Otsuka Patient Support™

FOR HEALTHCARE PROVIDER (HCP) OFFICES AND STAFF

FULL GUIDE TO THE BENEFITS VERIFICATION & COVERAGE PROCESS

This guide provides information on benefits verification, coverage criteria and exceptions, and acquiring Otsuka products. Contact Otsuka Patient Support™ to learn more.

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GETTING STARTED

Navigating the Factors of Coverage

Coverage for treatments for mental health or brain conditions may vary across health plans, depending on the payer type, benefits verification, and site of care.

Payer type

Payer types include:

- Medicare
- Medicaid
- Dual eligible
  - Many individuals living with mental health or brain conditions are dual eligible, meaning they qualify for both Medicare and Medicaid
- Private/commercial payers, including plans purchased on state health insurance exchanges

Benefits verification

A benefits verification confirms the benefit category for the treatment, including:

- Insurance coverage requirements
- Benefit structure (ie, medical vs pharmacy benefit)
- Coverage criteria that may be required, including PA, step edits, quantity limits, and confirmation of medical necessity
- Patient financial responsibility (eg, copay, deductible, coinsurance)

Site of care

The site of care affects coverage, especially for provider-administered medications. These may include:

- Physician offices
- Certified community behavioral health clinics (CCBHCs)
- Inpatient and outpatient hospital settings
- Partial hospitalizations

The site of care may change over time, so be sure to cross-check the site of care with the patient's health plan and identify any coverage needs.

BENEFITS VERIFICATION

The Benefits Verification Confirms Cost and Coverage for Your Patients Prescribed Otsuka Treatments

Complete the **benefits verification** on the patient's primary insurance (and secondary plan if applicable).

The benefits verification reveals whether the drug is covered under the **medical** or **pharmacy benefit**, as well as the patient's insurance coverage and any additional criteria. These may include steps your practice needs to take to avoid delays in treatment approval.*

Therapies covered under the **medical benefit** are generally administered by a healthcare provider (HCP) at outpatient clinics or infusion centers.

Therapies covered under the **pharmacy benefit** are generally self-administered.

Note: Medications not listed as part of the pharmacy benefit may be covered under the medical benefit only.

Questions to ask during the benefits verification:

- Is the treatment covered on the health plan's medical or pharmacy benefit?
  - Verify coverage specifically by drug name and J-code
- Are there any plan limitations or exclusions around the prescribed treatment?
- Is a prior authorization (PA) required?
- Who is the pharmacy benefit manager? What is the best way to contact the organization?
- Is there a website with further policy guidance or relevant forms?

The benefits verification also identifies patient cost-sharing responsibilities, including copay, coinsurance, and out-of-pocket costs.

Your Practice Can Determine any Coverage Criteria Based on the Benefits Verification

Coverage criteria depend on the benefit type and specific payer requirements.

Common coverage criteria may include:

PA

Step edit

Quantity limits

Documentation of medical necessity

- Consider any additional necessary coverage requirements and forms, including support for diagnosis and any lab or test results, along with the phone number, fax, or website to request the PA
- If the treatment is not covered under one type of benefit (eg, pharmacy), check whether it is covered under the medical benefit
  - In some cases, the plan may require use of certain pharmacies under the medical benefit. Then, the HCP and patient may be responsible for completing the benefit assignment process and coordinating with the payer-mandated pharmacy

Be sure to document all communications during the verification process in case your practice needs to coordinate between multiple health plans. In addition, obtain a reference number for each phone call to the insurance company.

*This resource is provided for informational purposes only and does not guarantee coverage and reimbursement. For some health plans, the initial benefits verification may be an estimate and not include all details until the script is processed.

COVERAGE CRITERIA

Payers Often Require a PA Before Covering Therapy

Prior authorization (PA) (sometimes called preauthorization) is a request for approval by the healthcare provider (HCP) to get coverage for the patient's prescribed therapy. Payers usually note therapies that require a PA on their formulary and website.

- As part of the PA, the HCP must provide evidence for why the prescribed therapy is medically necessary for the patient based on clinical criteria
- Specific PA requirements, including the list of treatments that require a PA for approval, depend on the payer
  - PA requirements may also depend on regional requirements and site of care
  - In some instances, such as for treatments administered by HCPs, payers may mandate separate authorization processes for the therapy and administration services
- The PA decision may fall under the jurisdiction of pharmacy or medical policy staff, or a specific prior authorization department at the payer organization

COVERAGE DETERMINATION

The first step of the PA is the **coverage determination**: the plan's decision whether to cover the drug and, if so, at what cost share.

Before PA submission, please confirm any PA requirements and the preferred method of submission (phone, fax, or electronic), as well as whether the plan has a product- or category-specific PA form.

Checklist for Requesting Prior Authorization

The PA request may be submitted electronically or by phone or fax, depending on payer requirements.

In certain cases, the **payer may ask for a written request for treatment and/or additional documentation** such as a letter of medical necessity. Some payers may also provide specific forms to complete during the PA request.

The **time frame for PA decisions may vary across payers**. If the time frame for getting the patient started on therapy is urgent, the plan can usually expedite the PA request.

Checklist for Requesting Prior Authorization (continued)

The questions below may help your practice navigate the PA process

- Does the payer have a product- or category-specific PA form? If so, where can these forms be obtained?
- How should the PA be submitted? To which department? What are the relevant telephone and/or fax numbers?
- Is there a specific point of contact for PAs at the plan?
- What documentation is required?
- How long will the process take after submission of the PA request? Can the PA request be expedited if the patient's treatment needs are urgent?

covermymeds®

CoverMyMeds can assist with the PA process:
1-866-452-5017
(A third-party service contracted by Otsuka and Lundbeck)

Payers May Mandate Additional Criteria for Coverage

STEP EDIT

Payers may require that patients try certain medications before covering a prescribed therapy. In some instances, the payer may ask the HCP to initially prescribe a less expensive treatment (often a generic alternative).

The payer may waive the step therapy requirement in certain instances, including if the patient has experienced:

- Failure or lack of response to other treatments
- Inability to take preferred treatments (ie, adverse reactions, impediments to administration, allergies) or potential consequences to switching therapies
- Documented history of positive response to the prescribed therapy

QUANTITY LIMITS

Quantity limits define the amount of medication covered by plans during a designated period, generally based on common medical practices. The plan may require authorization if the prescribed treatment exceeds quantity limits.

Prescribing needs may exceed quantity limits due to patient weight or other considerations regarding how the patient metabolizes drugs.

Be sure to confirm the prescription and refills meet the payer's requirements.

Example Letter of Medical Necessity

The sample letter of medical necessity provided here may act as a starting point for your practice.

[Date]

[Health plan name] [Patient's Name]

ATTN: [Department] [Patient's plan-specific member ID]

[Medical/Pharmacy Director Name (if available)] [Date of birth]

[Health plan address] [Case number]

[City, State, ZIP code] [Dates of service]

Re: Letter of Medical Necessity for [prescribed treatment]

Dear [Medical/Pharmacy Director Name],

I am writing this letter of medical necessity on behalf of [patient name] to request coverage for [prescribed treatment] for the treatment of [clinical criteria for diagnosis] [relevant diagnosis codes]. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

I have been treating [patient name], [a/an] [age]-year-old [male/female], since [date] to manage their [clinical criteria associated with diagnosis]. My rationale for prescribing [prescribed treatment] is: [relevant medical information and why the prescribed is the most appropriate treatment option].

In my medical judgment, this patient is an appropriate candidate for treatment with [prescribed treatment]. I have included supporting clinical data.

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature] [Physician name] [Physician NPI] [Name of practice] [Phone number]

Enclosures: [List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, US Food and Drug Administration approval letter, clinical studies and efficacy data, PA number, and/or clinical practice guidelines.]

Note: This letter is provided as an example for educational purposes only. Form requirements vary across payers and regions.

Please keep track of all documentation and communication with the plan, including obtaining a reference number for each phone call.

As part of the letter of medical necessity, it may be helpful to include:

- The patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- International Classification of Diseases, 10th edition (ICD-10) codes to support diagnosis (primary and secondary)
- Rationale for treatment with the prescribed therapy
  - Patient diagnosis and comorbidities
- Current and previous therapies
- Why alternative therapies may not be clinically viable and/or result in the desired treatment outcomes
  - Patient intolerance to current therapies on formulary
  - Patient has not achieved adequate results from current or prior therapy (adverse reactions or potential allergies)
  - Lack of therapeutic equivalent for the prescribed therapy
- Relevant documentation
- Clinical support for recommendations

PATIENT COSTS

The Benefits Verification Process Helps Identify Patient Costs, Including Copays or Coinsurance

The copay amount may depend on relevant details about the benefit type.

- Plans with coverage under the medical benefit may require use of a payer-mandated specialty pharmacy, potentially affecting how the patient receives copay support

Otsuka Patient Support provides copay assistance to eligible patients with commercial insurance who have been prescribed an Otsuka medication (for both medical and pharmacy benefits).

Your patients with government insurance may be eligible for additional assistance.

Questions to ask about patient costs

- What is the patient's **deductible** and **out-of-pocket maximum** and/or **copay**?
- If the product is not covered, is a **formulary exception** needed?
- On which formulary tier is the medication? Can your practice and patient request a **tiering exception** to help reduce patient costs?
- Are patient costs impacted by the **site of care**?
- Is the **copay amount affordable**?

EXCEPTIONS

What to Do if the Prescribed Drug Is not on Formulary or Has High Patient Cost-sharing

An exception request is a type of coverage determination asking payers to consider more individualized coverage policies for specific patients whose plan coverage does not meet their medical needs.

As part of an exception request, the HCP must substantiate that the prescribed therapy is medically necessary for the patient. This includes submitting required supporting statements such as documentation regarding why covered drugs may be less effective or cause adverse effects.

Exception requests fall under 2 categories: **formulary** and **tiering exceptions**.

Formulary exceptions

- If a medication is not listed as a covered drug, the HCP can request a formulary exception asking the plan for approval
- A formulary exception may also be requested to waive restrictions (such as step therapy, prior authorization, or quantity limits) for drugs that are on formulary
- As part of the formulary exception, the HCP will need to prove that the prescribed drug is medically necessary

Learn more about **tiering exception**s on the next page.

Tiering Exceptions Can Help Lower Patient Costs

Health plans sort medications into groups called "**tiers**" on their formularies, which are lists of drugs covered by the plan. Tier structures vary across plans. In most cases, the higher the tier, the more expensive the cost to the patient.

Patients prescribed drugs in a higher or nonpreferred tier may face high copays and treatment delays.

Tier	Patient costs	Description
1	Lowest	Most generic prescription drugs
2	Medium	Some high-cost generic drugs; most common brand name drugs; preferred, brand-name prescription drugs
3	Higher	Nonpreferred, brand-name prescription drugs
Specialty	Highest	Unique or very high-cost prescription drugs

If the HCP believes the patient needs a specific treatment instead of a similar drug in a lower tier, the patient and the HCP can ask the plan for an exception to get a lower coinsurance or copay for the drug in the higher tier. **This process, known as a tiering exception request, is a way to potentially reduce cost-sharing for patients.**

Tiering exceptions can be requested when:

- A higher tier drug is necessary because the plan's preferred drugs are medically inappropriate
- A drug is no longer covered during a plan year, and there is no alternative available*
- The drug gets moved during the plan year from the preferred to the nonpreferred tier, and the patient cannot use any other drugs on the preferred tier

Getting Started With Tiering Exception Requests

1 Gather supporting documentation

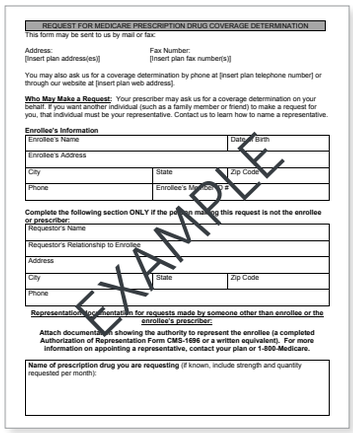
While requirements vary across payers, it is always helpful to submit a verbal or written **statement supporting medical necessity** from the prescriber outlining the medical reason for the tiering exception (see the next page to learn more).

2 Submit the tiering exception request

Depending on the direction from the plan, tiering exception requests and required documentation may be submitted in any format, including phone, fax, or email.

Tiering requests under Medicare Part D

The **Medicare Model Coverage Determination Request Form** may be downloaded at medicare.gov or from each Part D plan's website. Plans may provide specific tiering exception request templates or forms on their websites that must be used when making the request in addition to the Medicare Model Coverage Determination Request Form.


REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION

This form may be sent to us by mail or fax:

Address:
[insert plan address(es)]

Fax Number:
[insert plan fax number(s)]

You may also ask us for a coverage determination by phone at [insert plan telephone number] or through our website at [insert plan web address].

Who May Make a Request: Your prescriber may ask us for a coverage determination on your behalf. If you want another individual (such as a family member or friend) to make a request for you, that individual must be your representative. Contact us to learn how to name a representative.

Enrollee's Information

Enrollee's Name		Date of Birth
Enrollee's Address		
City	State	Zip Code
Phone	Enrollee's Medicare ID #	

Complete the following section ONLY if the person making this request is not the enrollee or prescriber:

Requestor's Name		
Requestor's Relationship to Enrollee		
Address		
City	State	Zip Code
Phone		

Representation documentation for requests made by someone other than enrollee or the enrollee's prescriber:

Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent). For more information on appointing a representative, contact your plan or 1-800-Medicare.

Name of prescription drug you are requesting (if known, include strength and quantity requested per month):

EXAMPLE

Example of Medicare Model Coverage Determination Request Form. Part D plan sponsors may have their own forms.

Exception request policies can generally be found in payer handbooks or websites, or by calling the payer's customer service department.

*A tiering exception request cannot be made if the required drug is in a specialty tier.

Example Tiering Exception Letter

The tiering exception request letter may be written and delivered by the HCP, the patient, or the patient's caregiver/legal representative. Both the patient, or the patient's authorized representative, and the HCP should sign the letter.

As part of the letter of support, it may be helpful to include:

- The patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ICD-10 codes to support diagnosis (primary and secondary)
- Rationale for treatment with the prescribed therapy
- Current and previous therapies
- Patient intolerance to current therapies or therapies on formulary
  - Whether the patient has not achieved adequate results from current or prior therapy
- Clinical support for recommendations

The sample letter of tiering exception provided here may act as a starting point for your practice.

[Date]

[Health plan name] [Patient's Name]

ATTN: [Department] [Patient's plan-specific member ID]

[Medical/Pharmacy Director Name (if available)] [Date of birth]

[Health plan address] [Case number]

[City, State, ZIP code] [Dates of service]

Re: Exception Letter of Support [prescribed treatment]

My name is [HCP name], a [HCP medical specialty]. I am writing to request a tier exception for [patient name]. Given [patient's] diagnosis of [clinical criteria for diagnosis] [relevant diagnosis codes], I believe that the prescription for [treatment, dosage, and frequency] is medically appropriate and necessary. I am requesting that [treatment] is deemed the preferred medication for my patient.

[Patient name] is currently receiving treatment with: [current treatment(s), start date(s), and dosage]. The patient is experiencing [potential reasons for discontinuation with current treatment, including side effects and unresolved symptoms].

[Patient name] has previously received treatment with other therapies:

[Past treatment name(s); start/stop dates; and reason(s) for discontinuing (side effects, lack of efficacy and/or tolerability, etc.)].

I am requesting a tier exception to prevent the cost of [treatment] from causing a financial burden on [patient name] and restricting [patient name] from receiving necessary treatment. I have also enclosed a copy of [patient name's] medical records and a Letter of Medical Necessity, as well as a statement of financial hardship.

Please contact me with any questions.

Sincerely,

[Physician's signature] [Physician name] [Physician NPI] [Name of practice] [Phone number]

Enclosures: [List and attach additional documents, which may include Letter of Medical Necessity, Statement of Financial Hardship, Prescribing Information, clinical notes/medical records, US Food and Drug Administration approval letter, clinical studies and efficacy data, PA number, and/or clinical practice guidelines.]

Note: This letter is provided as an example for educational purposes only. Form requirements vary across payers and regions.

Please keep track of all documentation and communication with the plan, including obtaining a reference number for each phone call.

Exception Timeline and Next Steps

Health plans vary in their timelines for exception requests.

As with PA requests, response times may change depending on the method of submission and whether appropriate documentation was provided. Expedited reviews may be requested if the patient urgently needs treatment.

Generally, an unfavorable coverage determination decision will outline any information needed to file a request for redetermination. As with PA denials, in some instances it may be necessary to arrange a conversation between the prescriber and the medical director.

The patient and HCP may also opt to initiate the appeal process again next year.

The Exceptions Process for Medicare Part D Plans

For requests for benefits:

- The Part D plan must provide a decision within 72 hours of receiving the request. For expedited reviews, the Part D plan will provide a decision within 24 hours
- The initial notice may be provided verbally if a written follow-up notice is mailed within 3 calendar days

For requests for payment that involve exceptions:

- The Part D plan must provide notice of its decision within 14 calendar days after receiving the request

Most plans align to Medicare Part D requirements for exception requests, outlined here.

ACQUIRING PRODUCT

Checklist: Confirm the Site of Care and Subsequent Coverage Needs

- Identify the required channels for product acquisition and cross-check the site of care with the payer, including how it may affect coverage needs
- Check whether the treatment is dispensed by a specific pharmacy or a specialty pharmacy provider
- Confirm any coverage needs depending on the pharmacy
  - In some cases, the pharmacy may help coordinate support and cost needs with your practice and patient
- Check with the health plan if/when confirmation of refills is needed (if filled under the medical benefit)

Otsuka Patient Support™ may be able to help your patients get their treatment

Our **Integrated Pharmacy Network (IPN)** connects patients, caregivers, and practices with experienced pharmacies that may be able to help coordinate and support access.

We can also connect patients to their **Local Care Center (LCC)** so they can choose the treatment location that works best for them.

Please see page 14 for Otsuka Patient Support™ contact information.

DENIALS AND APPEALS

Coverage Denials May Be Due to Insufficient Evidence of Medical Necessity

In these instances, please resubmit the coverage request with the additional information requested by the payer.

Documentation should include:

- The patient's medical history and treatment plan
- A copy of the original PA request and denial
- Any relevant clinical information substantiating use of the treatment

If the PA request is denied again, the HCP may reach out to the payer's medical director for a medical review. In certain cases, the HCP may ask that the request be reviewed by a physician in the same specialty.

Otsuka Patient Support is available to answer questions or coordinate during the PA process.

Unfavorable Coverage Determinations May Be Appealed

Appeals address improper reimbursement or denial of coverage of the prescribed therapy.

THE APPEALS PROCESS OCCURS ACROSS SEVERAL SUCCESSIVE LEVELS

- An unfavorable decision may move to the next level, with the payer response containing the information needed to escalate
- If the patient proceeds through all levels of internal appeals, they may be eligible for an external appeal with an independent organization (also known as an external review)
- The payer is required to accept the decision of the external review*

MOST PAYERS HAVE SIMILAR RULES FOR FILING APPEALS

- Usually, the request must be made in writing and the prescriber should provide a supporting statement explaining the medical reasons for the appeal
- To learn more and/or to access any required forms, please review the payer handbook or website, or call their customer service department

The Medicare Part D appeals process has 5 levels:

1. **Redetermination** by the Part D Plan Sponsor
2. **Reconsideration** by the Independent Review Entity
3. **Hearing** by an Administrative Law Judge or Attorney Adjudicator
4. **Review** by the Medicare Appeals Council
5. **Review** by a Federal District Court

Non-Medicare payers generally have their own appeals processes, and may vary by state.

*The external review process does not apply to self-funded plans.

Checklist: Getting Started With Appeals

1. **First, determine the reason for the coverage or PA denial**
2. Second, determine the steps for submitting the appeal. Steps may be different to submit an appeal for a coverage denial or a PA denial and should be confirmed with the payer

Initiating an appeal may require contact via phone. Review the payer handbook or website, or call their customer service department for details.

The questions below may help your practice navigate the appeal process:

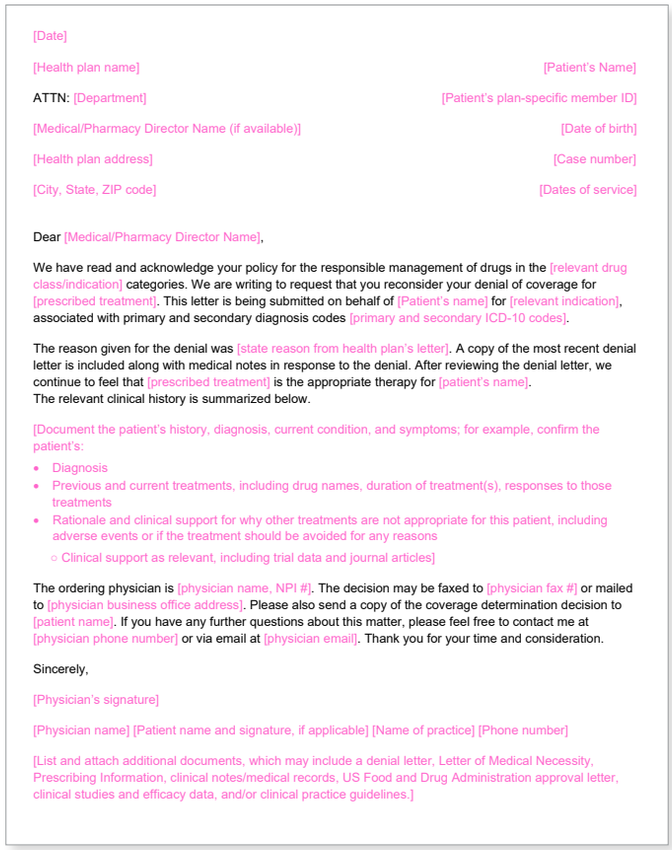
- What new documentation may be required?
- How should this information be submitted?
- What are time limits for filing?
- How long does the appeal process take?
- Can the appeal process be expedited?

Example Letter of Appeal

As part of the letter of appeal, it may be helpful to include:

- Denial information, including the denial letter(s) or explanation of benefits notification
- Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- Prior authorization/case number
- Patient's medical records and accompanying ICD-10 code(s)
- Copies of additional medical information
- Clinical support
- Current and previous therapies
- Why other treatments are not appropriate
- A letter of medical necessity and the US Food and Drug Administration (FDA) approval letter
- Additional information and documents
  - Reference number of existing claim decision, if applicable
  - Patient Authorization and Notice of Release of Information
  - Appeal letter signed by the patient or authorized representative, if applicable
- Other supporting documentation
  - Chart notes, current medications, test and lab results, and emergency department notes

The sample letter of appeals provided here may act as a starting point for your practice.



[Date]

[Health plan name] [Patient's Name]

ATTN: [Department] [Patient's plan-specific member ID]

[Medical/Pharmacy Director Name (if available)] [Date of birth]

[Health plan address] [Case number]

[City, State, ZIP code] [Dates of service]

Dear [Medical/Pharmacy Director Name],

We have read and acknowledge your policy for the responsible management of drugs in the [relevant drug class/indication] categories. We are writing to request that you reconsider your denial of coverage for [prescribed treatment]. This letter is being submitted on behalf of [Patient's name] for [relevant indication], associated with primary and secondary diagnosis codes [primary and secondary ICD-10 codes].

The reason given for the denial was [state reason from health plan's letter]. A copy of the most recent denial letter is included along with medical notes in response to the denial. After reviewing the denial letter, we continue to feel that [prescribed treatment] is the appropriate therapy for [patient's name].
The relevant clinical history is summarized below.

[Document the patient's history, diagnosis, current condition, and symptoms; for example, confirm the patient's:

- Diagnosis
- Previous and current treatments, including drug names, duration of treatment(s), responses to those treatments
- Rationale and clinical support for why other treatments are not appropriate for this patient, including adverse events or if the treatment should be avoided for any reasons
  - Clinical support as relevant, including trial data and journal articles]

The ordering physician is [physician name, NPI #]. The decision may be faxed to [physician fax #] or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to [patient name]. If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

[Physician name] [Patient name and signature, if applicable] [Name of practice] [Phone number]

[List and attach additional documents, which may include a denial letter, Letter of Medical Necessity, Prescribing Information, clinical notes/medical records, US Food and Drug Administration approval letter, clinical studies and efficacy data, and/or clinical practice guidelines.]

Note: This letter is provided as an example for educational purposes only. Form requirements vary across payers and regions.

Please keep track of all documentation and communication with the plan, including obtaining a reference number for each phone call.

Appeals Timeline and Next Steps

Payers vary in their timelines for appeals, although they are required to respond to each step of the process within specific time frames.

Response times may vary due to the method of submission and whether appropriate documentation was provided. Expedited reviews may be requested if the patient urgently needs treatment.

Medicare Part D payers must respond within 7 days for a standard appeals request and 72 hours for an expedited request. If the appeal advances to the second level, they must respond to the standard request within 7 days and the expedited request within 72 hours. Appeals that move beyond this level may result in longer time frames: 90 days for the standard process and 10 days for expedited.

The patient has 60 days to file at each level of appeal.

Otsuka Patient Support™ may be able to support the appeals process.

Otsuka Patient Support offers dedicated professionals and digital solutions to help make treatment more accessible for patients and provide ongoing support.

For questions about benefits verification and coverage, Otsuka Patient Support may be able to help provide answers.

Call Center

Representatives available to deliver personalized assistance and additional resources.

1-833-468-7852

Monday–Friday, 8 AM–8 PM ET

OtsukaPatientSupport.com

View educational resources and have your questions answered through a 24/7 chat.

Visit **Insurance Resources** for additional education on the access process, coverage authorizations, and Medicare programs.