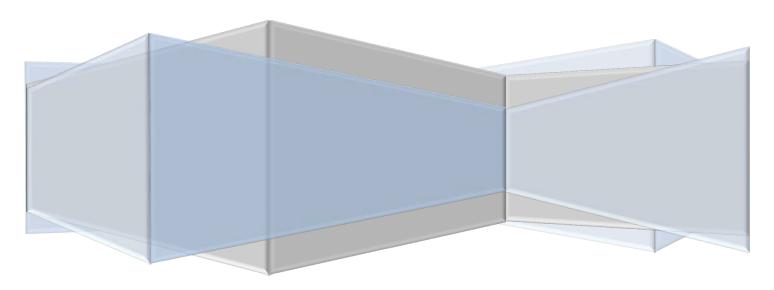


Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area

AUDIT PROCESS AND DATA REQUEST



PRA Disclosure Statement According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1000 (Expires: TBD). The time required to complete this information collection is estimated to average 701 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact 1-800-MEDICARE.

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Audit Purpose and General Guidelines

- 1. <u>Purpose</u>: To evaluate performance in the three areas outlined in this protocol related to coverage determinations, appeals, and grievances (CDAG). The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).
- **2. Review Period**: The review period for the CDAG Program Area will be decided based on your organization's total enrollment. CMS reserves the right to expand the review period to ensure sufficient universe size.
 - Plans with <50,000 enrollees: The review period will be the 3-month period preceding and including the date of the audit engagement letter.
 - Plans with \geq 50,000 but <250,000 enrollees: The review period will be the 2-month period preceding and including the date of the audit engagement letter.
 - Plans with ≥250,000 enrollees: The review period will be the 1-month period preceding and including the date of the audit engagement letter.
- 3. Responding to Documentation Requests: The sponsor is expected to present its supporting documentation during the audit and take screen shots or otherwise upload the supporting documentation, as requested, to the secure site using the designated naming convention and within the timeframe specified by the CMS Audit Team.
- 4. Sponsor Disclosed Issues: Sponsors will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS <u>prior</u> to the receipt of the audit start notice (which is also known as the "engagement letter"). Issues identified by CMS through ongoing monitoring or other account management/oversight activities during the plan year are not considered disclosed.

Sponsors must provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary template. This template is due within 5 business days after the receipt of the audit start notice. The sponsor's Account Manager will review the summary to validate that "disclosed" issues were known to CMS prior to receipt of the audit start notice.

When CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to beneficiaries has been mitigated, CMS will not apply the ICAR condition classification to that condition.

- 5. Impact Analysis (IA): An impact analysis must be submitted as requested by CMS. The impact analysis must identify all beneficiaries subjected to or impacted by the issue of non-compliance. Sponsors will have up to 10 business days to complete the requested impact analysis templates. CMS may validate the accuracy of the impact analysis submission(s). In the event an impact analysis cannot be produced, CMS will report that the scope of non-compliance could not be fully measured and impacted an unknown number of beneficiaries across all contracts audited.
- **6.** Calculation of Score: CMS will determine if each condition cited is an Observation (0 points), Corrective Action Required (CAR) (1 point) or an Immediate Corrective Action Required (ICAR) (2 points). Invalid Data Submission (IDS) conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts. IDS conditions will be worth one point.

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CMS will then add the score for that audit element to the scores for the remainder of the audit elements in a given protocol and then divide that number (i.e., total score), by the number of audit elements tested to determine the sponsor's overall CDAG audit score. Some elements and program areas may not apply to certain sponsors and therefore will not be considered when calculating program area and overall audit scores. Observations will be recorded in the draft and final reports, but will not be scored and therefore will not be included in the program area and audit scores.

7. Informing Sponsor of Results: CMS will provide daily updates regarding conditions discovered that day (unless the case has been pended for further review). CMS will provide a preliminary summary of its findings at the exit conference. The CMS Audit team will do its best to be as transparent and timely as possible in its communication of audit findings. Sponsors will also receive a draft audit report which they may formally comment on and then a final report will be issued after consideration of a sponsor's comments on the draft.

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Universe Preparation & Submission

1. Responding to Universe Requests: The sponsor is expected to provide accurate and timely universe submissions within 15 business days of the engagement letter date. CMS may request a revised universe if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue was identified. Sponsors will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, 3 attempts may not always be feasible depending on when the data issues are identified and the potential for impact to the audit schedule. When multiple attempts are made, CMS will only use the last universe submitted.

If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third failed attempt, or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

2. Pull Universes: The universes collected for this program area test whether the sponsor has deficiencies related to timeliness, clinical decision making and appropriateness, and grievances and the misclassification of requests in the area of CDAG. Sponsors will provide universes of all of their expedited and standard coverage determinations (CDs) (e.g., prior authorization, step therapy authorization, etc.), all expedited and standard CD exception requests (prior authorization exception, non-formulary exception, tiering exception, etc.), all expedited and standard redeterminations (RDs), all direct member reimbursement requests (initial CDs, RDs, and overturns by review entities), all expedited and standard IRE, Administrative Law Judge (ALJ), or Medicare Appeals Council (MAC) determinations that overturned the sponsor's decision, and all expedited and standard grievances (e.g., written correspondence, calls received by customer service representatives, etc.).

Instructions for what should be included in each universe are listed above the tables listed in Appendix A. For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and Plan Benefit Packages (PBPs) in its organization as identified in the audit engagement letter (e.g., all standard tiering exception CDs for all contracts and PBPs in your organization).

The universes should be 1) all inclusive, regardless of whether the request was determined to be favorable, partially favorable, unfavorable, auto-forwarded, dismissed, or reopened and 2) submitted in the appropriate record layout as described in Appendix A. These record layouts include:

- Table 1: Standard Coverage Determinations (SCD) Record Layout
- Table 2: Standard Coverage Determination Exception Requests (SCDER) Record Layout
- Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout
- Table 4: Expedited Coverage Determinations (ECD) Record Layout
- Table 5: Expedited Coverage Determination Exception Requests (ECDER) Record Layout
- Table 6: Standard Redeterminations (SRD) Record Layout
- Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) Record Layout
- Table 8: Expedited Redeterminations (ERD) Record Layout
- Table 9: Standard IRE, ALJ or MAC Determinations (SIAM) Record Layout
- Table 10: Direct Member Reimbursements decided by review entity other than sponsor (DMRRE) Record Layout

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- Table 11: Expedited IRE, ALJ or MAC Determinations (EIAM) Record Layout
- Table 12: Standard Grievances Part D (SGD) Record Layout
- Table 13: Expedited Grievances Part D (EGD) Record Layout
- 3. Submit Universes to CMS: Sponsors should submit each universe in the Microsoft Excel (.xlsx) file format with a header row (or Text (.txt) file format without a header row) following the record layouts shown in Appendix A, Tables 1 through 13. The sponsor should submit its universes in whole and not separately for each contract and PBP. If the Sponsor does not have any cases responsive to a particular universe request (e.g., if there were no direct member reimbursement request redeterminations during the review period), the sponsor must upload an Excel spreadsheet to the Health Plan Management System (HPMS) at the appropriate universe level that includes a statement explaining it does not have responsive cases for this particular universe during the requested audit period.
- **4.** <u>Timeliness Tests</u>: CMS will run the tests indicated below on each universe. For the effectuation tests, auditors will determine percentage of timely cases from a sponsor's approvals (favorable cases). For the notification timeliness tests, auditors will determine the percentage of timely cases from a full universe of approvals and denials. If more than one universe tests the same compliance standard, multiple timeliness tests results will be merged for one overall score.

| TABLE # | RECORD LAYOUT | UNIVERSE | COMPLIANCE STANDARD TO APPLY | CRITERIA (EFF. JANUARY 1, 2020) | TEST |
|------------|------------------|---|--|--|-----------------------------|
| 1 | SCD* | Standard CDs | No later than 72 hours. Late cases must be autoforwarded to the IRE within 24 hours of the expiration of the timeframe. | 42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(f) 42 CFR § 423.568(h) | Effectuation Notification |
| 2 | SCDER* | Standard CD Exception Requests | No later than 72 hours from the time the prescriber's supporting statement was received. | 42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(f) 42 CFR § 423.568(h) 42 CFR § 423.578(c)(1) | Effectuation Notification |
| 3 | DMRCD* | Part D Direct Member Reimbursement Request CDs | No later than 14 days. If DMR request involves an exception the case may not be tolled pending receipt of a prescriber's supporting statement. | 42 CFR § 423.568(c) 42 CFR § 423.568(h) | Notification Reimbursement |
| 4 | ECD* | Expedited CDs | No later than 24 hours. Late cases must be autoforwarded to the IRE within 24 hours of the expiration of the timeframe. | 42 CFR § 423.572(a) 42 CFR § 423.572(b) 42 CFR § 423.572(d) 42 CFR § 423.578(c)(1) 42 CFR § 423.572(d) 42 CFR § 423.578(c)(1) | Effectuation Notification |

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| TABLE | DECORD | UNIVERSE | CESS AND DATA REC | | TECT |
|------------|------------------|--------------------------|---|---|---------------|
| TABLE # | RECORD LAYOUT | UNIVERSE | COMPLIANCE | CRITERIA (EFF. JANUARY 1, 2020) | TEST |
| # | LATOUT | | STANDARD TO APPLY | (EFF. JANUARI 1, 2020) | |
| 5 | ECDER* | Expedited CDs | No later than 24 | 42 CFR § 423.572(a) | Effectuation |
| 3 | ECDEK. | _ | hours from the time | 42 CFR § 423.572(a) 42 CFR § 423.572(b) | Effectuation |
| | | Exception Requests | the prescriber's | 42 CFR § 423.572(d) | |
| | | Requests | supporting statement | 42 CFR § 423.578(c)(1) | Notification |
| | | | is received | | |
| | | | | | |
| 6 | SRD* | Standard RDs | No later than 7 days. | 42 CFR § 423.590(a)(1) | Effectuation |
| | | | Late cases must be | 42 CFR § 423.590(a)(2) 42 CFR § 423.590(c) | |
| | | | auto-forwarded to the | 42 CFR § 423.636(a)(1) | Notification |
| | | | IRE within 24 hours | 42 CFR § 423.636(a)(3) | |
| | | | of the expiration of | | |
| 7 | DMDDD* | Part D Direct | the timeframe. | 40 CED 8 402 500/1\/1\ | NI-416141 |
| 7 | DMRRD* | | No later than 14 days. | 42 CFR § 423.590(b)(1) | Notification |
| | | Member Reimbursement | Check mailed within | 42 CFR § 423.590(b)(2) | |
| | | | 30 days. | 42 CFR § 423.590(c) | D : 1 |
| | | Request RDs | | 42 CFR § 423.636(a)(2) | Reimbursement |
| 8 | ERD* | Expedited RDs | No later than 72 | 42 CFR § 423.590(d)(1) | Effectuation |
| | | | hours. Late cases | 42 CFR § 423.590(d)(2) | |
| | | | must be auto- | 42 CFR § 423.590(e) | Notification |
| | | | forwarded to the IRE | 42 CFR § 423.638(a)(1) | rvomication |
| | | | within 24 hours of the | 42 CFR § 423.638(a)(2) | |
| | | | expiration of the | | |
| | | | timeframe. | | |
| 9 | SIAM* | Standard IRE, | Effectuation of | 42 CFR § 423.636(b)(1) | Effectuation |
| | | ALJ or MAC | benefit or authorized | | |
| | | Determinations | reimbursement within | | |
| | | | 72 hours of notice | | |
| 10 | D) (DDE: | D . D D' | from appeal entity. | | Ticc |
| 10 | DMRRE* | Part D Direct | No later than 72 | 40 OED 9 400 606/13/03 | Effectuation |
| | | Member | hours to authorize/ | 42 CFR § 423.636(b)(2) | Reimbursement |
| | | Reimbursement | effectuate | | |
| | | Requests | reimbursement. | | |
| | | decided by review entity | No later than 30 days from date notified of | | |
| | | other than | CD reversal to issue | | |
| | | | reimbursement. | | |
| | | sponsor | reminum sement. | | |

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| TABLE | RECORD | UNIVERSE | COMPLIANCE | CRITERIA | TEST |
|-------|--------|-----------------|------------------------|------------------------|--------------|
| # | LAYOUT | | STANDARD TO | (EFF. JANUARY 1, 2020) | |
| | | | APPLY | | |
| 11 | EIAM | Expedited IRE, | Effectuation of | 42 CFR § 423.638(b)(1) | Effectuation |
| | | ALJ or MAC | benefit within 24 | | |
| | | Determinations | hours of notice from | | |
| | | | appeal entity. | | |
| 12 | SGD | Standard | No later than 30 days, | 42 CFR § 423.564(e)(1) | Notification |
| | | Grievances Part | plus 14 days (totaling | 42 CFR § 423.564(e)(2) | |
| | | D | 44 days) if an | | |
| | | | extension is used. | | |
| | | | | | |
| | | | | | |
| 13 | EGD | Expedited | No later than 24 | 42 CFR § 423.564(f) | Notification |
| | | Grievances Part | hours. | | |
| | | D | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

^{*}These universes may be combined with at least one other universe to determine an overall compliance rate. Merges include:

- o SCD will be combined with SCDER for effectuation and notification
- o ECD will be combined with ECDER for effectuation and notification
- o DMRRD will be combined with SRD for notification
- o SCD, SCDER, DMRCD, ECD, ECDER, ERD, SRD, and DMRRD will be combined for an IRE auto-forward test
- o DMRRE will be combined with SIAM for effectuation

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Audit Elements

- I. Timeliness Coverage Determinations, Appeals and Grievances (TCDAG)

 (Performed via webinar prior to the entrance conference, results communicated to so
 - (Performed via webinar prior to the entrance conference, results communicated to sponsor during live portion of the audit)
- 1. <u>Select Sample Cases</u>: CMS will randomly select 5 cases from record layouts 1 through 13 for a total of up to 65 cases.
- 2. Verify Universe Submission: Prior to the live portion of the audit, CMS or its contractor, when applicable, will schedule a separate webinar with the sponsor to verify that the dates and times provided in the universe submissions are accurate. In addition, for the exception universes (SCDER and ECDER), CMS will be evaluating that the cases provided are actually exception requests. The sponsor should have available the information and documents necessary to demonstrate that the dates and times provided in the record layouts were accurate. The sponsor will need access to the following documents during both the pre-audit webinar and the live audit webinar and may be requested to produce screenshots of any of the following:

2.1. For requests for coverage determinations or redeterminations:

- Initial 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 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, including:
 - Documentation showing denial, partial denial, or approval notification to the beneficiary and/or their representative and prescriber, if applicable.
 - 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.
- Any other reports, system notes, or logs that document beneficiary notification.
- Documentation of effectuation of request, including:
 - Approval in coverage determinations/redeterminations system(s) and evidence of effectuation in sponsor claims system clearly showing date and time override was entered.
- If case was untimely, include the following:
 - Documentation showing when the sponsor auto-forwarded the request to the IRE.

2.2. For cases overturned by IRE/ALJ/MAC:

- Copy of overturn notice from IRE/ALJ/MAC including date/time stamp of receipt by sponsor.
- Documentation of effectuation including approval in coverage determinations/ redeterminations system(s) and evidence of effectuation in sponsor claims system clearly

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showing date/time the override was entered. For approved exception requests, proof that the approval is effective for the remainder of the plan year.

- Copy of effectuation notice to IRE/ALJ/MAC including sent date/time stamp.
- 3. <u>Apply Compliance Standard</u>: At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CDAG requirements not being met.
 - **3.1. Universe Accuracy Standard:** CMS will test Tables 1 13 by confirming the data through the 5 selected cases (65 total cases). The integrity of the universe will be questioned if more than 1 of the 5 sample cases observed during the audit does not match the data provided in the universe. If this occurs CMS will request a new universe to test timeliness for that universe. Sponsors will be expected to produce the new universe prior to the live portion of the audit per CMS instructions. If the sponsor cannot produce an accurate universe after three submissions, CMS will cite all applicable IDS conditions relative to timeliness.

Are the dates and times observed during the pre-audit webinar consistent with the timeliness fields in the universe submission?

3.2. Calculate Universe Timeliness: CMS or its contractor, when applicable, will then calculate the applicable timeliness tests as identified in the record layout chart above. Some universes will have two timeliness tests performed; one for effectuation of approvals and one for notification of all requests. Other universes may only have one timeliness test performed. For each timeliness test in the universe, the number of late cases will be divided by the total number of cases applicable for that test in each universe. For instance, for effectuation of standard coverage determinations, all approvals that were effectuated untimely will be divided by all approvals in the universe. Once the percentage of late cases is determined, CMS will calculate the percentage of timely cases (100% - % late cases) and apply the compliance threshold for that test.

CMS has determined 3 timeliness thresholds that apply to every test in each universe. Sponsors that fall at or above the first threshold will generally not be cited a condition. Sponsors that fall within the second threshold will generally be cited for a corrective action required (CAR) for unmet timeliness requirements. Sponsors falling below the third threshold may be cited an immediate corrective action (ICAR) for unmet timeliness requirements.

Are the sponsor's universes timely in accordance with the CMS compliance standards referenced in the table above?

4. Inform Sponsor of Results: CMS will inform the sponsor of the results of its analysis for each of the 13 universes supplied during the live audit portion of the review; including if any conditions will be cited, and if so, which condition(s).

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

- 1. Select Sample Cases: CMS will select a targeted sample of 40 cases (30 denials and 10 approvals) that appear clinically significant. CMS may select an additional 5 cases to review dismissals and/or re-openings to assess whether the request was appropriately classified and processed. CMS will attempt to ensure that the sample set is representative of various types of coverage determinations (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.). The sample set for the 40 clinical appropriateness cases will be generally selected from the universe categories as follows:
 - 10 coverage determination denials (standard cases)
 - 5 redetermination denials (standard cases)
 - 5 expedited cases (either coverage determination denials or redetermination denials)
 - 10 IRE, ALJ, or MAC overturns
 - 5 coverage determination approvals (standard and expedited)
 - 5 redetermination approvals (standard and expedited)

In sampling, CMS will ensure that 15 of the 30 denial cases are protected class drug denials. If the universe does not include a total of 15 different protected class drug denials, CMS will include as many as are in the universe to get closest to 15.

2. Review Sample Case Documentation: CMS will review all sample case file documentation for proper notification and clinical appropriateness of the decision. The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following:

2.1. For requests for coverage determinations or redeterminations:

- Initial request:
 - Copy of request, if request was received via fax/mail/email.
 - If request was received via phone, copy of CSR notes and/or documentation of call and call details.
- Copy of appointment of representative (AOR), or other conforming instrument, if patient's representative placed request and/or received response.
- Copy of all notices, letters, call logs, or other documentation showing when the sponsor 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 call details.
 - If information was received via phone, copy of CSR notes and/or documentation of call.
- Documentation of case review steps including any standard operating procedures or standard decision trees used by clinical personnel.
- Name and title of final reviewer and rationale for the decision. Additional documentation will include, but is not limited to: sponsor formulary/EOC, sponsor clinical criteria, Federal Regulations, CMS Guidance, compendia, peer reviewed

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literature (where allowed), or any other documentation used when considering the request.

- Documentation of the decision, including:
 - Documentation showing denial, partial denial, or approval notification to the beneficiary and/or their representative and prescriber, if applicable.
- Copy of the written decision letter.
- If oral notification was given, copy of CSR notes and/or documentation of call.
- Any other reports, system notes, or logs that document denial or approval of the request and beneficiary notification.
- For approvals, documentation of effectuation of request, 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 effective for the remainder of the plan year.
 - Documentation showing approval notification to the beneficiary and/or their representative and prescriber, as applicable.
- If rejection, explanation for why drug rejected (i.e., refill too soon).
- 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.
- 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.
- For dismissals::
 - A copy of the initial request
 - Copies of any case notes as to why the case was dismissed
 - Any notification regarding the dismissal.
- If applicable, all documentation to support the sponsor'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.

2.2. For cases overturned by IRE/ALJ/MAC:

- Copy of overturn notice from IRE/ALJ/MAC.
- Documentation of effectuation including approval in coverage determinations/ redeterminations system(s) and evidence of effectuation in sponsor claims system. For approved exception requests, proof that the approval is effective for the remainder of the plan year.
- Copy of effectuation notice to IRE/ALJ/MAC.
- Screen print of all claims for the requested drug after effectuation dates.
- If rejection, explanation for why drug rejected (i.e., refill too soon).
- 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.

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3. Apply Compliance Standard: At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CDAG requirements not being met.

3.1. Clinical Appropriateness/ Approvals:

- 3.1.1. Was appropriate notification (i.e., correct notice and approval language understandable for enrollee) provided to the enrollee (or authorized representative) and provider/physician, if applicable?
- 3.1.2.If representative received response, was an appointment of representative (AOR), or other conforming instrument, on file?
- 3.1.3. Was approval effectuated for appropriate length of time? (i.e., duration of therapy on CMS-approved PA criteria, end of the plan year, or prescriber-specified time)

3.2. Clinical Appropriateness/ Denials:

- 3.2.1. Was appropriate notification (i.e., correct notice and denial language detailed, specific to the facts of the case, understandable for enrollee; appeal rights; etc.) provided to the enrollee (or representative) and provider/physician, if applicable?
- 3.2.2.If representative received response, was an appointment of representative (AOR), or other conforming instrument, on file?
- 3.2.3. Was the request reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise including knowledge of Medicare coverage criteria?
- 3.2.4. Was the redetermination reviewed by a different physician with expertise in the field of medicine that is appropriate for the services at issue?
- 3.2.5.Did the sponsor appropriately consider clinical information and comply with CMS coverage and notification requirements?
- 3.2.6.Did the sponsor make reasonable and diligent efforts to obtain all medical records and other pertinent documentation within the required timeframes, as necessary?
- **3.3. IRE, ALJ, or MAC Overturns:** If a reviewer determines the IRE, ALJ or MAC reversal was in error, the sponsor will receive a score of pass for that case. For all other IRE, ALJ and MAC cases, apply the following compliance criteria:
 - 3.3.1.Did the IRE, ALJ or MAC receive additional information that would have changed the sponsor's decision to deny the case?
 - 3.3.2. Did the sponsor attempt to obtain that information?

3.4. For Dismissals and/or Re-openings:

- 3.4.1.Did the sponsor appropriately classify and process the coverage request?
- 3.4.2.If the request was a re-opening, did the sponsor follow 42 CFR 423 Subpart U requirements?
- **4.** Sample Case Results: CMS will test each of the 40 to 45 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

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III. Grievances and Misclassification of Requests

- 1. <u>Select Sample Cases</u>: CMS will select a targeted sample of 20 total grievances: 15 from the standard grievances record layout and 5 from the expedited grievances record layout (Appendix A, Tables 12 and 13). If the sponsor does not have enough expedited grievances, the auditors will sample additional cases from the standard grievance universe.
- 2. Review Sample Case Documentation: CMS will review all sample cases file documentation to determine that grievances were appropriately classified and that the notification properly addressed the issue raised in the grievance. The sponsor will need access to the following documents or audio files during the live webinar and may be requested to produce screenshots or transcripts of any of the following:

2.1 For Grievances:

- 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 other conforming instrument, if patient's representative filed grievance or received notification.
- Documentation explaining the grievance issue(s).
- Copy of all notices, letters, call logs, or other documentation showing when the sponsor received the grievance 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.
- If the enrollee is complaining about a specific drug or about not having received a drug, provide any information relative to the drug in question and whether a coverage request was initiated.
- Copy of all supplemental information submitted by beneficiary 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 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.
- Documentation showing resolution notification to the beneficiary and/or their representative.
 - Copy of the written decision letter sent and documentation of date/time letter was mailed.
 - If oral notification was given, copy of CSR notes and/or documentation of call.
- **3. Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CDAG requirements not being met.
 - 3.1. Was the case (e.g., grievance) or call correctly classified, and if not, was it quickly transferred to the appropriate process?

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- **3.2.** For grievances, did the grievance notification appropriately address all issues raised in the complaint?
- **4.** Sample Case Results: CMS will test each of the 20 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

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Appendix

Appendix A—Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts

The universes for the Part D Coverage Determination, Appeals and Grievances (CDAG) program area must be submitted in the Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Do not include the Column ID variable which is shown in the record layout as a reference for a field's column location in an Excel or Text file. Do not include additional information outside of what is dictated in the record layout. Submissions that do not strictly adhere to the record layout will be rejected.

Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field. Please ensure that all case information (dates and times) are included in the specific time zone that the case was received.

If you don't have data for any of the fields identified below, please discuss that with your Auditor in Charge (AIC) prior to populating or submitting your universes.

NOTE: There is a maximum of 4,000 characters per record row. Therefore, should additional characters be needed for a variable, enter this information on the next record at the appropriate start position.

Table 1: Standard Coverage Determinations (SCD) Record Layout

- <u>Include</u> all requests <u>processed</u> as standard coverage determinations.
- <u>Exclude</u> all direct member reimbursement requests, exception requests, withdrawn requests and requests <u>processed</u> as expedited coverage determinations.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|------------------------------|----------------------------|-----------------|---|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the coverage determination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |

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| | | | | TA REQUEST |
|--------|--|----------------------------|--------|--|
| Column | Field Name | Field Type | Field | Description |
| ID | | | Length | |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Was the beneficiary residing in a long term care facility? | CHAR Always Required | 1 | Indicate whether the beneficiary was identified as residing in a long term care facility when the coverage determination was received. Valid values are: Y = Yes N = No U = Unknown |
| Н | Date the request was received | CHAR Always Required | 10 | Provide the date the request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| I | Time the request was received | CHAR Always Required | 8 | Provide the time of day the request was received from the enrollee, their representative, or their prescriber. Time is in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if time is not available. |
| J | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |
| K | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| L | AOR Receipt Time | CHAR Always Required | 8 | Time the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in HH:MM:SS format (e.g., 23:45:59). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| M | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |

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| | | | | A REQUEST |
|--------------|--|----------------------------|-----------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| N | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. |
| | | | | When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. |
| | | | | If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. |
| | | | | For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "00000000000" consistent with the NDC 11 format. |
| О | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |
| P | Is this a protected class drug? | CHAR Always Required | 1 | Protected class drug Yes (Y)/No (N) indicator. |
| Q | Was request made under the expedited timeframe but processed by the plan under the standard timeframe? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the request made under expedited timeframe was processed under the standard timeframe based on plan deciding that expedited case was unnecessary. Answer NA if the request was made under the standard timeframe. |
| R | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed. |
| S | Was the request denied for lack of medical necessity? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether request denied for lack of medical necessity. Answer NA if the request was not denied (i.e., approved, auto-forwarded, dismissed). |
| Т | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| U | Time of plan decision | CHAR Always Required | 8 | Time of the plan decision (e.g., denied). Submit in HH:MM:SS military time format (e.g., 23:59:59). |
| V | Date effectuated in the plan's system | CHAR Always Required | 10 | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for requests that were not approved (e.g. denials/auto-forwards). |

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| | AUDIT PROCESS AND DATA REQUEST | | | | | |
|--------|--|----------------------------|--------|---|--|--|
| Column | Field Name | Field Type | Field | Description | | |
| ID | | | Length | | | |
| W | Time effectuated in the plan's system | CHAR Always Required | 8 | Time effectuated in the plan's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for requests that were not approved (e.g. denials/ auto-forwards). | | |
| X | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification provided to enrollee (or their authorized representative). Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. | | |
| Y | Time oral notification provided to enrollee | CHAR Always Required | 8 | Time oral notification provided to enrollee (or their authorized representative). Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no oral notification was provided to enrollee. | | |
| Z | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. | | |
| AA | Time written notification provided to enrollee | CHAR Always Required | 8 | Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided to enrollee. | | |
| AB | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. | | |
| AC | Time forwarded to IRE | CHAR Always Required | 8 | Provide the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for timely decision or if request was not forwarded to the IRE. | | |

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Table 2: Standard Coverage Determination Exception Requests (SCDER) Record Layout

- <u>Include</u> all requests <u>processed</u> as standard coverage determination exception requests.
- <u>Exclude</u> all requests <u>processed</u> as standard coverage determination requests, including direct member reimbursement requests resolved under the exceptions process.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|--|-------------------------|-----------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the coverage determination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Was the beneficiary residing in a long term care facility? | CHAR Always Required | 1 | Indicate whether the beneficiary was identified as residing in a long term care facility when the coverage determination was received. Valid values are: Y = Yes N = No U = Unknown |
| Н | Date the request was received | CHAR Always Required | 10 | Provide the date the request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |

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| | | IT PROCESS A | | |
|--------------|---|----------------------------|-----------------|--|
| Column ID | Field Name | Field Type | Field Length | Description |
| I | Time the request was received | CHAR Always Required | 8 | Provide the time of day the request was received from the enrollee, their representative, or their prescriber. Time is in HH:MM:SS military time format (e.g., 23:59:59). |
| J | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |
| K | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| L | AOR Receipt Time | CHAR Always Required | 8 | Time the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in HH:MM:SS format (e.g., 23:45:59). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| M | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |
| N | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "000000000000" consistent with the NDC 11 format. |
| O | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |

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| G 1 | | IT PROCESS | | |
|--------|---------------------------|------------|--------|--|
| Column | Field Name | Field Type | Field | Description |
| ID | T 11 | CHAD | Length | D 1 1 1 W (MALAY) |
| P | Is this a protected class | CHAR | 1 | Protected class drug Yes (Y)/No (N) |
| | drug? | Always | | indicator. |
| Q | Was request made | CHAR | 2 | Yes (Y)/No (N) indicator of whether the |
| | under the expedited | Always | | request made under expedited timeframe |
| | timeframe but | Required | | was processed under the standard |
| | processed by the | | | timeframe based on plan deciding that |
| | plan under the | | | expedited case was unnecessary. Answer |
| | standard timeframe? | | | NA if the request was made under the |
| D | T | CILLAD | 25 | standard timeframe. |
| R | Exception Type | CHAR | 25 | Type of exception request. Valid values |
| | | Always | | are: tiering exception, non-formulary |
| | | Required | | exception, formulary UM exception, |
| C | Francis IIM | CHAD | | hospice, and safety edit exception. |
| S | Formulary UM | CHAR | 2 | If the case was a formulary UM exception; |
| | Exception | Always | | please indicate what criteria the enrollee |
| | Туре | Required | | was attempting to waive. Valid fields are: |
| | | | | PA, ST, or QL. Enter NA if the request |
| | | | | was not a formulary UM exception. |
| T | List expiration date | CHAR | 10 | Expiration date of the exception approval. |
| | of the approval | Always | | Submit in CCYY/MM/DD format (e.g., |
| | | Required | | 2020/01/01). Answer NA if the exception |
| | | | | was not approved. |
| U | Date prescriber | CHAR | 10 | Date the prescriber's supporting statement |
| | supporting | Always | | was received. Submit in CCYY/MM/DD |
| | statement received | Required | | format (e.g., 2020/01/01). Answer NA if |
| | | | | no prescriber supporting statement was |
| X. | TD: '1 | CHAD | 0 | received. |
| V | Time prescriber | CHAR | 8 | Time the prescriber's supporting statement |
| | supporting | Always | | was received. Submit in HH:MM:SS |
| | statement received | Required | | military time format (e.g., 23:59:59). |
| | | | | Answer NA if no prescriber supporting |
| W | Danier Diamanitian | CHAD | 20 | statement was received. |
| W | Request Disposition | CHAR | 20 | Status of the request. Valid values are: |
| | | Always | | approved, denied, IRE auto-forward, |
| | | Required | | dismissed, re-opened approved, or re- opened denied. Answer NA if the |
| | | | | - F |
| | | | | request was never resolved/processed. |
| X | Was the request | CHAR | 2 | Yes (Y)/No (N) indicator of whether |
| | denied for lack of | Always | | request denied for lack of medical |
| | medical necessity? | Required | | necessity. Answer NA if the request was |
| | | | | not denied (i.e., approved, auto-forwarded, |
| | | | | dismissed). |
| Y | Date of plan decision | CHAR | 10 | Date of the plan decision (e.g., denied). |
| | | Always | | Submit in CCYY/MM/DD format (e.g., |
| | | Required | | 2020/01/01). |
| Z | Time of plan decision | CHAR | 8 | Time of the plan decision (e.g., denied). |
| | | Always | | Submit in HH:MM:SS military time |
| | | Required | | format (e.g., 23:59:59). |

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| Column | Field Name | Field Type | Field | Description |
|--------|---|----------------------------|--------|---|
| ID | rieiu Name | Field Type | Length | Description |
| AA | Date effectuated in the plan's system | CHAR Always Required | 10 | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for requests that were not approved (e.g., denials/ autoforwards). |
| AB | Time effectuated in the plan's system | CHAR Always Required | 8 | Time effectuated in the plan's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for requests that were not approved (e.g., denials/ auto-forwards). |
| AC | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification provided to enrollee (or their authorized representative). Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. |
| AD | Time oral notification provided to enrollee | CHAR Always Required | 8 | Time oral notification provided to enrollee (or their authorized representative). Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no oral notification was provided to enrollee. |
| AE | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. |
| AF | Time written notification provided to enrollee | CHAR Always Required | 8 | Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided to enrollee. |
| AG | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. |
| АН | Time forwarded to IRE | CHAR Always Required | 8 | Provide the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for timely decision or if request was not forwarded to the IRE. |

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Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout

- <u>Include</u> all requests <u>processed</u> as coverage determination direct member reimbursement requests.
- Exclude all requests processed as standard coverage determination requests.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|-------------------------------|----------------------------|--------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the coverage determination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Date the request was received | CHAR Always Required | 10 | Provide the date the request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Н | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |

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| | | | AND DATA I | |
|--------------|---|----------------------------|--------------|--|
| Column ID | Field Name | Field Type | Field Length | Description |
| I | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| J | Authorization or Claim Number | CHAR Always Required | 40 | The associated claim or payment request number assigned by the sponsor for this request. If a claim or payment request number is not available, please provide your internal tracking or case number. Answer NA if there is no claim, payment request or other tracking numbers available. |
| K | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |
| L | Was this request processed as an exception? | CHAR Always Required | 1 | Exception request Yes (Y)/No (N) indicator. |
| M | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "000000000000" consistent with the NDC 11 format. |
| N | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |
| 0 | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed. |

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| | | | AND DATA I | |
|--------------|--|----------------------------|--------------|--|
| Column ID | Field Name | Field Type | Field Length | Description |
| P | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Q | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. |
| R | Date reimbursement provided | CHAR Always Required | 10 | Date check or reimbursement provided to the enrollee (i.e., mailed to the enrollee). Submit in CCYY/MM/DD format (e.g., 2020/01/01). 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 NA if the request was not approved. |
| S | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. |

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Table 4: Expedited Coverage Determinations (ECD) Record Layout

- <u>Include</u> all requests <u>processed</u> as expedited coverage determination requests.
- Exclude all requests <u>processed</u> as exception requests.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|--|-------------------------|-----------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the coverage determination was received Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Was the beneficiary residing in a long term care facility? | CHAR Always Required | 1 | Indicate whether the beneficiary was identified as residing in a long term care facility when the coverage determination was received. Valid values are: Y = Yes N = No U = Unknown |
| Н | Date the request was received | CHAR Always Required | 10 | Provide the date the request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |

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| ~ · | | | S AND DATA | |
|--------------|---|----------------------------|--------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| I | Time the request was received | CHAR Always Required | 8 | Provide the time of day the request was received from the enrollee, their representative, or their prescriber. Time is in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if time is not available. |
| J | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |
| K | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| L | AOR Receipt Time | CHAR Always Required | 8 | Time the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in HH:MM:SS format (e.g., 23:45:59). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| M | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |
| N | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "0000000000000" consistent with the NDC 11 format. |
| О | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |

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| | | | S AND DATA | |
|--------------|--|----------------------------|--------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| P | Is this a protected class drug? | Always Required | 1 | Protected class drug Yes (Y)/No (N) indicator. |
| Q | Was request initially made under the standard timeframe but processed by the plan under the expedited timeframe? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the initial request made under the standard timeframe was processed under the expedited timeframe based on updated request to expedite from enrollee, their authorized representative, or their prescriber, or based on medical exigency as determined by the sponsor. Answer NA if the initial request was made under the expedited timeframe. |
| R | Date request was upgraded to expedited | CHAR Always Required | 10 | Provide the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the sponsor determined the request should be expedited. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if the initial request was made under the expedited timeframe. |
| S | Time request was upgraded to expedited | CHAR Always Required | 8 | Provide the time of day the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the sponsor determined the request should be expedited. Time is in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if the initial request was made under the expedited timeframe. |
| Т | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed. |
| U | Was the request denied for lack of medical necessity? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether request denied for lack of medical necessity. Answer NA if the request was not denied (i.e., approved, autoforwarded, dismissed). |
| V | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| W | Time of plan decision | CHAR Always Required | 8 | Time of the plan decision (e.g., denied). Submit in HH:MM:SS military time format (e.g., 23:59:59). |

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| AUDIT PROCESS AND DATA | | | | |
|------------------------|---|----------------------------|--------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| X | Date effectuated in the plan's system | CHAR Always Required | 10 | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for requests that were not approved (e.g., denials/auto-forwards). |
| Y | Time effectuated in the plan's system | CHAR Always Required | 8 | Time effectuated in the plan's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for requests that were not approved (e.g., denials/ auto-forwards). |
| Z | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification provided to enrollee (or their authorized representative). Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. |
| AA | Time oral notification provided to enrollee | CHAR Always Required | 8 | Time oral notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no oral notification was provided to enrollee. |
| AB | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. |
| AC | Time written notification provided to enrollee | CHAR Always Required | 8 | Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided to enrollee. |
| AD | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. |
| AE | Time forwarded to IRE | CHAR Always Required | 8 | Provide the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for timely decision or if request was not forwarded to the IRE. |

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Table 5: Expedited Coverage Determination Exception Requests (ECDER) Record Layout

- <u>Include</u> all request <u>processed</u> as expedited coverage determination exception requests.
- Exclude all requests processed as expedited coverage determination requests.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column | Field Name | Field Type | Field Length | Description |
|----------|--|--------------------|--------------|---|
| ID | Danafiaiana Finat | CHAR | 50 | First years of the honeficient |
| A | Beneficiary First Name | Always | 30 | First name of the beneficiary. |
| В | Beneficiary Last | CHAR | 50 | Last name of the beneficiary. |
| Б | Name | Always | 30 | Last name of the beneficiary. |
| С | Enrollment Effective | CHAR | 10 | Effective date of beneficiary's |
| | Date | Always | 10 | enrollment for the PBP that the |
| | Bute | Required | | beneficiary was enrolled in when the |
| | | rioquirou | | coverage determination was received. |
| | | | | Submit in CCYY/MM/DD format |
| | | | | (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR | 11 | Enter the Medicare Beneficiary |
| | | Always | | Identifier (MBI) of the enrollee. An |
| | | Required | | MBI is the non-intelligent unique |
| | | | | identifier that replaced the HICN on |
| | | | | Medicare cards as a result of The |
| | | | | Medicare Access and CHIP |
| | | | | Reauthorization Act (MACRA) of |
| | | | | 2015. The MBI contains uppercase |
| | | | | alphabetic and numeric characters |
| | | | | throughout the 11-digit identifier and |
| | | | | is unique to each Medicare enrollee. This number must be submitted |
| | | | | |
| - | G · · · ID | CHAD | _ | excluding hyphens or dashes. |
| E | Contract ID | CHAR | 5 | The contract number (e.g., H1234) of |
| F | Plan ID | Always CHAR | 3 | the organization. |
| Г | Pian ID | | 3 | The plan number (e.g., 001) of the organization. |
| <u>C</u> | Was the house Calour | Always | 1 | |
| G | Was the beneficiary | CHAR | 1 | Indicate whether the beneficiary was |
| | residing in a long term care facility? | Always Required | | identified as residing in a long term care facility when the coverage |
| | term care facility? | Required | | determination was received. Valid |
| | | | | values are: |
| | | | | Y = Yes |
| | | | | N = No |
| | | | | U = Unknown |
| Н | Date the request was | CHAR | 10 | Provide the date the request was |
| | received | Always | | received from the enrollee, their |
| | | Required | | representative, or their prescriber. |
| | | • | | Submit in CCYY/MM/DD format |
| | | | | (e.g., 2020/01/01). |

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| | | | S AND DATA K | |
|--------|-------------------------------|----------------|--------------|---|
| Column | Field Name | Field Type | Field Length | Description |
| ID | | | | |
| I | Time the request was received | CHAR Always | 8 | Provide the time of day the request was received from the enrollee, their |
| | received | Required | | representative, or their prescriber. |
| | | Required | | Time is in HH:MM:SS military time |
| | | | | format (e.g., 23:59:59). Answer NA if |
| | | | | time is not available. |
| J | Required AOR | CHAR | 1 | Yes (Y)/ No (N) indicator of whether |
| | | Always | | the request was made by a |
| | | Required | | representative or someone claiming to |
| | | | | be a representative. |
| K | AOR Receipt Date | CHAR | 10 | Date the Appointment of |
| | | Always | | Representative (AOR) form or other |
| | | Required | | appropriate documentation received |
| | | | | by the sponsor. Submit in |
| | | | | CCYY/MM/DD format (e.g., |
| | | | | 2020/01/01). Answer None if no |
| | | | | AOR was received. Answer NA if no |
| | | | | AOR form was required. |
| L | AOR Receipt Time | CHAR | 8 | Time the Appointment of |
| | _ | Always | | Representative (AOR) form or other |
| | | Required | | appropriate documentation received |
| | | | | by the sponsor. Submit in HH:MM:SS |
| | | | | format (e.g., 23:45:59). Answer None |
| | | | | if no AOR was received. Answer NA |
| | | | | if no AOR form was required. |
| M | Issue Description | CHAR | 2000 | Provide a description of the issue |
| | | Always | | and, for denials, an explanation of |
| | | Required | | why the decision was denied. |

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| Column | Field Name | Field Type | Field Length | Description |
|--------|--|----------------------------|--------------|--|
| N N | NDC | CHAR Always Required | 15 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "00000000000000" consistent with the NDC 11 format. |
| О | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |
| P | Is this a protected class drug? | CHAR Always Required | 1 | Protected class drug Yes (Y)/No (N) indicator. |
| Q | Was request initially made under the standard timeframe but processed by the plan under the expedited timeframe? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the initial request made under the standard timeframe was processed under the expedited timeframe based on updated request to expedite from enrollee, their authorized representative, or their prescriber, or based on medical exigency as determined by the sponsor. Answer NA if the initial request was made under the expedited timeframe. |

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| | AUDIT PROCESS AND DATA REQUEST | | | | | |
|--------------|--|----------------------------|--------------|---|--|--|
| Column ID | Field Name | Field Type | Field Length | Description | | |
| R | Date request was upgraded to expedited | CHAR Always Required | 10 | Provide the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the sponsor determined the request should be expedited. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if the initial request was made under the expedited timeframe. | | |
| S | Time request was upgraded to expedited | CHAR Always Required | 8 | Provide the time of day the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the sponsor determined the request should be expedited. Time is in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if the initial request was made under the expedited timeframe. | | |
| Т | Exception Type | CHAR Always Required | 25 | Type of exception request. Valid values are: tiering exception, non-formulary exception, formulary UM exception, hospice, and safety edit exception. | | |
| U | Formulary UM Exception Type | CHAR Always Required | 2 | If the case was a formulary UM exception; please indicate what criteria the enrollee was attempting to waive. Valid fields are: PA, ST, or QL. Enter NA if the request was not a formulary UM exception. | | |

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| AUDIT PROCESS AND DATA REQUEST | | | | | | |
|--------------------------------|---|----------------------------|--------------|---|--|--|
| Column ID | Field Name | Field Type | Field Length | Description | | |
| V | List expiration date of the approval | CHAR Always Required | 10 | Expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if the exception was not approved. | | |
| W | Date prescriber supporting statement received | CHAR Always Required | 10 | Date the prescriber's supporting statement was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no prescriber supporting statement was received. | | |
| X | Time prescriber supporting statement received | CHAR Always Required | 8 | Time the prescriber's supporting statement was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no prescriber supporting statement was received. | | |
| Y | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE autoforward, dismissed, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed. | | |
| Z | Was the request denied for lack of medical necessity? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether request denied for lack of medical necessity. Answer NA if the request was not denied (i.e., approved, autoforwarded, dismissed). | | |
| AA | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). | | |
| AB | Time of plan decision | CHAR Always Required | 8 | Time of the plan decision (e.g., denied). Submit in HH:MM:SS military time format (e.g., 23:59:59). | | |
| AC | Date effectuated in the plan's system | CHAR Always Required | 10 | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if request was not approved (e.g. denials/ auto- forwards). | | |
| AD | Time effectuated in the plan's system | CHAR Always Required | 8 | Time effectuated in the plan's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if request was not approved (e.g., denials/ autoforwards). | | |
| AE | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification provided to enrollee (or their authorized representative). Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. | | |

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| | AUDIT PROCESS AND DATA REQUEST | | | | | | | |
|--------|--|----------------------------|--------------|--|--|--|--|--|
| Column | Field Name | Field Type | Field Length | Description | | | | |
| ID | | | | | | | | |
| AF | Time oral notification provided to enrollee | CHAR Always Required | 8 | Time oral notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no oral notification was provided to enrollee. | | | | |
| AG | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. | | | | |
| АН | Time written notification provided to enrollee | CHAR Always Required | 8 | Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided to enrollee. | | | | |
| AI | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. | | | | |
| AJ | Time forwarded to IRE | CHAR Always Required | 8 | Provide the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for timely decision or if request was not forwarded to the IRE. | | | | |

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Table 6: Standard Redeterminations (SRD) Record Layout

- <u>Include</u> all requests <u>processed</u> as standard pre-service redetermination requests.
- <u>Exclude</u> requests <u>processed</u> as direct member reimbursement redetermination requests or expedited pre-service redetermination requests.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|-------------------------------|----------------------------|--------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the redetermination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Date the request was received | CHAR Always Required | 10 | Provide the date the redetermination request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Н | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |

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| | | | S AND DATA | |
|---------|--|----------------------------|--------------|---|
| Column | Field Name | Field Type | Field Length | Description |
| ID I | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| J | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |
| K | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "000000000000" consistent with the NDC 11 format. |
| L | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |
| M | Is this a protected class drug? | CHAR Always Required | 1 | Protected class drug Yes (Y)/No (N) indicator. |
| N | Was request made under the expedited timeframe but processed by the plan under the standard timeframe? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the request made under expedited timeframe was processed under the standard timeframe based on plan deciding that expedited case was unnecessary. Answer NA if the request was made under the standard timeframe. |
| 0 | Was this request processed as an exception? | CHAR Always Required | 1 | Exception request Yes (Y)/No (N) indicator. |

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| | | | S AND DATA | |
|--------------|---|----------------------------|--------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| P | Exception Type | CHAR Always Required | 25 | Type of exception request. Valid values are: tiering exception, non-formulary exception, formulary UM exception, hospice and safety edit exception. Answer NA if request was not processed as an exception. |
| Q | List expiration date of the approval | CHAR Always Required | 10 | Expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if request was not processed as an exception or if the exception was not approved. |
| R | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed. |
| S | Was the coverage determination request denied for lack of medical necessity? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether initial request denied for lack of medical necessity. |
| Т | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| U | Date effectuated in the plan's system | CHAR Always Required | 10 | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for requests that were not approved (e.g. denials/auto-forwards). |
| V | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. |
| W | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. |
| X | Time forwarded to IRE | CHAR Always Required | 8 | Provide the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for timely decision or if request was not forwarded to the IRE. |

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Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) Record Layout

- <u>Include</u> all requests <u>processed</u> as redeterminations for direct member reimbursement requests.
- Exclude all requests processed as pre-service redetermination requests.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|-------------------------------|----------------------------|--------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the redetermination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Date the request was received | CHAR Always Required | 10 | Provide the date the redetermination request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Н | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |
| I | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |

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| C I | Field Name | | AND DATA I | |
|--------------|---|----------------------------|--------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| J | Authorization or Claim Number | CHAR Always Required | 40 | The associated claim or payment request number assigned by the sponsor for this request. If a claim or payment request number is not available, please provide your internal tracking or case number. Answer NA if there is no claim, payment request or other tracking numbers available. |
| K | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |
| L | Was this request processed as an exception? | CHAR Always Required | 1 | Exception request Yes (Y)/No (N) indicator. |
| M | Exception Type | CHAR Always Required | 25 | Type of exception request. Valid values are: tiering exception, non-formulary exception, formulary UM exception and hospice. Answer NA if request was not processed as an exception. |
| N | List expiration date of the approval | CHAR Always Required | 10 | Expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if request was not processed as an exception or if the exception was not approved. |
| 0 | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "0000000000000" consistent with the NDC 11 format. |
| P | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |

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| | AUDIT PROCESS AND DATA REQUEST | | | | |
|--------------|---|----------------------------|--------------|--|--|
| Column ID | Field Name | Field Type | Field Length | Description | |
| Q | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed. | |
| R | Was the coverage determination request denied for lack of medical necessity? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether initial request denied for lack of medical necessity. | |
| S | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). | |
| Т | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. | |
| U | Date reimbursement provided | CHAR Always Required | 10 | Date check or reimbursement provided to the enrollee (i.e., mailed to the enrollee). Submit in CCYY/MM/DD format (e.g., 2020/01/01). 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 NA if the request was not approved. | |
| V | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. | |

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Table 8: Expedited Redeterminations (ERD) Record Layout

- <u>Include</u> all requests <u>processed</u> as expedited redetermination requests.
- Exclude all withdrawn requests.
- Submit cases based on the date the sponsor's decision was rendered or should have been rendered (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|-------------------------------|----------------------------|--------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the redetermination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Date the request was received | CHAR Always Required | 10 | Provide the date the redetermination request was received from the enrollee, their representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Н | Time the request was received | CHAR Always Required | 8 | Provide the time of day the redetermination request was received from the enrollee, their authorized representative, or their prescriber. Time is in HH:MM:SS military time format (e.g., 23:59:59). |
| Ι | Required AOR | CHAR Always Required | 1 | Yes (Y)/ No (N) indicator of whether the request was made by a representative or someone claiming to be a representative. |

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| | | | S AND DATA | |
|--------------|--------------------------------------|----------------------------|--------------|--|
| Column ID | Field Name | Field Type | Field Length | Description |
| J | AOR Receipt Date | CHAR Always Required | 10 | Date the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| K | AOR Receipt Time | CHAR Always Required | 8 | Time the Appointment of Representative (AOR) form or other appropriate documentation received by the sponsor. Submit in HH:MM:SS format (e.g., 23:45:59). Answer None if no AOR was received. Answer NA if no AOR form was required. |
| L | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue and, for denials, an explanation of why the decision was denied. |
| M | NDC | CHAR Always Required | 11 | Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "0000000000000" consistent with the NDC 11 format. |
| N | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |
| 0 | Is this a protected class drug? | CHAR Always Required | 1 | Protected class drug Yes (Y)/No (N) indicator. |

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| | | | S AND DATA | |
|--------------|--|----------------------------|--------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| P | Was request initially made under the standard timeframe but processed by the plan under the expedited timeframe? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the initial request made under the standard timeframe was processed under the expedited timeframe based on updated request to expedite from enrollee, their authorized representative, or their prescriber, or based on medical exigency as determined by the sponsor. Answer NA if the initial request was made under the expedited timeframe. |
| Q | Date request was upgraded to expedited | CHAR Always Required | 10 | Provide the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the sponsor determined the request should be expedited. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if the initial request was made under the expedited timeframe. |
| R | Time request was upgraded to expedited | CHAR Always Required | 8 | Provide the time of day the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the sponsor determined the request should be expedited. Time is in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if the initial request was made under the expedited timeframe. |
| S | Was this request processed as an exception? | CHAR Always Required | 1 | Exception request Yes (Y)/No (N) indicator. |
| T | Exception Type | CHAR Always Required | 25 | Type of exception request. Valid values are: tiering exception, non-formulary exception, formulary UM exception, hospice and safety edit exception. Answer NA if request was not processed as an exception request. |
| U | List expiration date of the approval | CHAR Always Required | 10 | Expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if request was not processed as an exception or if the exception was not approved. |
| V | Request Disposition | CHAR Always Required | 20 | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, re-opened approved or re-opened denied. Answer NA if the request was never resolved/processed. |

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| | | | <u>S AND DATA</u> | |
|--------------|---|----------------------------|-------------------|---|
| Column ID | Field Name | Field Type | Field Length | Description |
| W | Was the coverage determination request denied for lack of medical necessity? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether initial request denied for lack of medical necessity. |
| X | Date of plan decision | CHAR Always Required | 10 | Date of the plan decision (e.g., denied). Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Y | Time of plan decision | CHAR Always Required | 8 | Time of the plan decision (e.g., denied). Submit in HH:MM:SS military time format (e.g., 23:59:59). |
| Z | Date effectuated in the plan's system | CHAR Always Required | 10 | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for requests that were not approved (e.g. denials/auto-forwards). |
| AA | Time effectuated in the plan's system | CHAR Always Required | 8 | Time effectuated in the plan's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if the request was not approved (e.g., denied/ auto-forward). |
| AB | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification provided to enrollee (or their authorized representative). Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. |
| AC | Time oral notification provided to enrollee | CHAR Always Required | 8 | Time oral notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no oral notification was provided to enrollee. |
| AD | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. |
| AE | Time written notification provided to enrollee | CHAR Always Required | 8 | Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided to enrollee. |
| AF | Date forwarded to IRE | CHAR Always Required | 10 | Provide the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA for timely decision or if request was not forwarded to the IRE. |
| AG | Time forwarded to IRE | CHAR Always Required | 8 | Provide the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA for timely decision or if request was not forwarded to the IRE. |

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Table 9: Standard IRE, ALJ or MAC Determinations (SIAM) Record Layout

- <u>Include</u> all requests <u>processed</u> as standard pre-service coverage determination or redetermination requests that were overturned by the IRE, ALJ, or MAC. This includes requests that were auto-forwarded to the IRE and overturned by the IRE, ALJ, or MAC (i.e., a favorable decision was rendered).
- Exclude all requests processed as reimbursement requests or expedited requests.
- Exclude all withdrawn requests.
- Submit cases based on the date of receipt of the IRE, ALJ, or MAC overturn decision (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|---|----------------------------|--------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the coverage determination or redetermination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue. |
| Н | Was this request processed as an exception? | CHAR Always Required | 1 | Exception request Yes (Y)/No (N) indicator. |
| I | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |

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| | AUDIT PROCESS AND DATA REQUEST | | | | |
|--------|--------------------------------|------------|--------------|---|--|
| Column | Field Name | Field Type | Field Length | Description | |
| ID | | | | | |
| J | Date of receipt of | CHAR | 10 | Date the sponsor received the | |
| | IRE/ALJ/MAC | Always | | IRE/ALJ/MAC overturn decision. | |
| | decision | Required | | Submit in CCYY/MM/DD format (e.g., | |
| | | | | 2020/01/01). | |
| K | Time of receipt for | CHAR | 8 | Time the sponsor received the | |
| | IRE/ALJ/MAC | Always | | IRE/ALJ/MAC overturn decision. | |
| | decision | Required | | Submit in HH:MM:SS military time | |
| | | | | format (e.g., 23:59:59). | |
| L | Date effectuated in the | CHAR | 10 | Date overturn decision effectuated in the | |
| | plan's system | Always | | plan's system. Submit in | |
| | | Required | | CCYY/MM/DD format (e.g., | |
| | | | | 2020/01/01). Answer NA if not | |
| | | | | effectuated in the plan's system. | |
| M | Time effectuated in the | CHAR | 8 | Time overturn decision effectuated in | |
| | plan's system | Always | | the plan's system. Submit in HH:MM:SS | |
| | | Required | | military time format (e.g., 23:59:59). | |
| | | | | Answer NA if not effectuated in the | |
| | | | | plan's system. | |
| N | List expiration date of | CHAR | 10 | Expiration date of the exception | |
| | the exception approval | Always | | approval. Submit in CCYY/MM/DD | |
| | | Required | | format (e.g., 2020/01/01). Answer NA if | |
| | | | | request was not processed as an | |
| | | | | exception or if the exception was not | |
| | | | | approved. | |

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Table 10: Direct Member Reimbursements decided by review entity other than sponsor (DMRRE) Record Layout

- <u>Include</u> all requests <u>processed</u> as coverage determination or redetermination reimbursement requests that were overturned by the IRE, ALJ, or MAC. This includes requests that were auto-forwarded to the IRE and overturned by the IRE, ALJ, or MAC (i.e., a favorable decision was rendered).
- Exclude all withdrawn requests.
- <u>Exclude</u> all requests <u>processed</u> as pre-service coverage determination or redetermination requests.
- Submit cases based on the date of receipt of the IRE, ALJ, or MAC overturn decision (the date the request was initiated may fall outside of the review period).

| Column | Field Name | Field Type | Field Length | Description |
|---------|----------------------------------|----------------------------|--------------|--|
| ID A | Beneficiary First | CHAR | 50 | First name of the beneficiary. |
| | Name | Always Required | | |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the reimbursement (coverage determination or redetermination) was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Authorization or Claim Number | CHAR Always Required | 40 | The associated claim or payment request number assigned by the sponsor for this request. If a claim or payment request number is not available, please provide your internal tracking or case number. Answer NA if there is no claim, payment request or other tracking numbers available. |

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| | AUDIT PROCESS AND DATA REQUEST | | | | | |
|--------|--------------------------------|------------|--------------|--|--|--|
| Column | Field Name | Field Type | Field Length | Description | | |
| ID | | | | | | |
| Н | Issue Description | CHAR | 2000 | Provide a description of the issue. | | |
| | | Always | | | | |
| | | Required | | | | |
| I | Was this request | CHAR | 1 | Exception request Yes (Y)/No (N) | | |
| | processed as an | Always | | indicator. | | |
| | exception? | Required | | | | |
| J | Drug Name, Strength | CHAR | 150 | Provide the drug name, strength, and | | |
| | & Dosage Form | Always | | dosage form. | | |
| | | Required | | | | |
| K | Date of receipt of | CHAR | 10 | Date the sponsor received the | | |
| | IRE/ALJ/MAC | Always | | IRE/ALJ/MAC overturn decision. Submit | | |
| | decision | Required | | in CCYY/MM/DD format (e.g., | | |
| | | | | 2020/01/01). | | |
| L | Date sponsor | CHAR | 10 | Date that appeal entity overturn was | | |
| | authorized | Always | | authorized in the plan's system. Submit in | | |
| | reimbursement of | Required | | CCYY/MM/DD format (e.g., 2020/01/01). | | |
| | overturn decision in | | | Answer NA if reimbursement was not | | |
| | their system | CYY L D | 10 | authorized. | | |
| M | Date reimbursement | CHAR | 10 | Date check or reimbursement provided to | | |
| | provided | Always | | the enrollee (i.e., mailed to the enrollee). | | |
| | | Required | | Submit in CCYY/MM/DD format (e.g., | | |
| | | | | 2020/01/01). 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 NA if the request was not | | |
| NT. | T' 1 1 C | CHAD | 10 | approved. | | |
| N | List expiration date of | CHAR | 10 | Expiration date of the exception approval. | | |
| | the exception approval | Always | | Submit in CCYY/MM/DD format (e.g., | | |
| | | Required | | 2020/01/01). Answer NA if request was not | | |
| | | | | processed as an exception or if the | | |
| | | | | exception was not approved. | | |

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Table 11: Expedited IRE, ALJ or MAC Determinations (EIAM) Record Layout

- <u>Include</u> all requests <u>processed</u> as expedited coverage determination or redetermination requests that were overturned by the IRE, ALJ, or MAC. This includes requests that were auto-forwarded to the IRE and overturned by the IRE, ALJ, or MAC (i.e., a favorable decision was rendered).
- <u>Exclude</u> all requests <u>processed</u> as standard coverage determination or redetermination requests or reimbursement requests.
- Exclude all withdrawn requests.
- Submit cases based on the date of receipt of the IRE, ALJ, or MAC overturn decision (the date the request was initiated may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|---|----------------------------|--------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the coverage determination or redetermination was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Issue Description | CHAR Always Required | 2000 | Provide a description of the issue. |
| Н | Was this request processed as an exception? | CHAR Always Required | 1 | Exception request Yes (Y)/No (N) indicator. |
| I | Drug Name, Strength & Dosage Form | CHAR Always Required | 150 | Provide the drug name, strength, and dosage form. |

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| C I | | | E' III | |
|--------|-------------------------|------------|--------------|---|
| Column | Field Name | Field Type | Field Length | Description |
| ID | | | | |
| J | Date of receipt of | CHAR | 10 | Date the sponsor received the |
| | IRE/ALJ/MAC | Always | | IRE/ALJ/MAC overturn decision. |
| | decision | Required | | Submit in CCYY/MM/DD format (e.g., |
| | | | | 2020/01/01). |
| K | Time of receipt for | CHAR | 8 | Time the sponsor received the |
| | IRE/ALJ/MAC | Always | | IRE/ALJ/MAC overturn decision. |
| | decision | Required | | Submit in HH:MM:SS military time |
| | | | | format (e.g., 23:59:59). |
| L | Date effectuated in the | CHAR | 10 | Date overturn decision effectuated in the |
| | plan's system | Always | | plan's system. Submit in |
| | | Required | | CCYY/MM/DD format (e.g., |
| | | | | 2020/01/01). Answer NA if overturn |
| | | | | decision not effectuated in the plan's |
| | | | | system. |
| M | Time effectuated in the | CHAR | 8 | Time overturn decision effectuated in |
| | plan's system | Always | | the plan's system. Submit in HH:MM:SS |
| | | Required | | military time format (e.g., 23:59:59). |
| | | | | Answer NA if overturn decision not |
| | | | | effectuated in the plan's system. |
| N | List expiration date of | CHAR | 10 | Expiration date of the exception |
| | the exception approval | Always | | approval. Submit in CCYY/MM/DD |
| | | Required | | format (e.g., 2020/01/01). Answer NA if |
| | | | | request was not processed as an |
| | | | | exception or if the exception was not |
| | | | | * |
| | | | | approved. |

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Table 12: Standard Grievances Part D (SGD) Record Layout

- <u>Include</u> all requests <u>processed</u> as standard oral and written grievances.
- Exclude CTM complaints, however if a sponsor received both a grievance and a CTM complaint concerning the same issue, the sponsor should include the grievance.
- Exclude all withdrawn requests.
- Submit cases based on date of resolution notification of the standard oral and written grievances (the date the grievance was received may fall outside of the review period).

| Column | Field Name | Field Type | Field | Description |
|--------|---|----------------------------|--------|--|
| ID | D C' L' L' AM | CHAD | Length | |
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the grievance was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Date Grievance/Complaint was received | CHAR Always Required | 10 | Date the grievance/complaint was received from the enrollee or their authorized representative. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Н | How was the grievance/complaint received? | CHAR Always Required | 7 | Describe how the grievance/complaint was first received from the enrollee or authorized representative. Valid fields include: Oral or Written. |

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| | AUDIT PROCESS AND DATA REQUEST | | | | |
|--------|---|----------------------------|--------|---|--|
| Column | Field Name | Field Type | Field | Description | |
| ID | | | Length | | |
| I | Category of the grievance/complaint | CHAR Always Required | 50 | Describe the category of the grievance/complaint. At a minimum, categories must include each of the following: Enrollment/Disenrollment; Plan Benefits; Pharmacy Access; Marketing; Customer Service; Coverage Determinations/Redetermination Process; Quality of Care; CMS Issues; | |
| | | A | 1000 | or; Other. | |
| J | Grievance/ Complaint Description | CHAR Always Required | 1800 | Provide a description of the grievance/complaint issue. | |
| K | Was this a quality of care grievance? | CHAR Always Required | 1 | Yes (Y)/No (N) indicator of whether the grievance was a quality of care grievance. | |
| L | Was a timeframe extension taken? | CHAR Always Required | 1 | Yes (Y)/No (N) indicator of whether grievance timeframe was extended. | |
| M | If an extension was taken, did the plan notify the member of the reason(s) for the delay? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the sponsor notified the enrollee of the delay. Answer NA if no timeframe extension was taken. | |
| N | If the extension was taken because the plan needed more information, did the notice include how the delay was in the best interest of the enrollee? | CHAR Always Required | 2 | Yes (Y)/No (N) indicator of whether the sponsor notified the enrollee of how the extension of the timeframe was in the interest of the enrollee. Answer NA if no timeframe extension was taken. | |
| 0 | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification of resolution provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. | |
| P | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification of resolution provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. | |
| Q | Resolution Description | CHAR Always Required | 1800 | Provide a full description of the grievance resolution. | |

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Table 13: Expedited Grievances Part D (EGD) Record Layout

- <u>Include</u> all requests <u>processed</u> as expedited oral and written grievances.
- Exclude all withdrawn requests.
- Submit cases based on date of resolution notification of the expedited oral and written grievances (the date the grievance was received may fall outside of the review period).

| Column ID | Field Name | Field Type | Field Length | Description |
|--------------|---|----------------------------|-----------------|--|
| A | Beneficiary First Name | CHAR Always Required | 50 | First name of the beneficiary. |
| В | Beneficiary Last Name | CHAR Always Required | 50 | Last name of the beneficiary. |
| С | Enrollment Effective Date | CHAR Always Required | 10 | Effective date of beneficiary's enrollment for the PBP that the beneficiary was enrolled in when the grievance was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| D | Enrollee ID | CHAR Always Required | 11 | Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes. |
| Е | Contract ID | CHAR Always Required | 5 | The contract number (e.g., H1234) of the organization. |
| F | Plan ID | CHAR Always Required | 3 | The plan number (e.g., 001) of the organization. |
| G | Date Grievance/Complaint was received | CHAR Always Required | 10 | Date the grievance/complaint was received from the enrollee or their authorized representative. Submit in CCYY/MM/DD format (e.g., 2020/01/01). |
| Н | Time Grievance/Complaint was received | CHAR Always Required | 8 | Time of day the grievance/complaint was received from the enrollee or their authorized representative. Time is in HH:MM:SS military time format (e.g., 23:59:59). |
| I | How was the grievance/complaint received? | CHAR Always Required | 7 | Describe how the grievance/complaint was received from the enrollee or authorized representative. Valid fields include: Oral or Written. |

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| | AUDIT PROCESS AND DATA REQUEST | | | | | |
|--------------|--|----------------------------|--------------|---|--|--|
| Column ID | Field Name | Field Type | Field Length | Description | | |
| J | Category of the grievance/complaint | CHAR Always Required | 50 | Describe the category of the grievance/complaint. If this grievance was over the plan's refusal to expedite a request, indicate Refusal to Expedite in this field. If the sponsor expedited a grievance for any other issue, please indicate "other". | | |
| K | Grievance/Complaint Description | CHAR Always Required | 1800 | Provide a description of the grievance/complaint issue. | | |
| L | Date oral notification provided to enrollee | CHAR Always Required | 10 | Date oral notification of resolution provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no oral notification was provided to enrollee. | | |
| M | Time oral notification provided to enrollee | CHAR Always Required | 8 | Time oral notification of resolution provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no oral notification was provided to enrollee. | | |
| N | Date written notification provided to enrollee | CHAR Always Required | 10 | Date written notification of resolution provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Answer NA if no written notification was provided to enrollee. | | |
| О | Time written notification provided to enrollee | CHAR Always Required | 8 | Time written notification of resolution provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided to enrollee. | | |
| P | Resolution Description | CHAR Always Required | 1800 | Provide a full description of the grievance resolution. | | |

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