

ATTACHMENT II-B
Part D Coverage Determinations, Appeals and Grievances (CDAG)
Sample Case File Minimum Documentation Required

Purpose: To advise plan sponsor of the minimum documentation required for each of the sample cases requested by CMS to conduct audit activities.

Instructions: The plan sponsor must include all documentation detailed below for each sample case. The plan sponsor may include additional documentation not specifically requested for the purpose of providing additional detail or clarity. Such additional documentation may include, but is not limited to, a narrative summary of the case. Where appropriate, case documentation should be provided via screen prints/screen shots from the plan sponsor's (or PBM's) coverage determination/ redetermination/ grievance/ claims adjudication systems. The plan sponsor should mark each element on the screen print or provide a sample case as a legend.

I. Effectuation Timeliness - Coverage Determinations and Appeals

Minimum documentation to include:

1. For requests for coverage determination or redetermination:
 - a. Initial request:
 - i. If request was received via fax/mail/email, copy of original request including date/time stamp of receipt.
 - ii. If request was received via phone, copy of CSR notes and/or documentation of call including date/time stamp of call and call details.
 - b. Where applicable, copy of all notices, letters, call logs, or other documentation showing when the plan sponsor requested additional information from the prescriber including date/time stamp of the request. If the request was made via phone call, copy of call log detailing what was communicated to the prescriber.
 - c. Copy of all supplemental information submitted by the prescriber.
 - d. Documentation of effectuation including approval in coverage determinations/ redeterminations system(s) and evidence of effectuation in sponsor claims system clearly showing date and time override was entered. For approved exception requests, proof that the approval is good for the remainder of the plan year.
 - e. Documentation showing approval notification to the beneficiary and/or their representative and prescriber, as applicable.
 - i. Copy of the written decision letter and documentation of date/time letter was printed and mailed.
 - ii. If oral notification was given, copy of CSR notes and/or documentation of call including date/time stamp.
 - f. Screen print of all claims for the requested drug after effectuation dates.
 - i. If rejection, explanation for why drug rejected (i.e. refill too soon).\
 - ii. If there are no claims for drug after date of effectuation, narrative explaining member has not attempted to receive the drug since date of

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effectuation and a screen print showing all claims for member since date of effectuation.

2. For cases overturned by IRE/ALJ/MAC:
 - a. Copy of overturn notice from IRE/ALJ/MAC including date/time stamp of receipt by plan sponsor.
 - b. Documentation of effectuation including approval in coverage determinations/redeterminations system(s) and evidence of effectuation in sponsor claims system clearly showing date and time override was entered. For approved exception requests, proof that the approval is good for the remainder of the plan year.
 - c. Copy of effectuation notice to IRE/ALJ/MAC including sent date/time stamp.
 - d. Screen print of all claims for the requested drug after effectuation dates.
 - i. If rejection, explanation for why drug rejected (i.e. refill too soon).
 - ii. If there are no claims for drug after date of effectuation, narrative explaining member has not attempted to receive the drug since date of effectuation and a screen print showing all claims for member since date of effectuation.

II. Appropriateness of Clinical Decision-Making & Compliance with CDA Processing Requirements

Minimum documentation to include:

1. For requests for coverage determination or redetermination
 - a. Initial request:
 - i. If request was received via fax/mail/email, copy of original request including date/time stamp of receipt.
 - ii. If request was received via phone, copy of CSR notes and/or documentation of call including date/time stamp of call.
 - b. Where applicable, copy of all notices, letters, call logs, or other documentation showing when the plan sponsor requested additional information from the prescriber including date/time stamp of the request. If the request was made via phone call, copy of call log detailing what was communicated to the prescriber.
 - c. Copy of all supplemental information submitted by the prescriber.
 - i. If information was received via fax/mail/email, copy of documentation provided including date/time stamp and call details.
 - ii. If information was received via phone, copy of CSR notes and/or documentation of call including date/time stamp
 - d. Documentation of case review steps including name and title of final reviewer and rationale for denial. This may include but is not limited to: Sponsor

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formulary/EOC, Sponsor clinical criteria, Federal Regulations, CMS Guidance, compendia, peer reviewed literature (where allowed), or any other documentation used when considering the request.

- e. Documentation showing denial notification to the beneficiary and/or their representative and prescriber, if applicable.
 - i. Copy of the written decision letter and documentation of date/time letter was printed and mailed.
 - ii. If oral notification was given, copy of CSR notes and/or documentation of call including date/time stamp.
 - f. If case was untimely, include the following:
 - i. Narrative explaining reason case was not processed timely.
 - ii. Narrative explaining how case was discovered as untimely.
 - iii. Screen print showing date/time case was forwarded to the IRE.
 - iv. Documentation showing when the beneficiary was notified their case had been forwarded to the IRE for review including copy of notification letter and screen print showing the date/time letter was printed and mailed.
2. For cases overturned by IRE/ALJ/MAC
- a. Copy of overturn notice from IRE/ALJ/MAC including date/time stamp of receipt by plan sponsor.
 - b. Documentation of effectuation including approval in coverage determinations/redeterminations system(s) and evidence of effectuation in sponsor claims system clearly showing date and time override was entered. For approved exception requests, proof that the approval is good for the remainder of the plan year.
 - c. Copy of effectuation notice to IRE/ALJ/MAC including sent date/time stamp.
 - d. Screen print of all claims for the requested drug after effectuation dates.
 - i. If rejection, explanation for why drug rejected (i.e. refill too soon).
 - ii. If there are no claims for drug after date of effectuation, narrative explaining member has not attempted to receive the drug since date of effectuation and a screen print showing all claims for member since date of effectuation.

III. Grievances

Minimum documentation to include:

1. Initial complaint:
 - a. If complaint was received via fax/mail/email, copy of original complaint including date/time stamp of receipt.
 - b. If request was received via phone, copy of CSR notes and/or documentation of call including date/time stamp of call and call details.

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2. Where applicable, copy of all notices, letters, call logs, or other documentation showing when the plan sponsor sent acknowledgement of grievance receipt to the beneficiary and/or requested additional information from the beneficiary and/or their representative date/time stamp of the request. If request was made via phone call, copy of call log detailing what was communicated to the enrollee.
3. If the enrollee is complaining about a specific drug or about not having received a drug, provide any information relative to rejected claims for that drug.
4. Copy of all supplemental information submitted by beneficiary and/or their representative.
 - a. If information was received via fax/mail/email, copy of documentation provided including date/time stamp.
 - b. If information was received via phone, copy of CSR notes and/or documentation of call including date/time stamp.
5. Documentation showing the steps the Sponsor took to resolve the issue, including appropriate correspondence with other departments within the organization, referral to sponsor's fraud, waste, and abuse department, outreach to network pharmacies, and description of the final resolution.
6. Documentation showing resolution notification to the beneficiary and/or their representative.
 - a. Copy of the written decision letter sent and documentation of date/time letter was printed and mailed.
 - b. If oral notification was given, copy of CSR notes and/or documentation of call including date/time stamp.