Part D Coverage Determinations, Appeals, and Grievances (CDAG)

PROGRAM AUDIT PROTOCOL AND DATA REQUEST

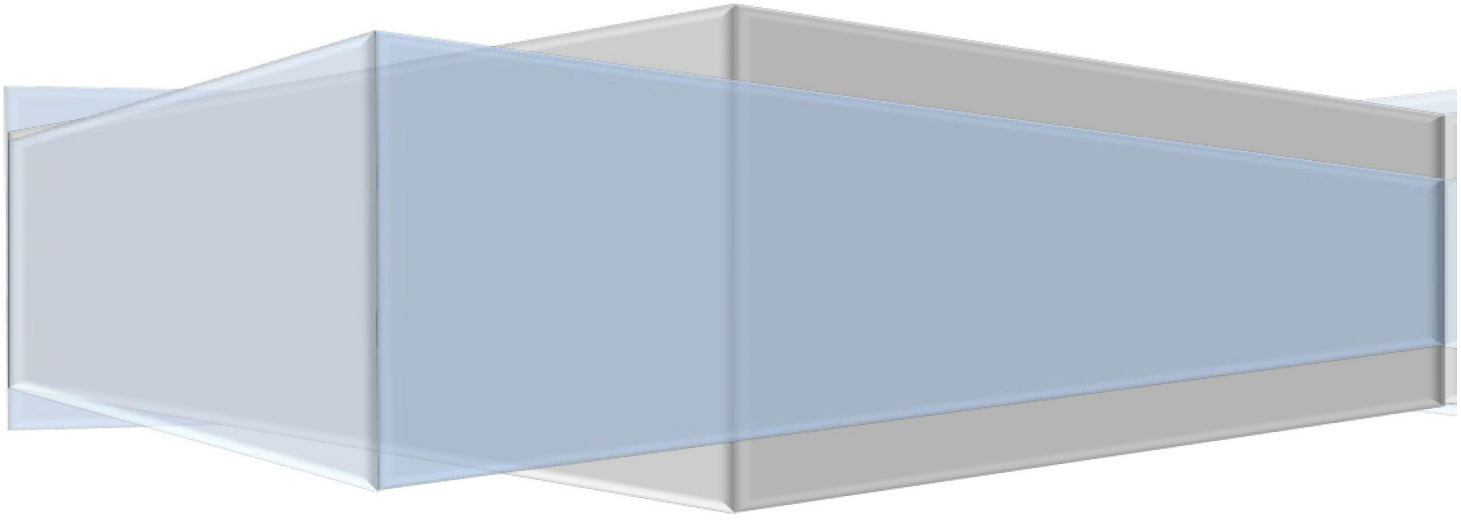

Table of Contents

Program Audit Protocol

Purpose

To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Coverage Determinations, Appeals and Grievances (CDAG). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CDAG Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below but reserves the right to modify its scope as requirements are added or revised and reserves the right to select additional samples if further investigation of an issue is required and/or replace samples if the original sample selection is not relevant to the review.

Audit Elements Tested

1. Timeliness
2. Processing of Coverage Requests
3. Classification of Requests

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Not Applicable	Universe Integrity Testing	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determination and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD) Universe Table 5: Part D Effectuations of Overturned Decisions by the IRE, ALJ, or MAC (EFF_D) Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Select 5 cases from each universe, Tables 1 through 6 for a total of 30 cases. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within the universe submissions, and to confirm effectuation of approved requests for each of the sampled cases. For Universe Table 2, verify during the webinar that the sampled cases are exception requests. Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization's systems and/or other supporting documentation. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.505(e) 42 CFR § 423.505(f)
Timeliness	1.1	Universe Table 1: Standard and Expedited Coverage Determination (CD)	Conduct timeliness test at the universe level on standard coverage determinations to determine whether the Sponsoring organization provided notification of its determination no later than 72 hours after receipt of the request.	42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Timeliness	1.2	Universe Table 1: Standard and Expedited Coverage Determination (CD)	Conduct timeliness test at the universe level on expedited coverage determinations to determine whether the Sponsoring organization provided notification of its determination no later than 24 hours after receipt of the request.	42 CFR § 423.572(a) 42 CFR § 423.572(b)
Timeliness	1.3	Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER)	Conduct timeliness test at the universe level on standard coverage determination exception requests to determine whether the Sponsoring organization provided notification of its determination no later than 72 hours after the Sponsoring organization received the physician's or other prescriber's supporting statement. If a supporting statement was not received by the end of 14 calendar days from receipt of the exceptions request, determine whether the Sponsoring organization provided notification of its determination no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.	42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(f)
Timeliness	1.4	Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER)	Conduct timeliness test at the universe level on expedited coverage determination exception requests to determine whether the Sponsoring organization provided notification of its determination no later than 24 hours after the Sponsoring organization received the physician's or other prescriber's supporting statement. If a supporting statement was not received by the end of 14 calendar days from receipt of the exceptions request, determine whether the Sponsoring organization provided notification of its determination no later than 24 hours from the end of 14 calendar days from receipt of the exceptions request.	42 CFR § 423.572(a) 42 CFR § 423.572(b)
Timeliness	1.5	Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D)	Conduct timeliness test at the universe level on payment coverage determinations to determine whether the Sponsoring organization provided notification of its determination and made payment (when applicable) no later than 14 calendar days after receipt of the request.	42 CFR § 423.568(c)
Timeliness	1.6	Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D)	Conduct timeliness test at the universe level on payment coverage redeterminations to determine whether the Sponsoring organization issued its redetermination no later than 14 calendar days after the Sponsoring organization received the redetermination request and made payment (when applicable) no later than 30 calendar days after receipt of the request.	42 CFR § 423.590(b) 42 CFR § 423.636(a)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Timeliness	1.7	Universe Table 4: Standard and Expedited Redeterminations (RD)	Conduct timeliness test at the universe level on standard redeterminations to determine whether the Sponsoring organization provided notification no later than 7 calendar days after receipt of the request.	42 CFR § 423.590(a)
Timeliness	1.8	Universe Table 4: Standard and Expedited Redeterminations (RD)	Conduct timeliness test at the universe level on expedited redeterminations to determine whether the Sponsoring organization provided notification no later than 72 hours after receipt of the request.	42 CFR § 423.590(d)
Timeliness	1.9	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on pre-benefit standard decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization authorized or provided the benefit under dispute no later than 72 hours after receipt of the notice reversing the determination.	42 CFR § 423.636(b)
Timeliness	1.10	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on standard at-risk determination decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization implemented the change to the at-risk determination no later than 72 hours after receipt of the notice reversing the determination.	42 CFR § 423.636(b)
Timeliness	1.11	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on post-service (payment) decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization authorized the payment no later than 72 hours after receipt of the notice reversing the determination and whether the Sponsoring organization made payment no later than 30 calendar days after receipt of the notice reversing the determination.	42 CFR § 423.636(b)
Timeliness	1.12	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on pre-benefit expedited decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization authorized or provided the benefit under dispute no later than 24 hours after receipt of the notice reversing the determination.	42 CFR § 423.638(b)
Timeliness	1.13	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on expedited at-risk determination decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization implemented the change to the at-risk determination no later than 24 hours after receipt of the notice reversing the determination.	42 CFR § 423.638(b)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Timeliness	1.14	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Conduct timeliness test at the universe level on standard grievances to determine whether the Sponsoring organization notified the enrollee of its decision no later than 30 calendar days after receipt of the grievance, or, if an extension was taken, no later than 44 calendar days after receipt of the grievance.	42 CFR § 423.564(e)
Timeliness	1.15	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Conduct timeliness test at the universe level on expedited grievances to determine whether the Sponsoring organization responded to the enrollee's grievance no later than 24 hours after receipt of the grievance.	42 CFR § 423.564(f)
Timeliness	1.16	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Conduct review at the universe level. If notification was untimely and auto-forwarding to the Independent Review Entity (IRE) is required, determine if the Sponsoring organization auto-forwarded the case to the IRE. Also determine if the Sponsoring organization auto-forwarded adverse at-risk redeterminations to the IRE. Determine the total number of cases in Tables 1-4, the number of cases in Tables 1-4 that required auto-forwarding to the IRE, and the total number of cases in Tables 1-4 that were not auto-forwarded to the IRE as required.	42 CFR § 423.568(h) 42 CFR § 423.572(d) 42 CFR § 423.578(c) 42 CFR § 423.590(c) 42 CFR § 423.590(e) 42 CFR § 423.590(i)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.1	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Select up to 10 approval cases. Ensure sample set represents various types of CDs (e.g., prior authorization, step therapy authorization, tiering exception, formulary exception (including both non-formulary drugs and formulary drugs with a UM requirement, reimbursement request etc.). Also sample reopening case(s) and review case file documentation for proper reopening and notification. For each approval case, review case file documentation for proper notification of the approval decision. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. If a prescriber requested the coverage, review case file to determine if notification of the decision was also sent to the prescriber. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.560 42 CFR § 423.566 42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(e) 42 CFR § 423.572(a) 42 CFR § 423.572(c) 42 CFR § 423.590(a) 42 CFR § 423.590(d) 42 CFR § 423.590(h) 42 CFR § 423.1980 42 CFR § 423.1982 42 CFR § 423.1986

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.2	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	For each sampled approval case, review case file documentation for proper effectuation and duration.	42 CFR § 423.578(c)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.3	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Select up to 30 denial cases. Target cases that are protected class drug denials. Ensure sample set represents various types of CDs (e.g., prior authorization, step therapy authorization, tiering exception, formulary exception, including both non-formulary drugs and formulary drugs with a UM requirement, reimbursement request etc.). Also sample reopening case(s) and review case file documentation for proper reopening and notification. For each denial case, review case file documentation for proper notification, appropriateness of the denial, and appropriate consideration of clinical information. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. If a prescriber requested the coverage, review case file to determine if notification of the decision was also sent to the prescriber. With respect to drugs which may be available under Part B, or under Part D, review case file documentation for coordination of all benefits administered by the Sponsoring organization. Review to determine whether the Sponsoring organization issued the determination and authorized or provided the benefit under Part B or Part D as expeditiously as the enrollee's health condition requires, in accordance with regulatory requirements. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 422.112(b)(7) 42 CFR § 423.560 42 CFR § 423.562(a) 42 CFR § 423.566 42 CFR § 423.568 42 CFR § 423.570 42 CFR § 423.572(a) 42 CFR § 423.572(c) 42 CFR § 423.578 42 CFR § 423.580 42 CFR § 423.590(d) 42 CFR § 423.590(g) 42 CFR § 423.1980 42 CFR § 423.1982 42 CFR § 423.1986

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.4	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D)	For each denial case sampled, review case file documentation for evidence that the Sponsoring organization's Medical Director (physician) or other appropriate health care professional with sufficient medical and other expertise reviewed the request for clinical accuracy.	42 CFR § 423.562(a) 42 CFR § 423.566(d)
Processing of Coverage Requests	2.5	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER)	For each case sampled, review case file documentation for proper downgrade from an expedited determination request to a standard determination and for proper notification to the enrollee and prescribing physician or other prescriber that explains that the Sponsoring organization must process the request using the 72 hour timeframe for standard determinations, informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Sponsoring organization not to expedite, informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support, and provides instructions about the Sponsoring organization's grievance process and its timeframes. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative.	42 CFR § 423.560 42 CFR § 423.570(c) 42 CFR § 423.570(d)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.6	Universe Table 3: Payment Coverage Determination and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	For the sampled redetermination cases review case file documentation for evidence that the person(s) who were involved in making the coverage determination did not conduct the redetermination, and if the denial of coverage was based on a lack of medical necessity, that the redetermination was made by a physician with expertise in the field of medicine that was appropriate for the services at issue.	42 CFR § 423.562(a) 42 CFR § 423.590(f)
Classification of Requests	3.1	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Select up to 10 dismissed cases from Tables 1-4. Review case file documentation to determine if the request was appropriately dismissed or whether it should have been treated as a coverage request or grievance. Review case file documentation for written notice of the dismissal stating the reason for the dismissal, the right to request that the Sponsoring organization vacate the dismissal action, and the right to request redetermination of the dismissal or to request review of the dismissal by the independent entity. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.560 42 CFR § 423.564 42 CFR § 423.566 42 CFR § 423.568(i) 42 CFR § 423.568(j) 42 CFR § 423.570(f) 42 CFR § 423.580 42 CFR § 423.582 42 CFR § 423.584 42 CFR § 423.590

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Classification of Requests	3.2	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Select up to 15 grievance sample cases from Table 6. Sample both oral and written grievances. Target samples that appear to relate to quality of care; involve multiple issues and do not appear in the coverage determination and redetermination universes; and appear to be misclassified requests. Review sample case file documentation to determine if proper notification (i.e., written or oral) was provided. If the Sponsoring organization extended the deadline, review case file for documentation stating how the delay is in the interest of the enrollee. Also review case file for written notification to the enrollee of the reason(s) for the delay. Review case file documentation to determine if the request was appropriately classified or whether it should have been treated as a coverage request or appeal. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.560 42 CFR § 423.564(a) 42 CFR § 423.564(b) 42 CFR § 423.564(e) 42 CFR § 423.564(g) 42 CFR § 423.566 42 CFR § 423.580 42 CFR § 423.582 42 CFR § 423.584

Program Audit Data Request: Audit Engagement and Universe Submission Phase

Universe Submissions

Sponsoring organizations must prepare each universe, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. The Excel or Text file must be converted into Zip file format (.zip) before uploading to the Health Plan Management System (HPMS) audit module. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Universe Requests

1. Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout
2. Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout
3. Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout
4. Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout
5. Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout
6. Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout

Universe Record Layout	Scope of Universe Request*
Table 1 Table 2 Table 3 Table 4 Table 5 Table 6	Sponsoring organizations with PDP/MAPD enrollment of – • <50,000 enrollees: submit the 12-week period preceding, and including, the date of the audit engagement letter. • ≥50,000 but <250,000 enrollees: submit the 8-week period preceding, and including, the date of the audit engagement letter. • ≥250,000 but <500,000 enrollees: submit the 4-week period preceding, and including, the date of the audit engagement letter. • ≥500,000 enrollees: submit the 2-week period preceding, and including, the date of the audit engagement letter.

***** CMS reserves the right to expand the review period.

General Record Layout Instructions:

- Exclude enrollees whose coverage is not yet effective as of the date of the engagement letter.
- Exclude requests that are pending a decision.
- Exclude requests where a decision has not been issued while the Sponsoring organization awaits the appropriate representative documentation.
- For all date fields submit in CCYY/MM/DD format (e.g., 2027/01/01).
- For all time fields submit in HH:MM:SS military time format (e.g., 23:59:59).
- Ensure dates and times are formatted as requested and that dates and times are listed in separate fields. All fields for a single line item within the universe must be submitted in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone.
- Sponsoring organizations may enter the time within universes instead of 'None' if the time is not required per the field description.
- Verify there are no blank fields.
- Do not skip any rows or columns.
- Ensure that all data fields are free of leading and/or trailing spaces.
- CMS expects the Sponsoring organization to validate all data submissions & universes before they are provided to CMS, including that the data is readable, complete, and contains the data or documentation specifically responsive to the request. CMS reserves the right to validate any and all data submissions.
- In cases where there is no data to be submitted for a record layout, upload a blank universe with headers with the following language "No Data to Report During the Review Period."

Please use the guidance below for the following record layout:

Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout

- Include all coverage determinations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period. The date of the Sponsoring organization's determination (Column ID U) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each coverage determination request must be listed as its own line item in the submitted universe.
    - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
    - Requests for a single drug involving multiple UM criteria (e.g., step therapy and a prior authorization) must be entered as a single line item, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
- Enter any request denied in whole or in part as Denied in the Request Determination field. For requests denied in part, include data regarding the approval and effectuation of the favorable portion of the decision in the applicable fields below.
- Exclude all requests processed as payment coverage determinations, direct member reimbursement requests, withdraws and exception requests.
- Exclude appeals of dismissals or requests to vacate dismissals.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP applicable for purposes of the request (e.g., 001). Enter None if there is no PBP number available.
F	Drug Name, Strength, and Dosage Form	Enter the drug name, strength, and dosage form requested.

Column ID	Field Name	Description
G	NDC	Enter the associated 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE. If there are no Part D ingredients for a multi-ingredient compound claim or the NDC is unknown enter None.
H	Is this a protected class drug?	Enter whether it is a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	Enter the date the request was received.
K	Time the request was received	Enter the time the request was received.
L	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Description
M	AOR/Equivalent notice Receipt Time	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
N	Request Determination	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
O	Was the request processed as Standard or Expedited?	Enter the manner by which the request was processed: • S for Standard • E for Expedited
P	Was the original request made under the standard timeframe and later requested to be expedited?	Enter: • Y for Yes • N for No • None if the request was made under the expedited timeframe.
Q	Date request was upgraded to expedited	Enter the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, their prescriber, or the Sponsoring organization determined the request should be expedited. Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.

Column ID	Field Name	Description
R	Time the request was upgraded to expedited	Enter the time the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the Sponsoring organization determined the request should be expedited. Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
S	Issue Description	Enter a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
T	Formulary UM Type	Enter the formulary UM criteria the enrollee satisfied or was attempting to satisfy. Enter: • PA for Prior Authorization • ST for Step Therapy • SE for Safety Edit If multiple formulary UM criteria apply, enter the criteria applicable based on the approval or denial reason. Enter None if the enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria.
U	Date of Determination	Enter the date of the determination. For dismissed cases, enter the date the Sponsoring organization dismissed the request.
V	Time of Determination	Enter the time of the determination. Enter None for dismissed cases.
W	Date effectuated in the system	Enter the date the approved decision was effectuated in the system. Enter None for requests that were not approved.

Column ID	Field Name	Description
X	Time effectuated in the system	Enter the time the approved decision was effectuated in the system. Enter None for requests that were not approved.
Y	Date oral notification provided to enrollee	Enter the date oral notification was provided to enrollee. Enter None for dismissed cases, if no oral notification was provided, or if oral notice was not successful.
Z	Time oral notification provided to enrollee	Enter the time oral notification was provided to enrollee. Enter None for dismissed cases, if no oral notification was provided, or if oral notice was not successful.
AA	Date written notification provided to enrollee	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.
AB	Time written notification provided to enrollee	Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Enter None for dismissed cases or if no written notification was provided.
AC	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative • P for prescribing physician or other prescriber Enter None if case was re-opened by the Sponsoring organization.

Column ID	Field Name	Description
AD	Date auto-forwarded to IRE	Enter the date the request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.
AE	Time auto-forwarded to IRE	Enter the time the request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout

- Include all coverage determination exception requests the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto- forwarded to the IRE or dismissed for Part D coverage during the universe request period. The date of the Sponsoring organization's determination (Column ID X) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each exception request must be listed as its own line item in the submitted universe.
    - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
    - Requests for a single drug involving multiple exception types (e.g., tiering exception, prior authorization exception, quantity limit exception, and step therapy exception) must be entered as a single line item, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
    - Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item in Universe Table 2 only, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
    - If a request has multiple exception types and includes a tiering exception, enter the case as a tiering exception.
- Enter any request denied in whole or in part as Denied in the Request Determination field. For requests denied in part, include data regarding the approval and effectuation of the favorable portion of the decision in the applicable fields below.
- Exclude all requests processed as payment coverage determinations, direct member reimbursement requests, withdraws, and non-exception request coverage determinations.
- Exclude appeals of dismissals or requests to vacate dismissals.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.

Column ID	Field Name	Description
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP applicable for purposes of the request (e.g., 001). Enter None if there is no PBP number available.
F	Drug Name, Strength, and Dosage Form	Enter the drug name, strength, and dosage form requested.
G	NDC	Enter the associated 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE. If there are no Part D ingredients for a multi-ingredient compound claim or the NDC is unknown enter None.
H	Is this a protected class drug?	Enter whether it was a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	Enter the date the request was received.
K	Time the request was received	Enter the time the request was received.

Column ID	Field Name	Description
L	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
M	AOR/Equivalent notice Receipt Time	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
N	Request Determination	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
O	Was the request processed as Standard or Expedited?	Enter the manner by which the request was processed: • S for Standard • E for Expedited
P	Was the original request made under the standard timeframe and later requested to be expedited?	Enter: • Y for Yes • N for No • None if the original request was made under the expedited timeframe.
Q	Date request was upgraded to expedited	Enter the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, their prescriber, or the Sponsoring organization determined the request should be expedited. Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.

Column ID	Field Name	Description
R	Time request was upgraded to expedited	Enter the time the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the Sponsoring organization determined the request should be expedited. Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
S	Issue Description	Provide a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
T	Exception Type	Enter the type of exception request: • Tiering exception • Non-formulary exception • Formulary UM exception • Hospice • Safety edit exception If multiple exception types apply, enter the exception type applicable based on the approval or denial reason.
U	UM Exception Type	If the case was a UM exception, indicate what criteria the enrollee was attempting to waive. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit exception, enter: • SE for Safety Edit Enter None if the request was not a UM exception or safety edit exception. If multiple UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.

Column ID	Field Name	Description
V	Date prescriber supporting statement received	Enter the date the prescriber's supporting statement was received. If the prescriber statement was received with the initial request, enter the date the exception request was received. Enter None if no prescriber supporting statement was received.
W	Time prescriber supporting statement received	Enter the time the prescriber's supporting statement was received. If the prescriber statement was received with the initial request, enter the time the exception request was received. Enter None if no prescriber supporting statement was received.
X	Date of Determination	Enter the date of the determination. For dismissed cases, enter the date the Sponsoring organization dismissed the request.
Y	Time of Determination	Enter the time of the determination. Enter None for dismissed cases.
Z	Date effectuated in the system	Enter the date the approved decision was effectuated in the system. Enter None if the exception was not approved.
AA	Time effectuated in the system	Enter the time the approved decision was effectuated in the system. Enter None if the exception was not approved.
AB	Expiration date of the approval	Enter the expiration date of the exception approval. Enter None if the exception was not approved.

Column ID	Field Name	Description
AC	Date oral notification provided to enrollee	Enter the date oral notification was provided to enrollee. Enter None for dismissed cases, if no oral notification was provided, or if oral notice was not successful.
AD	Time oral notification provided to enrollee	Enter the time oral notification was provided to enrollee Enter None for dismissed cases, if no oral notification was provided, or if oral notice was not successful.
AE	Date written notification provided to enrollee	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.
AF	Time written notification provided to enrollee	Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Enter None for dismissed cases or if no written notification was provided.
AG	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative • P for prescribing physician or other prescriber Enter None if case was re-opened by the Sponsoring organization.
AH	Date auto-forwarded to IRE	Enter the date the request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.
AI	Time auto-forwarded to IRE	Enter the time the request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout

- Include all payment coverage determinations and redeterminations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period. The date of the Sponsoring organization's determination (Column ID T) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each payment request must be listed as its own line item in the submitted universe.
    - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
    - Requests for a single drug must be entered as a single line item, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
    - If the payment request also requires a clinical review, the clinical review aspect of the case is not to be included within any other CDAG universes, include the request in Universe Table 3 only.
- Enter any request denied in whole or in part as Denied in the Request Determination field. For requests denied in part, include data regarding the approval and effectuation of the favorable portion of the decision in the applicable fields below.
- Exclude requests for coverage that were withdrawn.
- Exclude appeals of dismissals or requests to vacate dismissals.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP applicable for purposes of the request (e.g., 001). Enter None if there is no PBP number available.
F	Drug Name, Strength, and Dosage Form	Enter the drug name, strength, and dosage form requested.

Column ID	Field Name	Description
G	NDC	Enter the associated 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE. If there are no Part D ingredients for a multi-ingredient compound claim or the NDC is unknown enter None.
H	Is this a protected class drug?	Enter whether it was a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	Enter the date the request was received. If the Sponsoring organization obtained information establishing good cause after the 65-day filing timeframe, enter the date the Sponsoring organization received the information establishing good cause.
K	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Description
L	Type of Request	Enter: • Payment coverage determination • Payment redetermination
M	Request Determination	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
N	Was the request processed as an exception request?	Enter: • Y for Yes • N for No
O	Issue Description	Enter a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
P	Exception Type	Enter the type of exception request: • Tiering exception • Non-formulary exception • Formulary UM exception • Hospice • Safety edit exception If multiple exception types apply, enter the exception type applicable based on the approval or denial reason. Enter None if the request was not an exception request.
Q	UM Exception Type	If the case was a UM exception, indicate what criteria the enrollee was attempting to waive. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit exception enter: • SE for Safety Edit Enter None if the request was not a UM exception or safety edit exception. If multiple UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.

Column ID	Field Name	Description
R	Date prescriber supporting statement received	Enter the date the prescriber's supporting statement was received. If the prescriber statement was received with the initial request, enter the date the exception request was received. Enter None if no prescriber supporting statement was received.
S	Was the coverage determination request denied for lack of medical necessity?	Enter: • Y for Yes • N for No • None if the request was not denied (i.e., approved, auto- forwarded, dismissed).
T	Date of Determination	Enter the date of the determination. For dismissed cases, enter the date the Sponsoring organization dismissed the request.
U	Date effectuated in the system	Enter the date the approved decision was effectuated in the system. Enter None if the payment request was not approved.
V	Expiration date of the approval	Enter the expiration date of the exception approval. Enter None if the exception was not approved or if the request was not an exception request.
W	Date written notification provided to enrollee	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.

Column ID	Field Name	Description
X	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative • P for prescribing physician or other prescriber Enter None if case was re-opened by the Sponsoring organization.
Y	Date reimbursement provided	Enter the date the check or reimbursement was provided to the enrollee. Enter NRD if the request was approved but no reimbursement was due to the enrollee. Enter NP if the payment has not been issued at the time of the universe submission. Enter None if the request was not approved.
Z	Date auto-forwarded to IRE	Enter the date the request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout

- Include all redeterminations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period. The date of the Sponsoring organization's determination (Column ID X) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each redetermination request must be listed as its own line item in the submitted universe.
    - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
    - Requests for a single drug involving multiple UM criteria (e.g., step therapy and a prior authorization) must be entered as a single line item, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
    - Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
    - If a request has multiple exception types and includes a tiering exception, enter the case as a tiering exception.
- Enter any request denied in whole or in part as Denied in the Request Determination field. For requests denied in part, include data regarding the approval and effectuation of the favorable portion of the decision in the applicable fields below.
- Exclude all requests processed as payment redeterminations and withdrawn cases.
- Exclude an appeal of a dismissal or request to vacate a dismissal.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP applicable for purposes of the request (e.g., 001). Enter None if there is no PBP number available.

Column ID	Field Name	Description
F	Drug Name, Strength, and Dosage Form	Enter the drug name, strength, and dosage form requested. Enter None if not applicable.
G	NDC	Enter the associated 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE. If there are no Part D ingredients for a multi-ingredient compound claim or the NDC is unknown enter None.
H	Is this a protected class drug?	Enter whether it is a protected class drug: • Y for Yes • N for No • None if not applicable
I	Authorization or Claim Number	Enter the associated authorization or claim number for the redetermination request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	Enter the date the request was received. If the Sponsoring organization obtained information establishing good cause after the 65-day filing timeframe, enter the date the Sponsoring organization received the information establishing good cause.

Column ID	Field Name	Description
K	Time the request was received	Enter the time the request was received. If the Sponsoring organization obtained information establishing good cause after the 65-day filing timeframe, enter the time the Sponsoring organization received the information establishing good cause. Enter None for standard cases.
L	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
M	AOR/Equivalent notice Receipt Time	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None for standard cases or if no AOR or equivalent written notice was received or required.
N	Is this an appeal of an at-risk determination?	Enter whether it was an appeal of an at-risk determination (e.g., request for a change in pharmacy and/or prescriber limitations, request for a change in the enrollee's at-risk determination status): • Y for Yes • N for No
O	Request Determination	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
P	Was the request processed as Standard or Expedited?	Enter the manner by which the request was processed: • S for Standard • E for Expedited

Column ID	Field Name	Description
Q	Was the original request made under the standard timeframe and later requested to be expedited?	Enter: • Y for Yes • N for No • None if the request was made under the expedited timeframe
R	Date request was upgraded to expedited	Enter the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, their prescriber, or the Sponsoring organization determined the request should be expedited. Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
S	Time request was upgraded to expedited	Enter the time the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the Sponsoring organization determined the request should be expedited. Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
T	Issue Description	Enter a description of the redetermination issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
U	Exception Type	Enter the type of exception request: • Tiering exception • Non-formulary exception • Formulary UM exception • Hospice • Safety edit exception If multiple exception types apply, enter the exception type applicable based on the approval or denial reason. Enter None if the request was not an exception request.

Column ID	Field Name	Description
V	UM Exception Type	If the case was a UM exception, indicate what criteria the enrollee was attempting to waive. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit exception enter: • SE for Safety Edit Enter None if the request was not a UM exception or safety edit exception. If multiple UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.
W	Was the coverage determination request denied for lack of medical necessity?	Enter: • Y for Yes • N for No • None if the request was auto-forwarded
X	Date of Determination	Enter the date of the determination. For dismissed cases, enter the date the Sponsoring organization dismissed the request.
Y	Time of Determination	Enter the time of the determination. Enter None for standard cases and dismissed cases.
Z	Date effectuated in the system	Enter the date the approved decision was effectuated in the system. Enter None for requests that were not approved.
AA	Time effectuated in the system	Enter the time the approved decision was effectuated in the system. Enter None for standard cases and requests that were not approved.

Column ID	Field Name	Description
AB	Expiration date of the approval	Enter the expiration date of the exception approval. Enter None if the exception was not approved or if it is not an exception request.
AC	Date oral notification provided to enrollee	Enter the date oral notification was provided to enrollee. Enter None for standard cases, dismissed cases, if no oral notification was provided, or if oral notice was not successful.
AD	Time oral notification provided to enrollee	Enter the time oral notification was provided to enrollee. Enter None for standard cases, dismissed cases, if no oral notification was provided, or if oral notice was not successful.
AE	Date written notification provided to enrollee	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.
AF	Time written notification provided to enrollee	Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Enter None for standard cases, dismissed cases or if no written notification was provided.
AG	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative • P for prescribing physician or other prescriber Enter None if case was re-opened by the Sponsoring organization.

Column ID	Field Name	Description
AH	Date auto-forwarded to IRE	Enter the date the redetermination request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.
AI	Time auto-forwarded to IRE	Enter the time the redetermination request was auto-forwarded to the IRE. Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout

- Include all coverage determinations, redeterminations, or at-risk determinations fully or partially overturned by the IRE, ALJ, or MAC requiring an effectuation as pre-benefit, post-service (payment), or an at-risk determination received from the IRE, ALJ, or MAC during the universe request period. The date of the Sponsoring organization's receipt of the overturn decision (Column ID J) must fall within the universe request period.
- If a case contains multiple drugs, enter each drug in a separate row.
- Exclude any cases that were re-opened by the Sponsoring organization.
- Exclude any cases that were dismissed or upheld by the IRE, ALJ, or MAC.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP applicable for purposes of the request (e.g., 001). Enter None if there is no PBP number available.
F	Drug Name, Strength, and Dosage Form	Enter the drug name, strength, and dosage form requested. Enter None if not applicable.

Column ID	Field Name	Description
G	NDC	Enter the associated 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE. If there are no Part D ingredients for a multi-ingredient compound claim or the NDC is unknown enter None.
H	Is this a protected class drug?	Enter whether it is a protected class drug: • Y for Yes • N for No • None if not applicable
I	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the overturn decision was received	Enter the date the overturn decision was received.
K	Time the overturn decision was received	Enter the time the overturn decision was received.
L	Type of Request reversed by review entity	Enter the type of request. The priority of the case is determined by the review entity. • Standard request for benefits • Standard request for payment • Standard request for at-risk determination • Expedited request for benefits • Expedited request for at-risk determination

Column ID	Field Name	Description
M	Date the overturn decision was effectuated in the system	Enter the date the benefit was provided, payment was authorized or the change to the at-risk determination was implemented. Enter None if the overturn decision was not effectuated or if no effectuation was required.
N	Time the overturn decision was effectuated in the system	Enter the time the benefit was provided, payment was authorized or the change to the at-risk determination was implemented. Enter None if the overturn decision was not effectuated or if no effectuation was required.
O	Date reimbursement provided	Enter the date the check or reimbursement was provided to the enrollee. Enter NRD if the request was approved but no reimbursement was due to the enrollee. Enter NP if the payment has not been issued at the time of the universe submission. Enter None if it was not a post-service (payment) request.
P	Expiration date of the approval	Enter the expiration date of the exception approval. Enter None if it was not an exception request.

Please use the guidance below for the following record layout:

Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout

- Include all grievances the Sponsoring organization processed, dismissed or were withdrawn during the universe request period. For processed cases, include cases responded to during the universe request period. Also include any grievances older than 30 days as of the time of the engagement letter but that have not received a response. The date the Sponsoring organization issued the resolution notification or should have issued the notification (Column ID P or R) must fall within the universe request period.
- Grievances with multiple issues must be entered as a single line item, unless the Sponsoring organization issued multiple notifications. Each notification must be a separate line item.
- Include grievances that have been extended.
-
- Exclude complaints filed only within the Complaints Tracking Module (CTM) in HPMS. If a complaint was processed both within the CTM and was also received as a grievance, exclude the CTM complaint but include the grievance as processed by the Sponsoring organization.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001) applicable for purposes of the grievance. Enter None if there is no PBP number available.
F	Date the grievance was received	Enter the date the grievance was received.
G	Time the grievance was received	Enter the time the grievance was received. Enter None for standard cases.
H	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Description
I	AOR/Equivalent notice Receipt Time	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None for standard cases or if no AOR or equivalent written notice was received or required.
J	How was the grievance received?	Enter: • Oral • Written
K	Was the grievance processed as Standard or Expedited?	Enter: • S for Standard • E for Expedited
L	Category of the issue	Enter the category of the grievance as assigned by the Sponsoring organization. Enter based on the Sponsoring organization's internal labeling system. If multiple categories apply, enter each category separated by comma.
M	Grievance Description	Enter the description of the grievance.
N	Was this processed as a quality of care grievance?	Enter: • Y for Yes • N for No
O	Was a timeframe extension taken?	Enter: • Y for Yes • N for No
P	Date oral notification provided to enrollee	Enter the date oral notification was provided to enrollee. Enter None if no oral notification was provided or if oral notification was not successful.
Q	Time oral notification provided to enrollee	Enter the time oral notification was provided to enrollee. Enter None for standard cases, if no oral notification was provided or if oral notification was not successful.
R	Date written notification provided to enrollee	Enter the date written notification was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.

Column ID	Field Name	Description
S	Time written notification provided to enrollee	Enter the time written notification was provided to enrollee. Enter None for standard cases or if no written notification was provided.
T	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative
U	Was the grievance withdrawn or dismissed?	Enter the disposition of the grievance: • W for withdrawn • D for dismissed • P if the grievance was processed and was not withdrawn or dismissed
V	Coverage Request Initiated?	Was a related coverage request (initial determination or redetermination) initiated as a result of the complaint/grievance being received? • Y for Yes • N for No
W	Date coverage request was initiated	Enter the date a coverage determination (initial determination or redetermination) was initiated following receipt of the grievance. Enter None if no coverage request was initiated.

Audit Field Work Phase

Sample Selection

During audit field work, CMS will review the selected samples to determine whether the Sponsoring organization is compliant with its Part D regulatory and contract requirements. If the audit fieldwork is done live via webinar, the Sponsoring organization will receive notice of the selected samples 1 hour in advance of the live review. CMS may conduct all or part of the review via desk review. If desk review is conducted, the Sponsoring organization will receive samples five (5) business days prior to fieldwork in order to prepare and submit full or partial case files. CMS will also prepare case file cover sheets for each type of file (approved coverage determination, denied coverage determination, etc.) that includes the specific documentation identified below that is applicable to each type of case.

Supporting Documentation Submissions

The Sponsoring organization must have access to, and the ability to save and upload, supporting documentation and data relevant for a particular case, including, but not limited to:

- The initial coverage request.
  - If request was received via fax/mail/email, copy of original request including date/time stamp of receipt.
  - If request was received via phone, copy of CSR notes and/or documentation of call including date/time stamp of call and call details.
- Copy of appointment of representative (AOR) or equivalent written notice, if patient's representative placed request and/or received response.
- Copy of all notices, letters, call logs, or other documentation showing when the Sponsoring organization requested additional information from the prescriber. If the request was made via phone call, copy of call log detailing what was communicated to the prescriber.
- Copy of all supplemental information submitted by the prescriber.
  - If information was received via fax/mail/email, copy of documentation provided including date/time stamp and call details.
  - If information was received via phone, copy of CSR notes and/or documentation of call including date/time stamp.
- Documentation of the decision (approved or denied), including:
  - Documentation showing denial, partial denial, or approval notification to the enrollee and/or their representative and prescriber, if applicable.
  - Name and title of final reviewer and rationale for the decision. Additional documentation will include, but is not limited to: Sponsoring organization formulary/EOC, Sponsoring organization clinical criteria, Federal Regulations, CMS Guidance, compendia, peer reviewed literature (where allowed), or any other documentation used when considering the request.
  - Copy of the written decision letter and documentation of date/time letter was mailed.
  - If oral notification was given, copy of CSR notes and/or documentation of call including date/time stamp.
- For approvals: documentation of effectuation of request, including:
  - Approval in coverage determinations/redeterminations system(s) and evidence of effectuation in Sponsoring organization claims system clearly showing date and time override was entered.
  - Documentation of paid or rejected claims following the approved coverage determination or redetermination.

  - For approved exception requests, proof that the approval is effective for the remainder of the plan year.
- If case was untimely:
  - Documentation showing when the Sponsoring organization auto-forwarded the request to the IRE.
- For reopenings:
  - Copy of any case notes as to why the decision was reopened,
  - Copy of any notice sent to the enrollee regarding the reason for the reopening,
  - Copy of all documentation relating to the decision of the reopening and any subsequent notification regarding the decision.
- If applicable, all documentation to support the Sponsoring organization's decision to process an expedited request under the standard timeframe, including any pertinent medical documentation, and any associated notices provided to the enrollee and the requesting provider/physician.
- If applicable, notice to the enrollee that their request is not being expedited and the right to file a grievance.
- All previous case history/ documentation of initial coverage determinations and/or redeterminations related to the overturn.
- Copy of overturn notice from IRE/ALJ/MAC including date/time stamp of receipt by Sponsoring organization.
- Documentation of effectuation including approval in coverage determinations/ redeterminations system(s) and evidence of effectuation in Sponsoring organization claims system clearly showing date/time the override was entered. For approved exception requests, proof that the approval is effective for the remainder of the plan year.
- Claims history for drug subsequent to the effectuation showing either paid or rejected claims.
- Copies of any case notes as to why the case was dismissed.
- Any notification regarding the dismissal.
- Initial complaint:
  - If complaint was received via fax/mail/email, copy of original complaint.
  - If request was received via phone, copy of CSR notes and/or documentation of call including the call details.
- Copy of appointment of representative (AOR) or equivalent written notice, if patient's representative filed grievance or received notification.
- Copy of all supplemental information submitted by enrollee and/or their representative.
  - If information was received via fax/mail/email, copy of documentation provided.
  - If information was received via phone, copy of CSR notes and/or documentation of call.
- Documentation showing the steps the Sponsoring organization took to resolve the issue, including appropriate correspondence with other departments within the organization, referral to Sponsoring organization's fraud, waste, and abuse department, outreach to network pharmacies, and description of the final response.
- Documentation showing response to the enrollee and/or their representative.
  - Copy of the written decision letter sent and documentation of date letter was mailed.
  - If oral notification was given, copy of CSR notes and/or documentation of call.
- Documentation that supports a Sponsoring organization's record layout population (e.g., mailroom policies).
- Documentation regarding timeliness.

Sponsoring organizations are expected to submit supporting documentation within two business days of the request unless otherwise instructed by CMS.

Root Cause Analysis Submissions

Sponsoring organizations may be required to provide a root cause analysis using the template provided by CMS. Sponsoring organizations have two business days from the date of request to respond.

Impact Analysis Submissions

When noncompliance with contract requirements is identified on audit, Sponsoring organizations must submit each requested impact analysis, comprehensive of all contracts and Plan Benefit Packages (PBPs) identified in the audit engagement letter using the requested impact analysis template. The Sponsoring organization must include all requests impacted by the issue of noncompliance during the impact analysis request period. Detailed descriptions along with clarifications of what must be included in each submission and data field are outlined in the corresponding excel document(s). Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each column. Sponsoring organizations must provide accurate and timely impact analysis submissions within 10 business days of the request. Submissions that do not strictly adhere to the data request specifications will be rejected.

Verification of Information Collected: CMS may conduct integrity tests to validate the accuracy of all universes, impact analyses, and other related documentation submitted in furtherance of the audit. If data integrity issues are noted, Sponsoring organizations may be required to resubmit their data.