Considerations for Submitting a Complete

MEDICAL EXCEPTION FORM

Akebia® THERAPEUTICS

A formulary or medical exception request is needed when the prescriber is requesting coverage for a non-formulary medication. Exception requests and prior authorization requests should be submitted using the same form—the Medicare Prescription Drug Coverage Determination Form.

FORM COMPLETION TIPS

- **To receive coverage for a prescription, a medical exception request may need to be submitted. This form can be accessed through the associated insurance provider**
- **This guide should be used by the insurance plan or Medicare enrollee, the enrollee's representative, or the enrollee's prescriber to help ensure the form is filled out completely and accurately**
- **Note, this is the standard CMS (Centers for Medicare & Medicaid Services) form that may be used by some insurance plans. Others may use a custom one, but it will likely be similar to this one**

The name of the Medicare enrollee, in addition to their date of birth, address, phone number, and Medicare member ID #, are all required to complete the request.

If you are the enrollee's representative, not the enrollee or prescriber, fill out the Requestor's section with your information. Proof of authorization to represent the enrollee is required.

In the box, include the prescription drug name and the dose given to the enrollee.

The type of Coverage Determination Request required is dependent on unique circumstances. Mark the box that accurately describes the request.

A fast (expedited) decision can be requested if the enrollee or the prescriber feel that the enrollee's health could be seriously harmed by waiting the standard timeline for appeal decisions.

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 Member 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):

Type of Coverage Determination Request

☐ I need a drug that is not on the plan's list of covered drugs (formulary exception).*

☐ I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (formulary exception).*

☐ I request prior authorization for the drug my prescriber has prescribed.*

☐ I request an exception to the requirement that I try another drug before I get the drug my prescriber prescribed (formulary exception).*

☐ I request an exception to the plan's limit on the number of pills (quantity limit) I can receive so that I can get the number of pills my prescriber prescribed (formulary exception).*

☐ My drug plan charges a higher copayment for the drug my prescriber prescribed than it charges for another drug that treats my condition, and I want to pay the lower copayment (tiering exception).*

☐ I have been using a drug that was previously included on a lower copayment tier, but is being moved to or was moved to a higher copayment tier (tiering exception).*

☐ My drug plan charged me a higher copayment for a drug than it should have.

☐I want to be reimbursed for a covered prescription drug that I paid for out of pocket.

***NOTE: If you are asking for a formulary or tiering exception, your prescriber MUST provide a statement supporting your request. Requests that are subject to prior authorization (or any other utilization management requirement), may require supporting information. Your prescriber may use the attached "Supporting Information for an Exception Request or Prior Authorization" to support your request.**

Additional information we should consider *(attach any supporting documents)*:

Important Note: Expedited Decisions

If you or your prescriber believe that waiting 72 hours for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 72 hours could seriously harm your health, we will automatically give you a decision within 24 hours. If you do not obtain your prescriber's support for an expedited request, we will decide if your case requires a fast decision. You cannot request an expedited coverage determination if you are asking us to pay you back for a drug you already received.

☐**CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 24 HOURS (if you have a supporting statement from your prescriber, attach it to this request).**

Signature:	**Date:**

Considerations for Submitting a Complete

MEDICAL EXCEPTION FORM

Akebia® THERAPEUTICS

The Supporting Information for an Exception Request or Prior Authorization form should be filled out by the prescriber if the exception request (see page 1) requires additional support.

- **Before completing this form, the enrollee's benefits and eligibility should be confirmed**
- **Benefits for services received are subject to eligibility and plan terms and conditions that are in place at the time services are provided**

All relevant diagnosis and medical information should be documented. This includes:

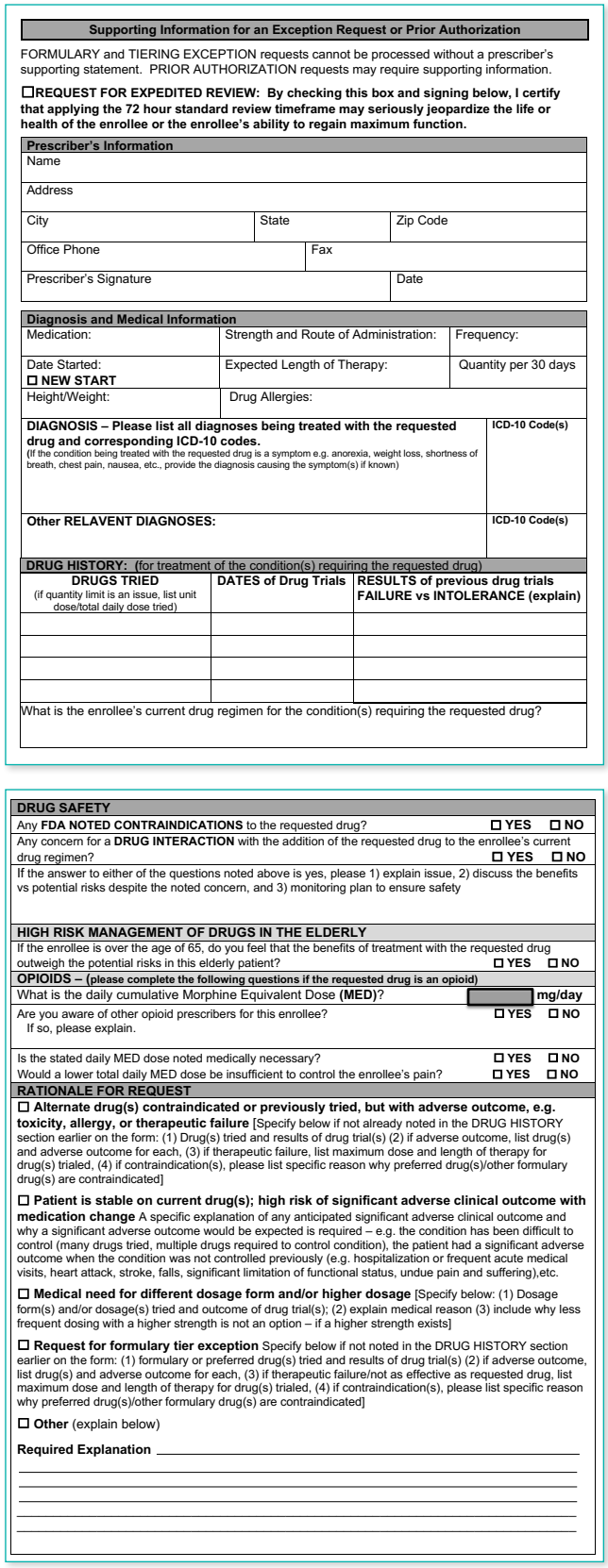
- The name of the requested medication, strength and route of administration, frequency, and date started
- The enrollee's height, weight, and known drug allergies
- A list of all diagnoses being treated with the requested drug and corresponding ICD-10 codes, as well as other relevant diagnoses

Fill out the enrollee drug history section for the treatment of condition(s) requiring the requested drug. Include drugs tried, dates of the drug trials, and results of previous drug trials.

Be sure to provide any FDA-noted contraindications to the requested drug or concerns for possible drug interactions with the enrollee's current drug regimen.

Eligibility for exception or prior authorization is dependent on each enrollee's unique circumstances. Please mark the box that best matches your rationale for this request.

AkebiaCares provides broad insurance coverage research and personalized support programs to help make access to prescription drugs as easy as possible for patients.



Supporting Information for an Exception Request or Prior Authorization

FORMULARY and TIERING EXCEPTION requests cannot be processed without a prescriber's supporting statement. PRIOR AUTHORIZATION requests may require supporting information.

☐ **REQUEST FOR EXPEDITED REVIEW: By checking this box and signing below, I certify that applying the 72 hour standard review timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.**

Prescriber's Information

Name		
Address		
City	State	Zip Code
Office Phone	Fax	
Prescriber's Signature		Date

Diagnosis and Medical Information

Medication:	Strength and Route of Administration:	Frequency:
Date Started: ☐ **NEW START**	Expected Length of Therapy:	Quantity per 30 days
Height/Weight:	Drug Allergies:	

DIAGNOSIS – Please list all diagnoses being treated with the requested drug and corresponding ICD-10 codes. (If the condition being treated with the requested drug is a symptom e.g. anorexia, weight loss, shortness of breath, chest pain, nausea, etc., provide the diagnosis causing the symptom(s) if known)	**ICD-10 Code(s)**
Other RELAVENT DIAGNOSES:	**ICD-10 Code(s)**

DRUG HISTORY: (for treatment of the condition(s) requiring the requested drug)

DRUGS TRIED (if quantity limit is an issue, list unit dose/total daily dose tried)	**DATES of Drug Trials**	**RESULTS of previous drug trials FAILURE vs INTOLERANCE (explain)**

What is the enrollee's current drug regimen for the condition(s) requiring the requested drug?

DRUG SAFETY

Any **FDA NOTED CONTRAINDICATIONS** to the requested drug? ☐ **YES** ☐ **NO**

Any concern for a **DRUG INTERACTION** with the addition of the requested drug to the enrollee's current drug regimen? ☐ **YES** ☐ **NO**

If the answer to either of the questions noted above is yes, please 1) explain issue, 2) discuss the benefits vs potential risks despite the noted concern, and 3) monitoring plan to ensure safety

HIGH RISK MANAGEMENT OF DRUGS IN THE ELDERLY

If the enrollee is over the age of 65, do you feel that the benefits of treatment with the requested drug outweigh the potential risks in this elderly patient? ☐ **YES** ☐ **NO**

OPIOIDS – (please complete the following questions if the requested drug is an opioid)

What is the daily cumulative Morphine Equivalent Dose **(MED)**? _____ **mg/day**

Are you aware of other opioid prescribers for this enrollee? ☐ **YES** ☐ **NO**
If so, please explain.

Is the stated daily MED dose noted medically necessary? ☐ **YES** ☐ **NO**

Would a lower total daily MED dose be insufficient to control the enrollee's pain? ☐ **YES** ☐ **NO**

RATIONALE FOR REQUEST

☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure** [Specify below if not already noted in the DRUG HISTORY section earlier on the form: (1) Drug(s) tried and results of drug trial(s) (2) if adverse outcome, list drug(s) and adverse outcome for each, (3) if therapeutic failure, list maximum dose and length of therapy for drug(s) trialed, (4) if contraindication(s), please list specific reason why preferred drug(s)/other formulary drug(s) are contraindicated]

☐ **Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change** A specific explanation of any anticipated significant adverse clinical outcome and why a significant adverse outcome would be expected is required – e.g. the condition has been difficult to control (many drugs tried, multiple drugs required to control condition), the patient had a significant adverse outcome when the condition was not controlled previously (e.g. hospitalization or frequent acute medical visits, heart attack, stroke, falls, significant limitation of functional status, undue pain and suffering),etc.

☐ **Medical need for different dosage form and/or higher dosage** [Specify below: (1) Dosage form(s) and/or dosage(s) tried and outcome of drug trial(s); (2) explain medical reason (3) include why less frequent dosing with a higher strength is not an option – if a higher strength exists]

☐ **Request for formulary tier exception** Specify below if not noted in the DRUG HISTORY section earlier on the form: (1) formulary or preferred drug(s) tried and results of drug trial(s) (2) if adverse outcome, list drug(s) and adverse outcome for each, (3) if therapeutic failure/not as effective as requested drug, list maximum dose and length of therapy for drug(s) trialed, (4) if contraindication(s), please list specific reason why preferred drug(s)/other formulary drug(s) are contraindicated]

☐ **Other** (explain below)

Required Explanation _____