

Exceptions and Appeals

How to help your patients access their diabetes treatment



Dear Healthcare Provider,

Ensuring your patients can access appropriate treatments is an important step in helping them manage their diabetes. While therapy disapproval by health plans may delay patients from getting their therapy, you and your patients may still have options. You can work with your patients and continue advocating for their treatment.

In this guide, you'll find helpful information and resources regarding the medical exceptions and appeals processes in order to get your patients access to their therapies.

Inside, you'll find information on how to

- Navigate access hurdles
- Write effective letters
- Engage with your patients and their health plans
- Help your patients offset their treatment and out-of-pocket costs
- Understand key insurance terms
- Assess your patients' coverage

Knowing how to handle coverage-related conversations can help your patients access their therapies. For more support throughout the process, don't hesitate to reach out to any of the organizations listed in this guide.

This guide was sponsored by Sanofi and was created in collaboration with the following organizations.



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This resource was created to help you navigate insurance issues, such as medical exceptions and appeals, and learn tips for communicating with your patients and their health plans.

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Overview of access hurdles

While treatment decisions are made by the provider and patient, the health plan may not always agree with that decision. This may be because



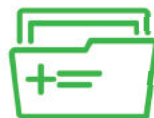
- The treatment prescribed is excluded from the health plan’s formulary
- The health plan has determined it is not medically necessary
- The treatment has not yet been reviewed by the health plan

With the right support and information, you can work through these challenges.

Requesting access to non-formulary therapies

In some cases, a treatment may not be available on a health plan’s formulary. This may be due to a number of reasons. Your patient’s plan may have decided to remove the therapy from its formulary, for example, during a yearly review. Or, your patient may have changed health plans, and the therapy is not covered under the new plan. Either way, you can submit a request to the health plan to make an exception for your patient based on medical necessity.

To request an exception, check with your patient’s plan to see if there is a process in place and determine what documents you’ll need to submit. These documents may include:



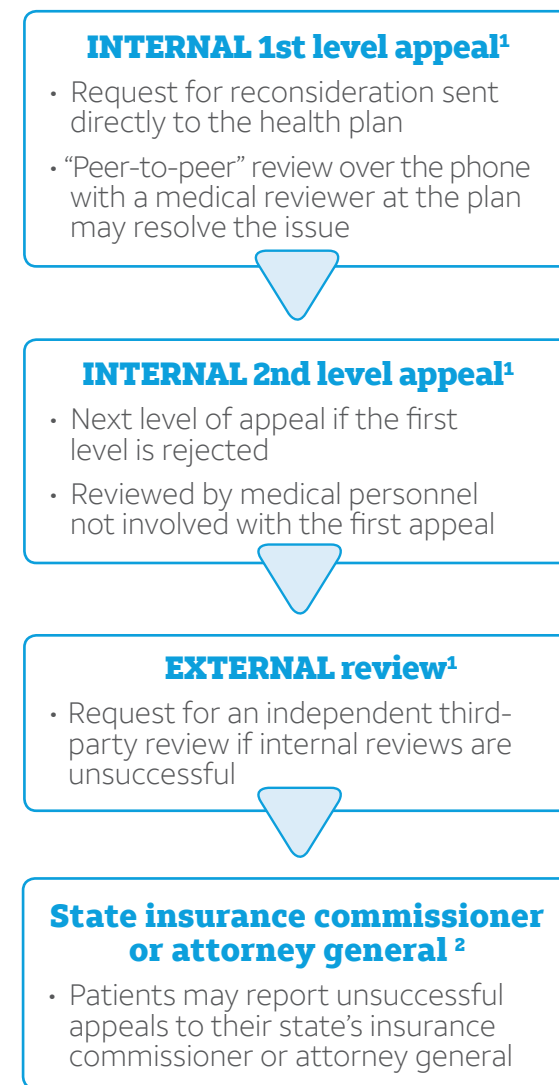
- A letter of medical necessity (see page 6 for a sample)
- Any plan-specific prior authorization forms
- Relevant chart notes
- Recent lab results

If the health plan decides not to make an exception, your patient may be responsible for the full cost of the therapy. However, you and your patient can ask the plan to reconsider by submitting an appeal.

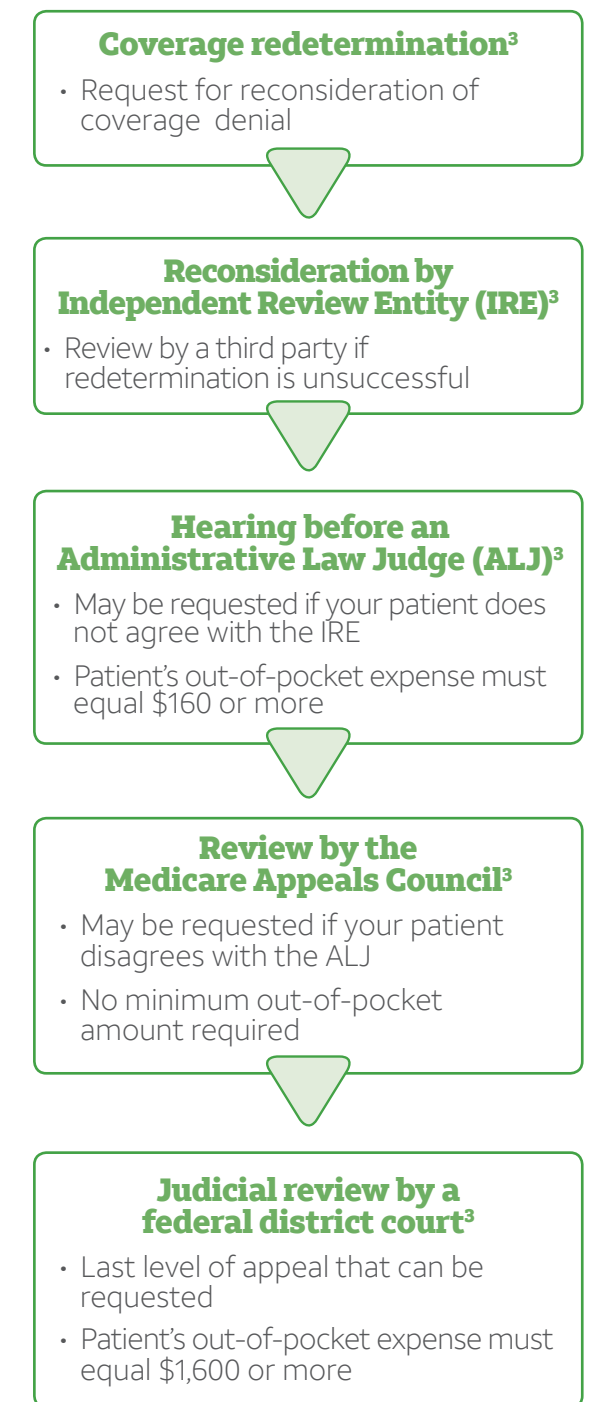
Appealing a coverage denial

If the health plan decides not to cover a therapy that you believe is medically necessary for your patient, your patient has the right to request several levels of appeals.¹ Keep in mind that the health plan may have specific prior authorization criteria that must be met for certain treatments to be approved. Each health plan also has its own process, so be sure to check with the plan before submitting an appeal. See the back cover of this guide for a checklist of commonly required documents to include when requesting an appeal.

Commercial appeals process (example)



Medicare Part D appeals process (example)



Research shows that internal appeals are successful ~50% of the time!⁴



Sample health plan communications

Effective letters to your patient's health plan may make the difference between getting access and receiving a denial. The Letter of Medical Necessity and Letter of Appeal give you a chance to provide support regarding the proposed treatment plan and explain why your patient needs the specific treatment. These templates may be helpful to you when writing these letters. You should draft the letter on your practice's letterhead.

Sample letter of medical necessity

[Contact name]
[Health plan name]
[Health plan address]
[Health plan city, state, ZIP]

Re: [Patient name]
[Patient date of birth]
Policy number: [policy number]
Group number: [group number]

Re: Medical Necessity of [insert treatment] for [insert patient name and policy number]

Dear [Contact name],

I am writing on behalf of my patient, [patient name], whose policy number is [insert policy number], to document the medical necessity of [therapy name] for the treatment of [diagnosis]. [Therapy name] is an FDA-approved treatment for [describe therapy]. This letter provides my patient's clinical history and rationale to support the use of [therapy name].

[Patient name] is a [age]-year-old [male/female] who has been in my care since [date]. [He/she] was diagnosed with [diagnosis and ICD-10 code] in [year] by [physician]. To treat [diagnosis], my patient is currently taking [describe current treatment plan] and has previously taken [describe past treatments]. [Describe any side effects and reasons for discontinuation of previous treatments].

I believe that [therapy name] is medically necessary for my patient because [list reasons to support treatment with therapy].

In summary, based on my clinical experience, I believe that [therapy name] is medically necessary and should be approved for [patient name]. Please contact me at [your phone number] or [your email address] if additional information is required for approval of this request.

Thank you for your attention to this important matter.

Sincerely,

[Your signature]

Enclosures (suggested):
[Therapy name] Prescribing Information
Relevant chart notes
Recent lab results

Sample appeals letter

[Contact name]
[Health plan name]
[Health plan address]
[Health plan city, state, ZIP]

Re: [Patient name]
[Patient date of birth]
Policy number: [policy number]
Group number: [group number]

Re: Appeal for reconsideration of [insert treatment] for [insert patient name and policy number]

Dear [Contact name],

This letter is an appeal for reconsideration of coverage for [therapy name] for my patient, [patient name], whose policy number is [insert number]. In a letter dated [date], [health plan] stated that [therapy name] would not be covered for [patient name] because of [reason for denial]. I have reviewed your letter with my patient and ask that you reconsider this decision. Based on my medical expertise and patient's medical history, I believe that [therapy name] is necessary for [patient name].

[Patient name] was diagnosed with [diagnosis with ICD-10 code] in [year] by [physician]. [Therapy name] is an FDA-approved treatment for [indication] and has been proven to [benefits of product]. My patient has tried [current and prior therapies], however, [describe side effects or reasons for discontinuation]. This treatment is medically necessary for [patient name] because [rationale for treating with therapy/response to specific reason for denial].

I have enclosed additional documents to further support the use of [therapy name] for [patient name]. Please contact me at [your phone number] or [your email address] if additional information is required.

Thank you for your attention to this important matter.

Sincerely,

[Your signature]

Enclosures (suggested):
[Therapy name] Prescribing Information
Relevant chart notes
Recent lab results



Make sure that all letters are sent on your office letterhead and include the correct contact information.



Engaging with payers and patients

Asking the right questions—and having the right answers—can help you get the most out of conversations with health plans and your patients. Consider asking these questions when speaking to the health plan on behalf of your patient:

1. Was there an administrative omission in the original request that can be fixed to resolve this issue?
2. Can I request a peer-to-peer review with one of your medical personnel?
3. How many levels of appeals can we go through after a coverage denial?
4. What type of clinical documentation do we need to provide to support this treatment?
5. When should we expect a coverage decision after submitting an appeal?

Suggestions for interacting with the health plan

Keep these helpful tips in mind when communicating with your patient’s plan:

1. Document and keep detailed notes of any conversations you have with the health plan for reference, including the name of the representative you spoke to and the date on which the call occurred.
2. Remember the names of the representatives you speak to for each of the health plan’s departments and ask to speak with the same person each time you call.
3. Have your patient’s clinical and insurance information readily available during your call.
4. Make sure any written correspondence is free of errors and is not missing any pertinent information (eg, your patient’s date of birth or ID number).
5. Reference any specific clinical guidelines that support the use of the therapy
6. When possible, use terms that will resonate with the health plan (eg, stating that you believe your proposed treatment plan will improve outcomes or quality of care).
7. Be collegial and collaborative in your conversation, but also be firm when needed.

Prepare your patients

Your patients can also initiate the appeal. Even if your patients submit an appeal by themselves, you and your office still play an important role. Being available to answer questions and provide support will help them work towards accessing the treatment they need.

Tips for supporting your patients

If your patient asks:

“Why do I need this therapy?”

Explain the benefits of the proposed treatment plan and why it was chosen over other possible treatments (eg, fewer observed side effects). Be sure to also include this information in a letter of medical necessity, which your patients can include in their own appeals submission.

If your patient asks:

“What happens if the appeal is denied?”

Let your patient know that a second appeal is possible if the first one is denied. If that is also denied, your patient has the right to an external review from a third party. If all levels of appeals are exhausted and the outcome is unsuccessful, your patient may be responsible for the full cost of the therapy! For potential sources of financial support that may help with the out-of-pocket costs, see page 10 of this guide.

If your patient asks:

“Should I submit an appeal on my own?”

Let your patients know that they can, and should, submit an appeal on their own. The request may be more impactful coming from your patient, as the health plan can get a firsthand account of how your patient’s diabetes affects day-to-day life.



Distribute the **“Take Control, Request Access”** brochure to your patients for more support throughout the process.



Support for your patients

In addition to support from your office, your patients can take advantage of resources available from a number of diabetes-focused organizations. These organizations may also have resources to help you and your patients with the appeals process. Have your patients contact any of these organizations to learn more about efforts in their area.

Aimed Alliance

1-202-559-0380
www.aimedalliance.org
www.coveragerights.org

DiabetesSisters

info@diabetessisters.org
www.diabetessisters.org

American Association of Diabetes Educators (AADE)

1-800-338-3633
www.diabeteseducator.org

The diaTribe Foundation

1-415-241-9500
www.diatribefoundation.org

Taking Control of Your Diabetes (TCOYD)

1-800-998-2693
www.tcoyd.org

Diabetes Patient Advocacy Coalition (DPAC)

1-202-629-0400
info@diabetespac.org
www.diabetespac.org

Consumer assistance programs

Your state may also offer a consumer assistance program to help patients through the appeals process and understand their rights. Your patient's plan is required to provide the contact information for the state's consumer assistance program on the denial letter.¹ To find out if your state offers a program, have your patients visit www.cms.gov/CCIIO/Resources/Consumer-Assistance-Grants.

If your state does not have a consumer assistance program, your state's Department of Insurance may be able to help your patients through the appeals process.⁵ State insurance departments can provide patients with the necessary paperwork and instructions to submit appeals on their own.

Patients may also be able to get help from their company's Human Resources department (for patients covered by commercial insurance), or from the Centers for Medicare and Medicaid Services (for patients covered by government-sponsored insurance).

Financial assistance for your patients

Your patients may be responsible for high out-of-pocket costs even if their health plans approve coverage for their therapies. Different types of financial support are available to your patients based on their type of insurance coverage.



Many manufacturers offer support to help patients cover their out-of-pocket costs for their treatments. For patients with commercial insurance, the manufacturer may offer a copay or savings card to help with the patient's out-of-pocket expenses. You and your patients can visit the manufacturer's website to check whether this support is available and if your patients are eligible.

Be sure to remind your eligible patients that they will need to activate copay cards before use. Patients can either activate cards online, or by calling the phone number printed on the card. If they receive a physical card, remind them to bring the card with them to the pharmacy. If the copay card program does not provide a physical card, your patient may only need the card number to get the savings.



For patients with Medicare Part D coverage, assistance may be available through the Low-Income Subsidy (also known as Extra Help). This program can help patients with prescription costs if they meet certain income requirements. Patients can visit www.medicare.gov or call 1-800-MEDICARE (1-800-633-4227) to find out if they're eligible. Patients can also purchase a Medigap plan from an insurance company to help cover services not paid for by original Medicare.⁶

Your patients may also be eligible for other programs that provide free or low-cost medicine, devices, and supplies. Direct them to the following websites, where they can search for their therapies and see what programs may be available.⁶

The Partnership for Prescription Assistance: (www.pparx.org)

NeedyMeds: (www.needymeds.org)

RxAssist: (www.rxassist.org)

Rx Outreach: (www.rxoutreach.org)



Key coverage terms

It's important to understand the terminology used by your patient's health plan. This will help simplify the process and facilitate more productive discussions.

Appeal:

A request for the health plan to reconsider its decision to deny coverage for a treatment or procedure. There are 3 main types of appeals. The number of appeals that you or your patient can submit may vary by plan.¹

First level appeal: Initial request to review whether the health plan incorrectly denied coverage.

Second level appeal: A second request reviewed by a health plan's medical review board not involved with the initial appeal.

External review: A review by a third party that is not affiliated with the health plan if all internal appeals are exhausted.

Benefit:

Services covered by your patient's health plan. There are 2 types of benefits^{7,8}:

Medical benefit: Coverage for services performed in your office, such as injections or infusions.

Pharmacy benefit: Coverage for prescription medications, such as oral or topical treatments used by patients at home.

Claim:

A request for a health plan to pay for a treatment provided by your office, a hospital, or other medical facility.⁹

Exceptions:

A process that allows your patients to challenge the exclusion of a medication from a health plan's formulary or the placement of a medication on a higher tier.⁹

Exclusions:

Medications that are not covered on a health plan's pharmacy benefit.⁹

Explanation of Benefits (EOB):

A statement from the health plan sent to you and your patient explaining the treatment, the amount billed for the treatment, the amount that your patient must pay, and how much the plan will cover. An EOB will also explain why coverage was denied.⁹

Formulary:

A list of medications and products covered by a health plan. A formulary may also be known as a preferred drug list. There are two types of formularies⁹:

Open: The health plan covers all formulary or non-formulary medications, but the patient may be responsible for additional out-of-pocket costs for non-formulary medications.

Closed: The health plan does not reimburse non-formulary medications. Your patient would have to request a formulary exception to receive reimbursement for a non-formulary medication.

Grievance:

A formal complaint about a medical or administrative issue, such as the quality of care received from a health plan representative. Grievances usually do not involve coverage or payment.⁹

Low-Income Subsidy:

A Medicare Part D program that helps eligible patients with out-of-pocket costs for their medication. This program is also known as "Extra Help."⁶

Prior authorization (PA):

An administrative tool used by health plans or pharmacy benefit managers requiring you to obtain pre-approval to prescribe specific medications. If a PA is required, your office must submit documentation proving that the medication is medically necessary for your patient.^{7,9}

Quantity limit:

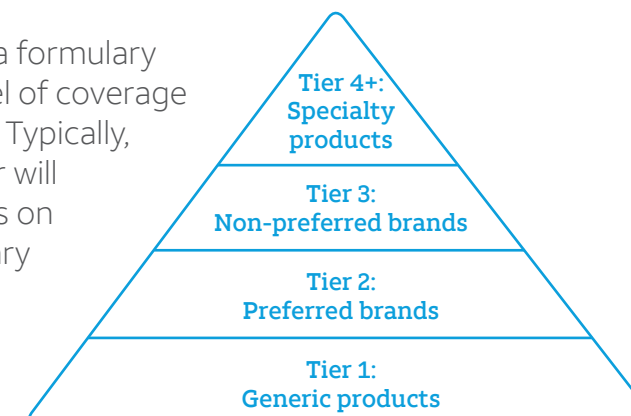
A set amount of refills or dispenses of a medication that the health plan will cover during a given period of time.⁹

Step therapy:

A coverage rule requiring your patient to try and fail on one or more medications before the health plan will authorize treatment with the prescribed medication.⁹

Tier:

A group of drugs on a formulary representing the level of coverage from the health plan. Typically, drugs on a higher tier will cost more than drugs on lower tiers. A formulary may include the following tiers^{9,11}:



Notes

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References

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- 8. Wehrwein P. Should specialty drugs be shifted from medical to pharmacy benefit? *Managed Care*. January 2015. Available from: Multimedia Managed Markets, Yardley, PA. <https://www.managedcaremag.com/archives/2015/1/should-specialty-drugs-be-shifted-medical-pharmacy-benefit>. Accessed May 24, 2018.
- 9. Academic of Managed Care Pharmacy. Managed care terms. <http://www.amcp.org/ManagedCareTerms/>. Accessed May 24, 2018.
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Patient coverage checklist

To help with the process, we've created these checklists for you to use before prescribing treatment or after your patient's coverage is denied. Visit the website for your patient's health plan to find a copy of the most recent drug formulary.

Is the therapy listed on the formulary for your patient's health plan?

Yes No

If you answered "No," you may be able to ask the plan to make an exception for your patient. See page 4 of this guide for more information.

If you answered "Yes," has the health plan placed any restrictions on the therapy?

Yes No

If the restriction is a **prior authorization**, make sure you have the required documentation and forms on hand to submit to the health plan.

If the restriction is **step therapy**, you will need to submit documentation to the health plan that your patient tried and failed on the required therapy.*

If the restriction is a **quantity limit**, check if there is a medical need for your patient to receive more refills or dispenses than the health plan allows.

In the case that your patient's health plan denies coverage for the therapy, be sure that you have the following documentation to submit an appeal.

- Letter of Medical Necessity (see page 6 for a template)
- Appeals letter written by your office and/or your patient (see page 7 for a template)
- Recent lab results
- Relevant chart notes
- Peer-reviewed articles of clinical trials supporting your treatment plan
- The therapy's prescribing information

*In some states, you can ask for an exception to bypass the step therapy process.