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Medicare Appeals

On March 13, 2020, the Centers for Medicare and Medicaid Services (CMS) announced it would use the President's declaration categorizing the coronavirus (COVID-19) pandemic a national emergency to activate a number of 1135 waivers to give providers more flexibility. The waivers include the following relevant updates to the Medicare Appeals Process. Effective March 1, 2020 and through the end of the public health emergency, the new waivers:

1. Grant Independent Review Entities (IREs) authority to allow extensions to file an appeal.
2. Allow IREs to waive timeliness requirements for additional information to adjudicate appeals.
3. Permit IREs to process appeals with incomplete Appointment of Representation forms.
4. Allow IREs to process appeals that do not meet the required elements.
5. Give IREs flexibilities with respect to other parts of the appeals process so long as good cause requirements are satisfied. Conditions for good cause can be found here: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c29.pdf**

Reference: Fact Sheet for Medicare Part D Blanket Waivers: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

CMS has a defined process for appeals of both Original Medicare and Part D coverage decisions. Both follow a similar 5-level structure, with specific deadlines and time limits for both standard and expedited requests. This brochure is for informational purposes only and is not intended to provide reimbursement or legal advice. Information sourced as of July 2021. Please confirm information as needed.

IMPORTANT: Healthcare providers are responsible for keeping current and complying with all applicable coverage requirements and for the selection of diagnosis and procedure codes that accurately reflect their patient's condition and the services rendered. Healthcare providers also are responsible for the accuracy of all claims and related documentation submitted for reimbursement. Additional insurance requirements may apply and healthcare providers should always contact the insurer directly to obtain complete and current information. Alkermes does not guarantee coverage or reimbursement. Under no circumstances will Alkermes, Inc., or its affiliates, employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages that may arise from, or be incurred in connection with, the information provided here or any use thereof.

Medicare Part D Prescription Drug Coverage Determination and Appeals Process[1,2]

Level	Details
Coverage Determination (Initial)	• Request submitted to patient's PDP or MA-PD • Standard - 72 hour time limit • Expedited - 24 hour time limit
LEVEL 1: Plan Redetermination	• If the plan denies the Coverage Determination, the patient or provider has 60 days to file the Level 1 appeal after receipt of initial denial of coverage • Request submitted to PDP or MA-PD • Standard - 7 day time limit for benefits; 14-day time limit for payments • Expedited - 72 hour time limit
LEVEL 2: Reconsideration by Part D Independent Review Entity (IRE)	• Patient or provider has 60 days to file after receipt of denial of Level 1 appeal • IREs are also sometimes called Part D Qualified Independent Contractors (QIC). Currently, C2C is the Part D IRE • The Part D C2C Appeal form can be found at: **https://partdappeals.c2cinc.com/Prescribers** • Standard - 7 day time limit for benefits; 14-day time limit for payments • Expedited - 72 hour time limit
LEVEL 3: Administrative Law Judge (ALJ) Hearing	• Patient or provider has 60 days to file after receipt of denial of Level 2 appeal • This level of appeal requires an "amount in controversy" (AIC) of $180.00 or more • An ALJ hearing may be held by telephone or video-teleconference or, in some cases, in person. The patient or provider may request a decision without a hearing, if evidence supports such a decision • Standard - 90 day time limit • Expedited - 10 day time limit
LEVEL 4: Medicare Appeals Council Hearing	• Patient or provider has 60 days to file after receipt of denial of Level 3 appeal • Standard - 90 day time limit • Expedited - 10 day time limit
LEVEL 5: Judicial Review – Federal District Court	• Patient or provider has 60 days to file after receipt of denial of Level 4 appeal • AIC must meet a minimum cost threshold requirement which is adjusted annually and can be found on the CMS website • The calendar year 2021 AIC threshold amount for judicial review is $1,760.00

Information sourced as of July 2021. Please confirm information as needed.

Part D Drug Coverage Appeals[3,4]

CMS has defined a 5-step process for prescription drug coverage appeals, with specific deadlines and procedures for each level.

Plans are required to accept any written request for a redetermination of coverage from patients, appointed representatives, the patient's physician, or other prescriber. A written request to appeal should include:

- **If the prescriber is acting as the patient's appointed representative in the appeal process, include proof of representation**
- The patient's name, address, Medicare number, and/or plan member identification number
- The name of the drug you want the plan to cover
- Stated reason from initial denial of claim, date the denial was issued, and a copy of the denial
- The reasons for the patient's appeal
- Include in your request any other information that may help support the appeal, such as medical records, patient history, or recent chart notes

For more information about Part D drug coverage appeals, consult the Medicare Prescription Drug Benefit Manual, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. This is available for download at: **https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html**

Medicare Part D Exception Process[3,5]

An exception request may include a request for benefits, a request for payment, or both. Following are reasons considered for an Exception request.

- Not on a Part D formulary (or subject to utilization management restrictions, e.g. step therapy, prior authorization or quantity limits) or,
- Not on a tier that the prescriber believes should not apply

Exception requests are granted when a plan sponsor determines that a requested drug is medically necessary for an enrollee. Supporting documentation will be required for the subscriber to submit an exception request.

- For formulary exceptions, the prescriber's supporting statement must indicate:
  - The medical necessity of the requested drug and preferred Part D treatment alternatives would not be effective or have adverse effects
  - The alternative listed on the formulary or required to be used in accordance with step therapy are likely to be less effective or have adverse effects; or the number of doses under a dose restriction has been or is likely to be less effective, or have adverse effects
- For tiering exceptions, the prescriber's supporting statement must indicate that the preferred drug(s) would not be as effective as the requested drug for treating the enrollee's condition, the preferred drug(s) would have adverse effects for the enrollee, or both

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How to Submit a Supporting Statement[3,4,5]

The prescriber may submit their supporting statement to the plan sponsor orally or in writing.

A prescriber may submit a written supporting statement on:

- The Model Coverage Determination Request Form found on the CMS website in the Download section on the web page (or in the link below), or;
- An exceptions request form developed by the patient's Medicare Advantage or Part D plan sponsor or other entity, or;
- Any other written document (e.g., a letter) prepared by the prescriber

An Exception Request Form can be found on the following link in the Model Coverage Determination Req Form and Instructions download section of the page.

https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html

How a Plan Sponsor Processes an Exception Request[3,4,5]

- Plan sponsor must provide a written notice of its decision within 24 hours after receiving the documentation from the prescriber (for expedited requests) or 72 hours (for standard requests)
- The initial notice may be provided orally so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the oral notification

For requests for payment that involve exceptions, a plan sponsor must provide notice of its decision (and make payment when appropriate) within 14 calendar days after receiving a request.

If the plan sponsor's coverage determination is unfavorable, the decision will contain the information needed to file a request for redetermination with the plan sponsor.

References:

1. Centers for Medicare and Medicaid Services. Medicare Prescription Drug (Part D) Coverage Determination and Appeals Process. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Flowchart-Medicare-Part-D.pdf. Accessed July 8, 2021.
2. https://www.federalregister.gov/documents/2020/09/28/2020-21254/medicare-program-medicare-appeals-adjustment-to-the-amount-in-controversy-threshold-amounts-for. Accessed July 8, 2021.
3. Centers for Medicare and Medicaid Services. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf. Accessed July 8, 2021.
4. Medicare.gov. Medicare prescription drug coverage appeals. https://www.medicare.gov/medicare-prescription-drug-coverage-appeals. Accessed July 8, 2021.
5. Centers for Medicare and Medicaid Services. Exceptions. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions. Accessed July 8, 2021.

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