AMGEN®

Amgen By Your Side
Insurance and Support Guides

THE INSURANCE APPROVAL PROCESS

How to understand your coverage and benefits

AMGEN BY your side

Insurance Review of Coverage for Medicine

Steps to coverage

When determining whether to cover an Amgen medicine, the review process that your health plan follows will likely include several steps:

1 Benefits investigation

After your doctor prescribes your medicine and you provide permission through a **Health Insurance Portability and Accountability Act (HIPAA)** release form, an Amgen By Your Side team member will contact your health plan to review your coverage. Some health plans will require you to make this request yourself; A team member from Amgen By Your Side can assist you in making the request. This review, called a **benefits investigation**, is conducted to learn:

- Whether the medicine you were prescribed is covered by your policy
- Your estimated **out-of-pocket costs**, including **deductibles**, **co-payments**, and **co-insurance**
- Whether your health plan requires **prior authorization** for coverage and, if so, the steps for completing that
- Whether your doctor must request a **medical exception**, using a **letter of medical necessity**

TIP: Your **Patient Access Liaison (PAL)** or **Clinical Nurse Educator (CNE)** will call you with information on the progress of your benefits investigation.

2 Prior authorization (PA)

Health plans sometimes require a PA before approving coverage of medicine. This is a process that your doctor must complete, describing the reasons you should be prescribed the medicine and why the health plan should cover the costs. A PA is sometimes also referred to as a preauthorization or precertification. (See more about PAs on page 5.)

3 Medical exception

If your health plan does not cover your Amgen medicine, your doctor can request a medical exception. This is a special request, requiring additional paperwork, explaining why you need treatment with an Amgen medicine. (See more about medical exceptions on page 6.)

4 Health plan decision

After receiving all required information, your health plan will determine whether it will cover your Amgen medicine. You and your doctor's office should receive a written decision from the health plan.

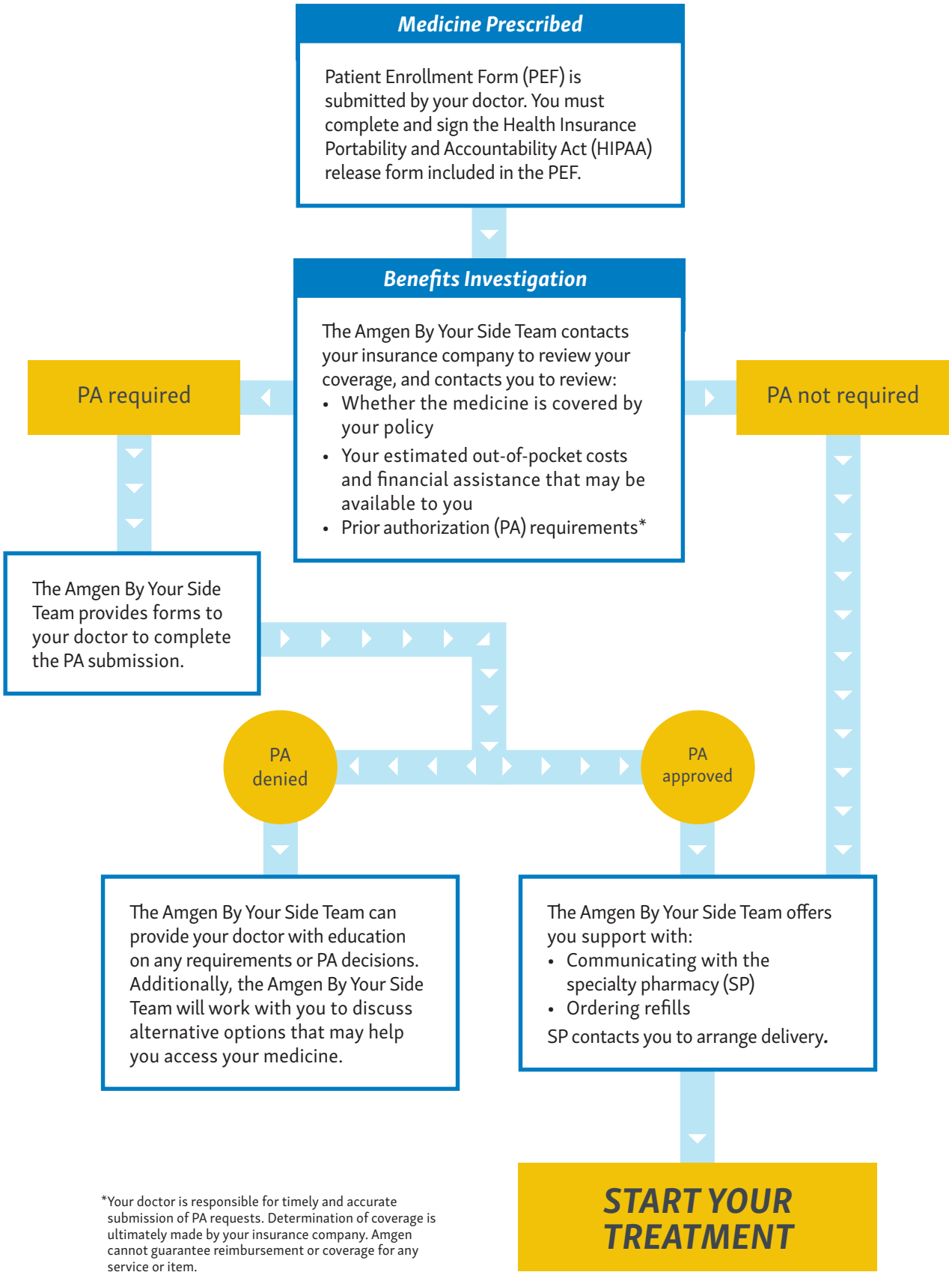
5 Appeal

If your health plan denies coverage for an Amgen medicine, you can work with your doctor's office to **appeal** the decision. The Amgen By Your Side Team can educate you and your doctor about this process.

For helpful definitions of all bolded terms, see the glossary on page 13.

Getting Your Medicine to You

The Amgen By Your Side Team provides support throughout the process of getting your medicine to your home. Here are the steps.



*Your doctor is responsible for timely and accurate submission of PA requests. Determination of coverage is ultimately made by your insurance company. Amgen cannot guarantee reimbursement or coverage for any service or item.

How long is the insurance review process?

The time it may take to get approval for an Amgen medicine can vary. The length of time depends on how long each step in the process takes, including the benefits investigation, the PA, the health plan's review of the materials, and an appeals process, if necessary. The turnaround time for any of these to be completed varies.

In addition, if you have insurance coverage through more than one health plan, each of the required steps must be coordinated and completed with each health plan.

If your doctor feels that treatment is urgent, he or she may make a formal request to speed up the review process. This is called an expedited review and typically reduces the review time to 72 hours; however, there is no set time for this to be completed.

How can Amgen help?

The Amgen By Your Side Team provides support throughout the insurance review process. Your team will:

- With your consent, contact your health plan to review your insurance coverage
- Provide your doctor with education on any requirements or PA decisions
- Go over alternative options you may use to access your medicine while the insurance review is underway
- Stay in touch with you throughout the process to keep you up to date on the status of the review

TIP: Make sure to provide your PAL or CNE with any new or updated information to avoid delays in the insurance review process.

Key Steps to Approval
Prior authorization (PA)

As mentioned already, health plans often require a PA before approving coverage of an Amgen medicine. This is a process that your doctor must complete, describing the reasons you need an Amgen medicine and why the health plan should cover the costs. A PA is sometimes also referred to as preauthorization or precertification.

PAs are commonly required for medicines that treat rare diseases. Each health plan is different, however, and some may require PAs while others don't.

The requirements for a PA will differ from health plan to health plan. Your doctor's office must complete and submit all required forms and provide other information and documents requested. Some of the items commonly required for a PA are:

- Health plan identification numbers
- Confirmation of your diagnosis, including test results
- Your medical history and all notes from your doctor related to your visits
- Medical articles about the disease and the Amgen medicine being prescribed
- A letter of medical necessity

The Amgen By Your Side Team can help educate your doctor about how to complete these requirements.

TIP: If you have questions about the status of your PA request, contact your PAL or CNE for an update.

Key Steps to Approval
Medical exception

Even when your medicine is not included in the health plan's list of covered prescription drugs (its **formulary**), your plan may agree to cover it if your doctor requests a medical exception. This is when your doctor can show that your condition represents a special case (an exception) and that you need the medicine to treat your condition—in other words, the medicine is **medically necessary**.

Medical exception requests are generally more complicated than PAs. They require more specific information and documents, such as a letter of medical necessity. Your doctor's office will generally handle this step in the review process.

TIP: If your medical exception is denied, there are steps you can take to appeal your health plan's decision. See more information on the next page.

When coverage is approved

Here's what usually happens after your health plan approves coverage of an Amgen medicine:

1 Your health plan will notify you or your doctor's office. You should:

- Follow up with your health plan to make sure you understand your coverage, including your out-of-pocket costs
- Check in with your doctor's office and your PAL or CNE to share any information from your health plan

2 The Amgen By Your Side Team offers support with:

- Connecting you with financial assistance for your out-of-pocket costs
- Communicating with the **specialty pharmacy** that will fill your prescription
- Educating you on the ways to administer your medicine

3 The Amgen medicine approval will be sent to a specialty pharmacy.

- The specialty pharmacy will process your prescription, which may take several days
- The specialty pharmacy will contact you to arrange delivery
- Your medicine is delivered to your home or other convenient location you choose

If Coverage Is Denied

Your right to know why

Even after you and your doctor complete all the requirements to have coverage for your Amgen medicine approved, coverage may be denied for a variety of reasons.

You have a right to know why your request for coverage was denied. Your health plan should give you the reason in writing; if it does not, contact the plan directly to obtain a written explanation.

Your access to medicine

Amgen has several programs to help eligible patients access their medicine while they and their doctors work to get insurance coverage approved.

TIP: Sometimes coverage is denied because of an error in the paperwork, such as using the wrong billing code for your condition. Your PAL or CNE may be able to educate your doctor on potential errors to avoid having to go through a formal appeal.

Your right to appeal

Your health plan may also provide you with information on how to appeal a coverage denial. An appeal is a formal process where you provide reasons why the coverage should have been approved. This may mean that you and your doctor's office will need to complete additional paperwork and provide detailed information about your health to the health plan.

Appealing a coverage denial

Appeals processes differ from health plan to health plan and from state to state. Nonetheless, there are generally 3 main steps:

1 First-level internal appeal

You or your doctor's office may request that your health plan reconsider its decision. Your doctor may request to speak with the health plan's medical reviewer to discuss the issue. This is sometimes called a **peer-to-peer review**.

2 Second-level internal appeal

This is typically a review by a medical director at the health plan who was not involved in determining your coverage denial. For treatments you have not received yet, the health plan must complete the internal appeals process within a certain number of days specified under state law.

3 External appeal

Once you have completed the internal appeals process, some plans may allow you to request an external appeal by an independent organization. If your plan allows external appeals, they are required to hire an outside review organization to conduct the assessments. The outside reviewer might be a doctor or other healthcare professional who is not associated with your health plan, and must not have any financial stake in how the decision turns out. **Under the law, your health plan must accept the decision of the external reviewer.**

You generally must request an external appeal in writing within a certain number of days specified under state law after your internal appeal was rejected. Some health plans allow you more time. The letter sent by your health plan denying your internal appeal should tell you how much time you have to request an external appeal.

If your external appeal is denied, some states may provide the option to file a complaint, or "grievance," against your health plan. You will likely need to submit a detailed summary of what has happened thus far in your appeals process, as well as a number of supporting documents. If you have questions or want more information about filing a grievance, contact your PAL or CNE.

TIP: If coverage is denied after your external appeal, there may be other programs to help you get your medicine. Contact your PAL or CNE for information.

In urgent situations, you can ask for an external appeal to be conducted at the same time as your internal appeal. Your medical situation could be considered urgent if your doctor believes that a delay in treatment could:

- **Put your life or health at risk**
- **Threaten your ability to attain, maintain, or regain maximum function**

If you have an additional health plan

Your primary and secondary health plans will usually conduct the approval process for your Amgen medicine at the same time. If your primary health plan denies coverage, you may be able to get your medicine covered by your secondary plan.

In this case, your doctor's office will need to provide paperwork from your primary health plan, showing that it denied coverage for your Amgen medicine. You should provide your doctor with the denial letter from your primary health plan.

You may be able to help your doctor's office with this request. Reach out to ask if you can provide any other records, copies of written letters or other communications, or additional information that might help the secondary health plan understand why you would benefit from an Amgen medicine.

For more about how benefits through primary and secondary health plans are coordinated, see the Amgen By Your Side guide on Understanding Health Plans and Making the Right Choice for You.

After Coverage Is Approved
Reauthorization

Health plans usually approve coverage for Amgen medicines only for a certain length of time. You will likely need to continue taking your medicine after this period ends.

In order to maintain coverage for your medicine, health plans often require **reauthorization**, which is renewal of your PA, after a set time period. You and your doctor may need to show that your Amgen medicine is helping you manage your condition.

TIP: Be sure to inform your PAL or CNE any time there is a change in your health plan or coverage.

If your reauthorization request is denied

You may be able to appeal your health plan's decision. (For more on the appeals process, see page 8.)

Consider keeping a journal of your health and progress while you are taking your Amgen medicine. This can include symptoms, as well as changes in the activities in which you can participate. Photos and videos may also help. Your journal may be used to support your application for reauthorization.

Health Plan Call Record

Use this sheet to keep track of information you receive from your health plan about topics like coverage for your medicine, PA requirements, or the appeals process in case coverage is denied.

Date of call: _____ Name of person I spoke with: _____

Best phone number or email to contact person I spoke with: _____

Reference or case number: _____

Topic that we talked about: _____

Information I received: _____

_____

Next steps: _____

_____

_____

Date of call: _____ Name of person I spoke with: _____

Best phone number or email to contact person I spoke with: _____

Reference or case number: _____

Topic that we talked about: _____

Information I received: _____

_____

Next steps: _____

_____

_____

Glossary

Appeal — a request to your health plan to review a decision denying coverage or payment.

Benefits investigation — a review of health plan coverage.

Clinical Nurse Educator (CNE) — If you're a patient on ACTIMMUNE® (Interferon gamma-1b), when you begin your therapy, you are assigned a Clinical Nurse Educator (CNE). Your CNE provides you with dedicated, one-on-one support. They work directly with you to answer non-medical, logistical questions and provide support once you have been prescribed ACTIMMUNE® and you have completed enrollment.

Co-insurance — the portion of a covered medical service that you pay (for example, 20%) after you have paid your deductible.

Co-payment — the fixed amount of a covered medical service that you pay (for example, $20) after you have paid your deductible.

Deductible — the amount you pay for covered medical services before your health plan starts to pay.

Formulary — a list of medicines covered by a health plan or prescription drug plan.

Health Insurance Portability and Accountability Act (HIPAA) — a federal law that requires data privacy and security to safeguard personal medical information.

Letter of medical necessity — a letter your doctor submits to the health plan to demonstrate that a medicine is needed for your condition and meets standards of care.

Medical exception — coverage for a medicine or treatment that is not otherwise covered by the health plan.

Medically necessary — medicines, medical supplies, and services that are needed to detect and treat an illness or condition.

Out-of-pocket costs — all the expenses for medical care not paid by your health plan, which you are responsible for paying. These include co-insurance, co-payments, deductibles, and expenses for services that are not covered. You will not have to pay more than the yearly maximum for out-of-pocket costs set by your health plan.

Patient Access Liaison (PAL) — Starting a new medicine or treatment often comes with a lot of questions. Once enrolled, you will be paired with a Patient Access Liaison (PAL). Your PAL provides you with dedicated, one-on-one support. They work directly with you to answer non-medical, logistical questions and provide support once you have been prescribed an Amgen medicine and you have completed enrollment.

Peer-to-peer review — discussion between a healthcare provider and a medical reviewer at a health plan, when a patient has been denied insurance coverage.

Prior authorization (PA) — a process that your doctor must complete, describing the reasons you need an Amgen medicine and why the health plan should cover the costs.

Reauthorization — this is renewal of the PA after a certain period of time. One factor considered in reauthorization is whether your condition has been stabilized or has improved on an Amgen medicine.

Specialty pharmacy — the pharmacy that delivers Amgen medicine to your home or other chosen location.

The information in this brochure is being provided for general educational purposes only. It does not constitute legal advice.

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