates and methods of correspondence with the payer.
- Record the names of contacts and reviewers with whom you speak and summarize your conversations.
  - Obtain and record reference numbers for all calls, if possible.
- Obtain a copy of the PA approval, including the effective dates and the authorization ID.
  - Submit the approval paperwork to the patient's dispensing specialty pharmacy or on-site dispensing pharmacy.

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LETTER OF MEDICAL NECESSITY

A payer may request documentation of medical necessity, which may include chart notes or a letter explaining why treatment with Doptelet® (avatrombopag) is appropriate for a patient. Below is a template of a letter of medical necessity that can be used when submitting a PA request. Be sure to include prior and/or failed therapies within this letter.

Please note that some payers may require a specific letter of medical necessity form.

Sample Letter of Medical Necessity—Doptelet® (avatrombopag)

[The following is a sample Letter of Medical Necessity. The text within pink brackets is templated and should be replaced with pertinent information for the individual patient on whose behalf you are submitting the letter. This paragraph and other italicized information within brackets are intended to provide additional guidance and should be omitted from the final letter. Healthcare providers should also consider using their organization's official letterhead.]

[Date]
[Payer Medical or Pharmacy Director Contact/Name]
[Payer Organization Name]
[Payer Street Address]
[Payer City, State, ZIP Code]

RE: [Patient Name]
Date of birth: [Patient's Date of Birth]
Policy ID/Group number: [Policy ID/Group Number]
Policy holder: [Policy Holder's Name]

Dear [Payer Medical or Pharmacy Director/Contact Name]:

I am [Physician Name, credentials, specialty, hospital/practice], and I am writing on behalf of my patient, [Patient Name], to document the medical necessity of Doptelet® (avatrombopag), which is prescribed to treat thrombocytopenia in adult patients with either chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment, or with chronic liver disease (CLD) who are scheduled to undergo a procedure.

1. Patient-Specific Rationale for Treatment
In brief, it is my medical opinion that initiating or continuing treatment with Doptelet for [Patient Name] is medically appropriate and necessary. Outlined below are [Patient Name]'s medical history and prognosis, and the rationale for treatment with Doptelet. The patient meets the following criteria for treatment: [List specific criteria here].

[Note: The following section is to be completed by the physician based on the patient's medical history and prognosis.]

2. Summary of Patient's Medical History *[You may be required to include:]*

- [Patient's diagnosis and current condition]
- [Relevant medical history or family history]
- [Previous therapies the patient has taken for the symptoms associated with chronic ITP or CLD]
- [Clinical notes]

3. Doptelet Dosing Information

[Note: Mention the starting dose and potential duration of therapy for Doptelet. You may choose to include details from the Prescribing Information attached to the end of this sample letter.]

Please call my office at [telephone number] if you require additional information. I look forward to receiving your timely response and approval of this authorization.

Sincerely,
[Physician Name]
[Title, Institution]
[Email/Phone Number]

[Note: Attach full Prescribing Information.]

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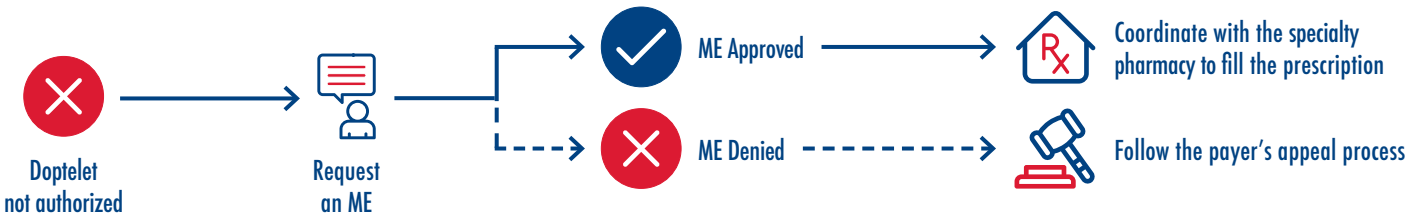
WHEN A MEDICAL EXCEPTION MAY BE NEEDED

If Doptelet® (avatrombopag) is not covered by a payer or for a certain patient, you may need to request an ME.



An ME communicates a physician's request to use a medication that is nonpreferred or not covered by the payer based on a patient's individual circumstances. **The ME process may also be used to request a waiver of step edits, quantity limits, or tier placement of a drug.**

In addition to submitting an ME, you may also need to submit

- A letter of medical necessity
- Patient's medical history and documentation supporting the rationale for the request
- Evidence of ≥1 previous treatment failure
- Patient's insurance information or a copy of the patient's insurance card
- A PA request letter
- A letter of financial hardship from the patient (if requesting an exception involving out-of-pocket costs)

It is important to follow the plan-specific guidelines when submitting an ME. Use any payer-required forms, submit the appropriate information in the manner requested, and follow the stated timelines. Be sure to follow up with the health plan to confirm receipt of the ME request and to check the decision status. Failure to follow a plan's rules may result in a denial.

DENIALS AND APPEALS

WHY A REQUEST MIGHT BE DENIED BY A HEALTH PLAN

A PA or an ME may be denied for many reasons, including incomplete and/or inaccurate information on the submitted form and/or clinical issues.

TYPES OF DENIALS

Administrative Denial

Denied due to an incorrect form, incomplete information, or inaccurate information

- Ensure that you are using the correct PA form.
- Carefully review the request to verify that the information is complete and correct.
- If the reason for the denial is not provided, call the patient's health plan for more information.
- Keep a copy of the denial letter.

NEXT STEPS

If you received an administrative denial, you may not need to submit an appeal. Instead, you may need to resubmit a complete and accurate PA.

Clinical Denial

Denied due to clinical reasons

- Ensure that the procedure or medical condition of the patient falls within recommended guidelines, payer policies, and/or the product label for Doptelet® (avatrombopag).
- It may be beneficial to submit documentation showing medical need.
- Documentation of step edits or step therapy may be required.

NEXT STEPS

To appeal a clinical denial, please see the steps **on page 9**.

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THE APPEAL PROCESS

If a patient's health plan denies a PA or an ME, the patient has the right to appeal the decision and you may be asked to submit the appeal to the patient's health plan.

It is helpful to review the payer's appeal process and documentation before beginning the process.

You may be asked to provide

- A letter of medical necessity
- Patient-specific rationale for the appeal*
- Supportive documentation for the rationale

Throughout the appeal process, be sure to track the status of the appeal and follow up as needed.

Remember the following:

- Keep a copy of everything submitted to the payer and a log of submissions and denials for each patient, including reference numbers.
- Keep track of dates and methods of correspondence with the payer.
- Record the names of contacts and reviewers with whom you speak and summarize your conversations.
  - Obtain and record reference numbers for all calls, if possible.
- If an appeal is denied, follow the appropriate steps to complete the next level of appeal.
- Once an appeal is approved, obtain a copy of the approval, including the effective dates and authorization ID.
  - Submit the approval paperwork to the patient's dispensing specialty pharmacy or on-site dispensing pharmacy.

*A supporting statement should indicate why all other products on the formulary would either be ineffective or have adverse effects.

STEPS OF THE APPEAL PROCESS

STEP 1: Review the denial notification

Review the denial notification to understand the reason for denial and the circumstances that need to be addressed and explained in the appeal. Make sure to follow any appeal instructions included in the denial letter. Call the patient's health plan, if necessary, to clarify the reason for denial.

STEP 2: Complete the appeals process

COMMERCIAL PLANS

Different commercial payers have varying processes, timing, and steps for appeals. Be sure to check the requirements for the specific payer or plan. Timelines for expedited appeals in commercial plans vary depending on the plan or state law.

Generally, the appeal process includes different levels of appeals.

First-Level Appeal	Second-Level Appeal
The first appeal is filed by the prescriber and/or the patient if they believe the denial is an error or if it is not in the best intention of the patient. The prescriber may request to speak with a medical reviewer at the health plan to review the appeal and challenge the decision.	If the payer upholds the denial, a second-level appeal can be filed. This process can be continued until an exception is granted or appeals have been exhausted. This level of appeal may be conducted by a third party. In this case, the payer must accept a decision in favor of the patient and cannot overturn it.

The steps in the appeal process must be followed in order and submitted in the manner requested. If these steps are not followed, the appeal will not be considered.

STEP 2 (cont'd): Complete the appeals process

MEDICARE PLANS

For Medicare payers, there are 5 levels of appeal with standard timelines for each that can be expedited if a delay may threaten a patient's life or health. Medicare expedited appeal timelines are set by federal law.

Appeal level	Time to decision
A **Level 1 Appeal** is a redetermination conducted by a Medicare Administrative Contractor or the Part D plan.[8]	≤7 days*
A **Level 2 Appeal** is a reconsideration conducted by an independent review entity. This appeal must be requested in writing. For more information about Level 2 Appeals, visit the Centers for Medicare & Medicaid Services (CMS) website.[9]	≤7 days*
A **Level 3 Appeal** is a hearing before an Administrative Law Judge or a review of the administrative record by an attorney adjudicator within the Office of Medicare Hearings and Appeals. The request must be made in writing. For more information about Level 3 Appeals, visit the CMS website.[10]	≤90 days†
A **Level 4 Appeal** is a request for review by the Medicare Appeals Council. The patient and/or prescriber should include a copy of the disputed decision and the reason for disagreement with the appeal. The request must be made in writing. For more information about Level 4 Appeals, visit the CMS website.[11]	≤90 days†
A **Level 5 Appeal** is a review by the Federal District Court and may be requested if any party is dissatisfied with the Medicare Appeals Council's decision. This type of appeal is escalated to the Federal District Court if the amount remaining in controversy meets the threshold requirement for the calendar year.[12]	Not applicable‡

*≤72 hours if a delay could cause imminent harm to the patient.
†≤10 days if a delay could cause imminent harm to the patient.
‡The case must meet a minimum dollar amount to be considered in federal court.

Medicare and commercial plans offer expedited appeal processes if a delay could cause imminent harm to the patient. Check the payer's policies regarding the process and timelines for expedited appeals.

STEP 2 (cont'd): Complete the appeals process

MEDICAID PLANS

The general steps of Medicaid appeals are listed below. Each state has a different appeals process. Be sure to check your state requirements for the specific process.[13]

Steps of the Appeal Process[13]	Explanation
Notice of action	States are required to inform patients of a denial in a timely manner. Patients have up to 90 days after receiving a denial to request a fair hearing.
Optional level of appeals prior to state fair hearing	Some states have procedures and requirements for filing and resolving an appeal without needing to progress to the level of a fair hearing.
Fair hearing	Federal law requires that a fair hearing at a reasonable time, date, and location takes place after adequate written notice. One or more third-party officials will make a decision based on all available information.
Receipt of decision	States are required to notify the beneficiary of the hearing decision and specify the methods and timeline.
Adverse decision	If the denial is upheld, depending on state laws, the appeal may be eligible for reconsideration or an additional judicial review.
Continuation of benefits	States identify which benefits will be provided throughout the appeals and hearing process in accordance with federal guidelines.

If the patient is enrolled, Doptelet Connect™ is able to provide you with resources to help with the appeals process.

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