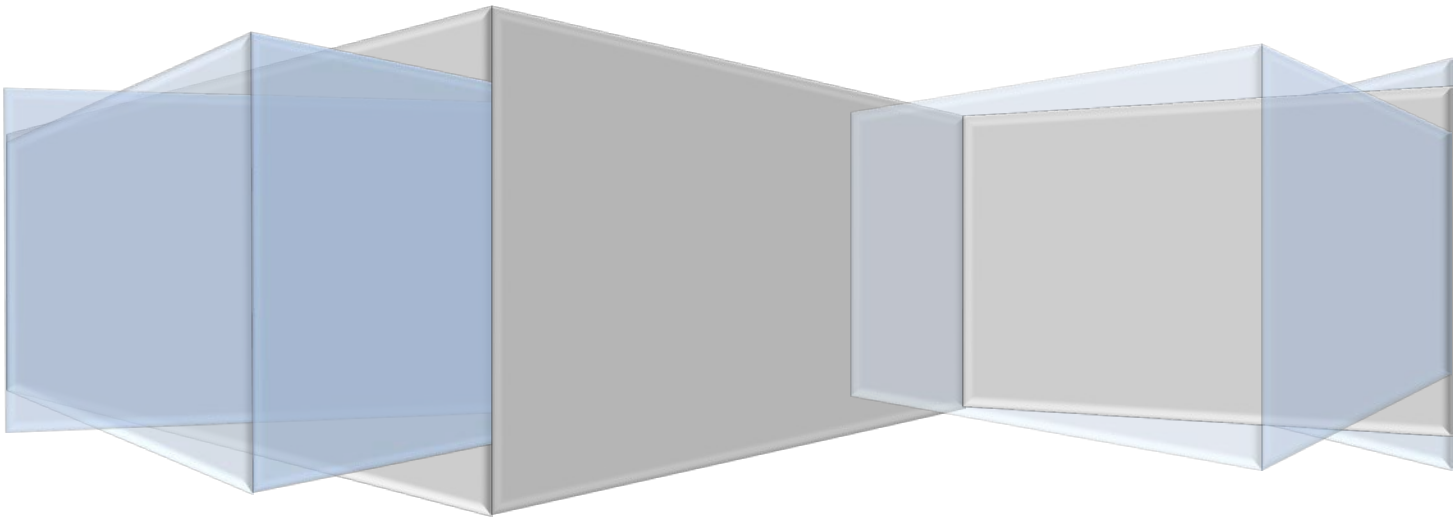
Part C Organization Determinations, Appeals, and Grievances (ODAG)

PROGRAM AUDIT PROTOCOL AND DATA REQUEST



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Program Audit Protocol

Purpose

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

Audit Elements Tested

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

Data Analyzed During Audit

CMS will use all available data to conduct the review of this audit, including information submitted to CMS as part of the Service Level Data Collection for Initial Determinations and Appeals (CMS-10905). CMS will collect audit universes from Sponsors, as needed, until the service level data is available. Once available, CMS will suspend collection of the audit universes in Tables 1-3. The compliance standards noted below will reference both the potential audit universes and the service level data; however, CMS does not intend to collect audit universes when Sponsors have successfully submitted service level data.

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Not Applicable	Universe Integrity Testing	Universe Table 1: Standard and Expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C), **OR** Service Level Data Collection for Initial Determinations and Appeals (All), **AND** Universe Table 4: Part C Standard and Expedited Grievances (GRV_C), **AND** Universe Table 5: Reopened Part C Determinations (RCD)	CMS will review the most recent information available at the time the engagement letter was issued that was submitted by the Sponsor during the reporting of Service Level Data Collection for Initial Determinations and Appeals (OMB-0938-1489). When service level data is not available, CMS will collect universes of data identified in Tables 1, 2 and 3 to assess and select samples. Additionally, CMS will collect and review a universe of standard and expedited grievances as well as a universe of reopened determinations. Select up to10 cases from each submitted audit universe and/or from the service level data universes (when available). Prior to field work, CMS will schedule a webinar with the Sponsoring organization to review all selected cases in order to verify accuracy of data within the universe submissions. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization's systems and/or other supporting documentation.	42 CFR § 422.504(e) 42 CFR § 422.504(f)
Timeliness	1.1	Universe Table 1: Standard and Expedited Organization Determinations (OD) **OR** Service Level Data Collection for Initial Determinations and Appeals: Initial Determinations (Coverage Decisions)	Conduct timeliness test at the universe level on standard initial determinations to determine whether the Sponsoring organization provided notification of its decision to the enrollee and physician/provider or prescriber (as appropriate) no later than the following: • For a service or item not subject to the prior authorization rules in § 422.122, 14 calendar days (28 calendar days if an extension was taken) after receiving the request • For a service or item subject to the prior authorization rules in § 422.122, 7 calendar days (or 21 calendar days if an extension was taken) after receiving the request. • For a Part B drug request, 72 hours after receipt of the request. When analyzing service level data submissions, CMS will request mitigating information from the Sponsor prior to citing noncompliance for any initial determinations that appear untimely.	42 CFR § 422.568(b) 42 CFR § 422.631(d)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Timeliness	1.2	Universe Table 1: Standard and Expedited Organization Determinations (OD) **OR** Service Level Data Collection for Initial Determinations and Appeals: Initial Determinations (Coverage Decisions)	Conduct timeliness test at the universe level on expedited initial determinations to determine whether the Sponsoring organization provided notification of its decision to the enrollee and physician/provider or prescriber (as appropriate) no later than the following: • For a service or item, 72 hours (17 days with extension) after receipt of the request • For a Part B drug, 24 hours after receipt of the request. When analyzing service level data submissions, CMS will request mitigating information from the Sponsor prior to citing noncompliance for any initial determinations that appear untimely.	42 CFR § 422.572(a) 42 CFR § 422.572(b) 42 CFR § 422.572(c) 42 CFR § 422.631(d)
Timeliness	1.3	Universe Table 2: Standard and Expedited Reconsiderations (RECON) **OR** Service Level Data Collection for Initial Determinations and Appeals: Reconsiderations (Coverage Decisions)	Conduct timeliness test at the universe level on standard reconsideration requests to determine whether the Sponsoring organization provided notification of its overturned decision to the enrollee or forwarded its upheld decision to the IRE no later than the following: • For a service or item, within 30 calendar days (44 calendar days with extension) after receipt of the request • For a part B drug, within 7 calendar days after receipt of the request For DSNP-AIPs, the timeliness assessment will ensure written notification of the upheld reconsideration decision was provided to the enrollee. When analyzing service level data submissions, CMS will request mitigating information from the Sponsor prior to citing noncompliance for any reconsiderations that appear untimely.	42 CFR § 422.590(a) 42 CFR § 422.590(c) 42 CFR § 422.590(d) 42 CFR § 422.590(f) 42 CFR § 422.633(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Timeliness	1.4	Universe Table 2: Standard and Expedited Reconsiderations (RECON) **OR** Service Level Data Collection for Initial Determinations and Appeals Reconsiderations (Coverage Decisions)	Conduct timeliness test at the universe level on expedited reconsideration requests to determine whether the Sponsoring organization provided notification of its overturned decision to the enrollee or forwarded its upheld decision to the IRE no later than the following: • For approved (overturned)services or item requests, within 72 hours (17 days with extension) after receipt of the request. • For denied (upheld) service or item requests, submits the case file to the IRE within 24 hours of its affirmation. • For a Part B drug, within 72 hours after receipt of the request. For DSNP-AIPs, the timeliness test will ensure written notification of the upheld reconsideration decision was also provided to the enrollee. When analyzing service level data submissions, CMS will request mitigating information from the Sponsor prior to citing noncompliance for any reconsiderations that appear untimely.	42 CFR § 422.590(e) 42 CFR § 422.590(f) 42 CFR § 422.590(g) 42 CFR § 422.633(f) 42 CFR § 422.634(a)
Timeliness	1.5	Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals: Initial Determinations (Payment)	Conduct timeliness test at the universe level on initial payment organization determinations to determine whether the Sponsoring organization paid or denied claims from non-contracted providers and enrollees no later than 60 calendar days after receipt of the request. When analyzing service level data submissions, CMS will request mitigating information from the Sponsor prior to citing noncompliance for any initial determinations that appear untimely.	42 CFR § 422.568(c)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Timeliness	1.6	Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals: Reconsiderations (Payment)	Conduct timeliness test at the universe level on payment reconsiderations to determine whether the Sponsoring organization paid overturned reconsideration claims from non-contracted providers and enrollees or forwarded its upheld decision to the IRE no later than 60 calendar days after receipt of the request. For DSNP-AIPs, the timeliness assessment will ensure whether the Sponsoring organization paid overturned reconsideration claims from non- contracted providers and enrollees or forwarded its upheld decision to the IRE no later than 30 calendar days or 44 days with extension after receipt of the request. When analyzing service level data submissions, CMS will request mitigating information from the Sponsor prior to citing noncompliance for any reconsiderations that appear untimely.	42 CFR § 422.590(b) 42 CFR § 422.618(a) 42 CFR § 422.633(f)
Timeliness	1.7	Universe Table 4: Part C Standard and Expedited Grievances (GRV_C)	Conduct timeliness test at the universe level on standard grievances to determine whether the Sponsoring organization notified the enrollee of its decision no later than 30 days after receipt of the grievance. If the Sponsoring organization extended the timeframe, determine whether the Sponsoring organization notified the enrollee of its decision no later than 44 days after receipt of the grievance.	42 CFR § 422.564(e) 42 CFR § 422.630(e)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.1	Universe Table 1: Standard and Expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals **AND** Universe Table 5: Reopened Part C Determinations (RCD)	Select up to 40 denied requests from the audit universes or the service level data submissions. CMS may select some approved appeals from Table 2 as part of the 40 samples in order to review the original denied organization determination and corresponding appeal. The number of requests from each universe will vary and will be used to assess compliance standards 2.1 through 2.7 as applicable. CMS may select requests that represent various Medicare covered items/services/Part B drugs available under Part A and Part B (e.g., ER services, outpatient hospital, inpatient hospital, urgent care, terminations and/or reductions of provider services, etc.), and supplemental services. For each sampled denial case, review case file to ensure the Sponsoring organization: (1) Made medical necessity decisions consistent with: • All applicable coverage and benefit criteria including: o National Coverage Determinations (NCDs), o General coverage and benefit conditions included in Original Medicare laws, o Local Coverage Determinations (LCDs), o Internal coverage criteria or other plan-created guidance documents • The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes • Whether the provision of items/services/Part B drugs was reasonable and necessary based on coverage criteria and enrollee medical record documentation (2) When applicable, if the Sponsoring organization denied a Part B drug request for Step Therapy (ST), ensure ST was applied only to a new administration of the requested drug by conducting a 365-day lookback. When applicable, for Dual Eligible Applicable Integrated Plan enrollees, ensure the Sponsoring organization continued benefits to enrollees who filed an appeal involving the termination, suspension, or reduction of a previously authorized service.	42 CFR § 422.100(c) 42 CFR § 422.101(a) 42 CFR § 422.101(b) 42 CFR § 422.101(c) 42 CFR § 422.105(a) 42 CFR § 422.136(a) 42 CFR § 422.632

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.2	Universe Table 1: Standard and Expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals	For each sampled denial case, CMS will note the expertise of the reviewer who rendered the decision in accordance with: (1) For initial decisions, a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue. (2) For reconsiderations, a physician with expertise in the field of medicine that is appropriate for the services at issue and was not involved in making the initial decision.	42 CFR § 422.566(d) 42 CFR §422.590(h)
Processing of Coverage Requests	2.3	Universe Table 1: Standard and Expedited Organization Determinations (OD) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals	For each sampled denial case, review notice of denial to ensure the notice: (1) Use approved notice language in a readable and understandable form (2) States the specific reason for the denial (3) Informed the enrollee of his or her right to a reconsideration (including a description of the standard and expedited reconsideration process (4) Complies with any other notice requirements specified by CMS. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative.	42 CFR § 422.568(e) 42 CFR § 422.572(e)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.4	Universe Table 1: Standard and Expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals **AND** Universe Table 5: Reopened Determinations (RCD)	When applicable, review selected denial cases to ensure the Sponsoring organization identified and applied coverage criteria appropriately, including: (1) Identified and applied the correct Medicare coverage criteria applicable to the service, item or drug, (2) If Sponsor used internal coverage criteria or plan policies (e.g., step therapy policies), ensure: • The criteria was created consistent with applicable Medicare rules. • The criteria was based on appropriate evidence • The criteria was reviewed and approved by the appropriate committee	42 CFR § 422.101(b) 42 CFR § 422.136(b) 42 CFR § 422.136(c) 42 CFR § 422.136(d)
Processing of Coverage Requests	2.5	Universe Table 1: Standard and expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) **OR** Service Level Data Collection for Initial Determinations and Appeals	<u>Extensions</u> When applicable, review each sampled case to ensure Sponsoring organization extended the timeframe for items and services: (1) Under the appropriate circumstances, and (2) Notified the enrollee in writing for the reasons for the delay and informed the enrollee of the right to file an expedited grievance.	42 CFR § 422.568(b) 42 CFR § 422.572(b) 42 CFR § 422.590(f) 42 CFR § 422.631(d)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Processing of Coverage Requests	2.6	Universe Table 1: Standard and expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) **OR** Service Level Data Collection for Initial Determinations and Appeals	<u>Denials of requests to expedite decisions</u> When applicable, review each sampled case to ensure the Sponsoring organization: (1) Appropriately denied a request to expedite a determination, and (2) Provided oral and written notice of the denial, and the notification includes: • How the request will be processed under the standard timeframe, • Informs the enrollee of both their right to file an expedited grievance and resubmit the request for an expedited decisions with any physician's support, and • Provides instructions about the grievance process and its timeframes.	42 CFR § 422.570 42 CFR § 422.584(d)
Processing of Coverage Requests	2.7	Universe Table 3: Payment Organization Determinations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals **AND** Universe Table 5: Reopening Determinations (RCD)	For each sampled case, review case file to ensure requests approved through a prior authorization or pre-service determination of coverage or payment, or through a concurrent determination made during the enrollee's receipt of inpatient or outpatient services were not later denied by the Sponsoring organization on the basis of lack of medical necessity or did not reopendecisions except for good cause or if there was reliable evidence of fraud or similar fault. Additionally, ensure the Sponsoring organization issued proper notification to the enrollee that explains the rationale for the reopening and revision, and any appeal rights.	42 CFR § 422.138(c) 42 CFR § 422.616
Classification of Requests	3.1	Universe Table 1: Standard and expedited Organization Determinations (OD) Universe Table 2: Standard and Expedited Reconsiderations (RECON) Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) **OR** Service Level Data Collection for Initial Determinations and Appeals	Select up to 10 dismissed requests. For each sampled case, review case file to ensure Sponsoring organization: (1) Dismissed the request for one of the allowed dismissals reasons, and (2) Issued written notice of dismissal that included: • The reason for dismissal, and • The enrollee's rights to request the Sponsoring organization vacate the dismissal, and • The enrollee's right to request a reconsideration of the dismissal.	42 CFR § 422.568(g) 42 CFR § 422.568(h) 42 CFR § 422.582(g) 42 CFR § 422.582(h) 42 CFR § 422.590 42 CFR § 422.564 42 CFR § 422.630

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Classification of Requests	3.2	Universe Table 4: Part C Standard and Expedited Grievances (GRV_C)	Select up to 15 grievance sample cases from Table 4. For each sampled case, review case file to determine if the Sponsoring organization informed the enrollee of the disposition of the grievance in accordance with the appropriate requirements. If the enrollee filed an expedited grievance, determine if Sponsoring organization responded to the enrollee's grievance within 24 hours. Review case file documentation to determine if the request was appropriately classified or whether it should have been treated as a coverage request or appeal. If the Sponsoring organization extended the deadline, review case file for documentation stating how the delay is in the interest of the enrollee and confirm the Sponsoring organization notified the enrollee in writing for the reasons for delay. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative.	42 CFR § 422.564(b) 42 CFR § 422.564(e) 42 CFR § 422.564(f)

Program Audit Data Request

Audit Engagement and Universe Submission Phase

Universe Submissions

CMS will utilize all available data submitted as a part of the reporting of Service Level Data Collection for Initial Determinations and Appeals (OMB-0938-1489) in order to limit additional data requests on audit. Prior to the service level data being available, CMS will collect universes of data as outlined below. CMS will collect one universe related to grievances for all audits, regardless of whether service level data is used to supplement the other universes.

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

Universe Requests

1. Universe Table 1: Standard and Expedited Organization Determinations (OD) Record Layout
2. Universe Table 2: Standard and Expedited Reconsiderations (RECON) Record Layout
3. Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout
4. Universe Table 4: Part C Standard and Expedited Grievances (GRV_C) Record Layout
5. Universe Table 5: Reopened Part C Determinations (RCD) Record Layout

Universe Record Layout	Scope of Universe Request*
Table 1 Table 2 Table 4 Table 5	Sponsoring organizations with MA/MAPD enrollment of – • <50,000 enrollees: submit the 16-week period , preceding and including, the date of the audit engagement letter. • ≥50,000 but <250,000 enrollees: submit the 12-week period preceding and including the date of the audit engagement letter. • ≥250,000 but <500,000 enrollees: submit the 4-week period preceding and including the date of the audit engagement letter. • ≥500,000 enrollees: submit the 2-week period preceding and including the date of the audit engagement letter.
Table 3	Sponsoring organizations with MA/MAPD enrollment of – • <500,000 enrollees: submit the 4-week period preceding and including the date of the audit engagement letter. • ≥500,000 enrollees: submit the 2-week period preceding and including the date of the audit engagement letter.

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

General Record Layout Instructions:

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

Please use the guidance below for the following record layout:
Universe Table 1: Standard and Expedited Organization Determinations (OD) Record Layout

- Include all organization determinations the Sponsoring organization approved, denied or dismissed during the universe request period. This includes all organization determinations related to items, services, and Part B drugs where a substantive (fully favorable, partially favorable, and adverse) decision has been made and all decisions to dismiss a request for coverage. This includes all:
  - Pre-service organization determinations made before the provision of the item, service, or Part B drug requested whether subject to or not subject to a plan's prior authorization requirements.
  - Organization determinations for items, services, and Part B drugs made contemporaneously while an enrollee is receiving the item, service, or Part B drug. This includes all substantive decisions made by a Sponsoring organization without first receiving a request including:
    - Inpatient hospital admissions (short term (STACH) and long term (LTACH) acute care hospitals, and inpatient rehabilitation facilities (IRF)) and post-acute care (PAC) admissions (home health (HH), comprehensive outpatient rehabilitation facilities (CORF), and skilled nursing facilities SNF))
    - Discharges from post-acute care facilities (HH, CORF, and SNF)
  - Reductions, or premature discontinuation, of a previously approved authorized ongoing course of treatment.
  - Failure of the Sponsoring organization to approve, furnish, or arrange for health care items, services, or Part B drugs in a timely manner, or to provide for the enrollee with timely notice of an adverse determination, such that delay would adversely affect the health of the enrollee.
- Organization determinations made by entities delegated by the Sponsoring organization to provide administrative or health care services to enrollees of the Sponsoring organization.
- The date of the Sponsoring organization's determination (Column ID P) must fall within the universe request period. Include all organization determinations processed under the standard and expedited timeframes.
- Include all organization determinations for supplemental services that meet the criteria defined in 42 CFR § 422.100(c)(2).
- If an organization determination includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination.
  - Enter any organization determination denied in whole or in part as denied.
- Exclude all requests processed as reconsiderations, requests for payment, reopenings, and withdrawals.
- Exclude all requests for Value Added Items and Services.
- Exclude all requests for Medicaid only services.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001).

Column ID	Field Name	Description
F	First Tier, Downstream, and Related Entity	Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the request. Enter None if the Sponsoring organization processed the request.
G	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, enter the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
H	Date the request was received	Enter the date the request was received/initiated. If a standard request was upgraded to expedited, enter the date the request was upgraded.
I	Time the request was received	For all expedited requests and standard Part B drug requests, enter the time the request was received/initiated. If a standard request was upgraded to expedited, enter the time the request was upgraded. Enter None for standard service requests and dismissed requests.
J	Part B Drug Request?	Enter: • Y for Yes • N for No
K	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
L	AOR/Equivalent notice Receipt Time	For all expedited requests and standard Part B drug requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None for standard service requests or if no AOR or equivalent written notice was received or required.
M	Request Determination	Enter: • Approved • Denied • Dismissed
N	Was the request processed as Standard or Expedited?	Enter the manner by which the request was processed: • S for Standard • E for Expedited
O	Was a timeframe extension taken?	Enter: • Y for Yes • N for No
P	Date of Determination	Enter the date of the determination. For dismissed requests, enter the date the Sponsoring organization dismissed the request.

Column ID	Field Name	Description
Q	Time of Determination	For all expedited requests and standard Part B drug requests, enter the time of the determination. Enter None for standard service requests and dismissed requests.
R	Date oral notification provided to enrollee	Enter the date oral notification was provided to enrollee. Enter None if no oral notification was provided.
S	Time oral notification provided to enrollee	For all expedited requests and standard Part B drug requests, enter the time oral notification was provided to enrollee. Enter None for standard service requests, dismissed requests, or if no oral notification was provided.
T	Date written notification provided to enrollee	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.
U	Time written notification provided to enrollee	For all expedited requests and standard Part B drug requests, enter the time written notification of determination was provided to enrollee. Do not enter the time a letter was generated or printed. Enter None for standard service requests, dismissed requests, or if no written notification was provided.
V	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative • CP for requests by a contract provider/facility • NCP for requests by a non-contract provider/facility • P for Plan
W	Issue description and type of service	For pre-service requests and determinations made contemporaneously (concurrent reviews), provide a description of the service, item, Part B drug, or level of care (SNF/CORF/HH admission, etc.) requested and why it was requested (if known). For denials, also provide an explanation of why the request was denied. For all other organization determinations (terminations and/or reductions of previously approved services, discharges from facilities, etc.), provide a description of the care being terminated/reduced or the type of facility the enrollee is being discharged from and why further care was denied. For dismissed requests, provide the reason for dismissal.
X	Was an expedited request made but processed as standard?	Enter: • Y for Yes if an expedited request was received but downgraded to standard • None for all other requests (e.g. the request was received as expedited and processed as expedited, the request was received as standard)

Column ID	Field Name	Description
Y	Was the request denied for lack of medical necessity?	Enter: • Y for Yes • N for No • None if the request was approved or dismissed.
Z	Is Prior Authorization Required?	• Y for Yes • N for No
AA	Notification Type	Enter the written notification provided to the enrollee: • IDN for Integrated Denial Notice • NOMNC for Notice of Medicare Non-Coverage • None if no written notification was provided.

Please use the guidance below for the following record layout:
Universe Table 2: Standard and Expedited Reconsiderations (RECON) Record Layout

- Include all reconsideration determinations of adverse organization determinations the Sponsoring organization approved, denied, auto-forwarded to the IRE, or dismissed during the universe request period. This includes all reconsideration determinations related to:
  - Initial adverse organization determinations for services, items, and Part B drug requests,
  - Favorable organization determinations that were reopened and revised,
  - Termination of SNF, CORF, and HH services made to the Sponsoring organization because the timeframe for filing with the QIO expired, and
  - Level of care denials
- The date of the Sponsoring organization's reconsidered determination (Column ID P) must fall within the universe request period.
- Include all reconsideration determinations for supplemental services that meet the criteria defined at 42 CFR § 422.100(c)(2).
- If a reconsideration includes more than one service, include all of the line items in a single row and enter multiple line items as a single reconsideration determination. Enter any determination denied in whole or in part as denied.
- Exclude all initial organization determinations and both initial and reconsideration payment determinations.
- Exclude all requests for Value Added Items and Services.
- Exclude withdrawals, appeals of dismissals, and requests to vacate dismissals.
- Exclude reopenings of reconsidered determinations that were initiated by the Sponsoring organization.
- Exclude appeals that were submitted timely to the QIO regarding a Sponsoring organization's decision to terminate coverage of SNF, CORF, and HH services.
- Exclude all reconsideration requests for Medicaid only services.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001).
F	First Tier, Downstream, and Related Entity	Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the request. Enter None if the Sponsoring organization processed the request.
G	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, enter the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.

Column ID	Field Name	Description
H	Date the request was received	Enter the date the reconsideration request was received. If a standard request was upgraded to expedited, enter the date the request was upgraded. If the Sponsoring organization obtained information establishing good cause after the 65-day filing timeframe, enter the date the Sponsoring organization received the information establishing good cause.
I	Time the request was received	For all expedited requests, enter the time the reconsideration request was received. If a standard request was upgraded to expedited, enter the time the request was upgraded. If the Sponsoring organization obtained information establishing good cause after the 65-day filing timeframe, enter the time the Sponsoring organization received the information establishing good cause. Enter None for standard and dismissed requests.
J	Part B Drug Request?	Enter: • Y for Yes • N for No
K	AOR/Equivalent Notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
L	AOR/Equivalent Notice Receipt Time	For all expedited requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None for standard requests or if no AOR or equivalent written notice was received or required.
M	Request Determination	Enter: • Approved • Denied • Dismissed
N	Was the request processed as Standard or Expedited?	Enter the manner by which the request was processed: • S for Standard • E for Expedited
O	Was a timeframe extension taken?	Enter: • Y for Yes • N for No
P	Date of Determination	Enter the date of the determination. For dismissed requests, enter the date the Sponsor dismissed the request.
Q	Time of Determination	For all expedited requests, enter the time of the determination. Enter None for standard and dismissed requests.

Column ID	Field Name	Description
R	Date oral notification provided to enrollee	Enter the date oral notification was provided to enrollee. Enter None for dismissed requests or if no oral notification was provided.
S	Time oral notification provided to enrollee	For all expedited requests, enter the time oral notification was provided to enrollee. Enter None for standard requests, dismissed requests, or if no oral notification was provided.
T	Date written notification provided to enrollee	Enter the date written notification was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided.
U	Time written notification provided to enrollee	For all expedited requests, enter the time written notification was provided to enrollee. Do not enter the time a letter is generated or printed. Enter None for standard requests, dismissed requests, or if no written notification was provided.
V	Date reconsidered determination effectuated in the system	Enter the date the reconsidered determination was effectuated in the system. Enter None if the determination was denied or dismissed.
W	Time reconsidered determination effectuated in the system	For all expedited requests, enter the time the reconsidered determination was effectuated in the system. Enter None for standard cases, dismissed cases, or if the request was denied.
X	Date forwarded to IRE	Enter the date the request was forwarded to the IRE. Enter None if the enrollee was notified of the approved reconsideration or if the request was not forwarded to the IRE.
Y	Time forwarded to IRE	For all expedited requests, enter the time the request was forwarded to the IRE. Enter None if the enrollee was notified of the approved reconsideration, if the request was not forwarded to the IRE, or for standard requests.
Z	Who made the request?	Enter the person who made the request: • E for enrollee • ER for enrollee's representative or purported representative • CP for requests by a contract provider/facility • NCP for requests by a non-contract provider/facility
AA	Issue description and type of service	Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the request was denied. For dismissed requests, provide the reason for dismissal.

Column ID	Field Name	Description
AB	Was an expedited request made but processed as standard?	Enter: • Y for Yes if an expedited request was received but downgraded to standard • None for all other cases (e.g. the request was received as expedited and processed as expedited, the request was received as standard, or the request was dismissed).
AC	Was the initial organization determination request denied for lack of medical necessity?	Enter: • Y for Yes • N for No

Please use the guidance below for the following record layout:

Universe Table 3: Payment Organization Determinations and Reconsiderations (PYMT_C) Record Layout

- Include all payment organization determinations and payment reconsiderations the Sponsoring organization approved, denied or dismissed from non-contract providers, enrollees, and non-contract pharmacies during the universe request period. This includes all fully favorable, partially favorable, and adverse payment organization or reconsideration determination for services, items, and Part B drug requests that meet the criteria defined in 42 CFR § 422.566 (b)(1) - (3) and (5).
- Submit payment organization determinations (e.g., claims) based on the date the claim was paid (Column ID O) or notification of either the denial or approval (if a claim was not submitted) to the provider (if provider submitted the request/claim - Column ID Q) or enrollee (if the enrollee submitted the request/claim – Column ID P). Submit payment reconsiderations based on the date the overturned payment reconsideration was paid (Column ID O) or, for upheld payment reconsiderations, submit based on the date the case was forwarded to the IRE. Submit dismissed requests based on the date of the decision to dismiss (Column ID N).
- Include all payment organization and reconsideration determinations for services, items, and Part B drugs.
- Include all payment organization and reconsideration determinations for supplemental services that meet the criteria defined at 42 CFR § 422.100(c)(2).
- If a payment organization or reconsideration determination includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination or reconsideration request.
  - Enter any determination denied in whole or in part as denied.
- Exclude all payment requests processed as:
  - Duplicate claims,
  - Payment adjustments, and
  - Withdrawals,
  - Reopenings
- Exclude all requests for Value Added Items and Services.
- Exclude any payment requests that were denied due to:
  - Invalid billing codes,
  - Eligibility (i.e., enrollees who were not enrolled on the date of service, providers not accepting assignment), or
  - Recoupment of payment, including pending determination of other primary insurance such as automobile, worker's compensation, etc.
- Exclude all initial payment and payment reconsideration requests for Medicaid only services.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001).

Column ID	Field Name	Description
F	First Tier, Downstream, and Related Entity	Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the request. Enter None if the Sponsoring organization processed the request.
G	Authorization or Claim Number	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, enter the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
H	Date the request was received	Enter the date the payment request was received. If the Sponsoring organization obtained information establishing good cause after the 65-day filing timeframe, enter the date the Sponsoring organization received the information establishing good cause.
I	AOR/Equivalent notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None for dismissed requests or if no AOR or equivalent written notice was received or required.
J	Waiver of Liability (WOL) Receipt Date	Enter the date the WOL form was received for non- contracted provider payment appeals. Enter None for ODs, enrollee submitted requests, or if a WOL was never received.
K	Was it a clean claim?	Enter: • Y for clean claim • N for unclean claim • None for if a claim was not submitted as part of the OD or for payment reconsiderations
L	Was the request processed as an OD or Recon?	Enter the manner by which the request was processed: • OD • Recon
M	Request Determination	Enter: • Approved • Denied • Dismissed
N	Date of Determination	Enter the date of the determination. This is the date the determination was entered in the system and may be the same as the date claim was paid. For dismissed requests, enter the date the Sponsoring organization dismissed the request.

Column ID	Field Name	Description
O	Date claim/reconsideration was paid	Enter the date the claim/reconsideration was paid. Enter None if payment was not provided, if the request was denied, or if the request was dismissed.
P	Date written notification provided to enrollee	Enter the date written notification was provided to enrollee. Enter None if no written notification was provided.
Q	Date written notification provided to provider	Enter the date written notification was provided to provider. Do not enter the date a letter is generated or printed. Enter None if no written notification was provided or if the enrollee submitted the request.
R	Date forwarded to IRE	Enter the date the reconsideration request was forwarded to the IRE. Enter None for organization determination requests, or if the reconsideration request was approved, dismissed, or not forwarded to the IRE.
S	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative • NCP for requests by a non- contract provider/pharmacy
T	Issue description and type of service	Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the payment organization determination or payment reconsideration request was denied. For dismissed requests, please provide the reason for dismissal.
U	Was the payment organization determination request denied for lack of medical necessity?	Enter: • Y for Yes • N for No • None if the request was approved or dismissed.

Please use the guidance below for the following record layout:

Universe Table 4: Part C Standard and Expedited Grievances (GRV_C) Record Layout

- Include all grievances the Sponsoring organization processed, dismissed, or were withdrawn during the universe request period. For processed cases, include cases responded to during the universe period. Also include any grievances older than 30 days as of the time of the engagement letter but that have not received a response. The date the Sponsoring organization issued the resolution notification, or should have issued the notification (Column ID Q or S), must fall within the universe period.
- Grievances with multiple issues must be entered as a single line item, unless the Sponsoring organization issued separate notifications. Each notification must be a separate line item.
- Include grievances that have been extended.
- Exclude complaints filed only within the Complaints Tracking Module (CTM) in HPMS. If a complaint was processed both within the CTM and was also received as a grievance, exclude the CTM complaint but include the grievance as processed by the Sponsoring organization.
- Sponsoring organizations determined to be an applicable integrated plan as defined by 42 CFR § 422.561 should populate the universe with grievances related to Medicare coverage only.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001) applicable for purposes of the grievance. Enter None if there is no PBP number available.
F	First Tier, Downstream, and Related Entity	Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the grievance. Enter None if the Sponsoring organization processed the grievance.
G	Date the grievance was received	Enter the date the grievance was received.
H	Time the grievance was received	Enter the time the grievance was received. Enter None for standard cases.
I	AOR/Equivalent Notice Receipt Date	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None if no AOR or equivalent written notice was received or required.
J	AOR/Equivalent Notice Receipt Time	For expedited grievances, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Enter None for standard grievances or if an AOR or equivalent written notice was not received or required.
K	How was the grievance received?	Enter the method of receipt of the grievance: • Oral • Written

Column ID	Field Name	Description
L	Was the grievance processed as Standard or Expedited?	Enter how the grievance was processed: • S for Standard • E for Expedited
M	Category of the issue	Enter the category of the grievance as assigned by the Sponsoring organization. Enter based on the Sponsoring organization's internal labeling system. If multiple categories apply, enter each category separated by a comma.
N	Grievance Description	Enter a description of the grievance.
O	Was this processed as a quality of care grievance?	Enter: • Y for Yes • N for No
P	Was a timeframe extension taken?	Enter: • Y for Yes • N for No
Q	Date oral notification provided to enrollee	Enter the date oral notification was provided to the enrollee. Enter None if oral notification was not provided or if oral notification was not successful.
R	Time oral notification provided to enrollee	Enter the time oral notification was provided to the enrollee. Enter None for standard cases, if oral notification was not provided, or if oral notification was not successful.
S	Date written notification provided to enrollee	Enter the date written notification was provided to enrollee. Do not enter the date a letter is generated or printed. Enter None if a written notification was not provided.
T	Time written notification provided to enrollee	Enter the time written notification was provided to enrollee. Enter None for standard cases or if a written notification was not provided..
U	Who made the request?	Enter who made the request: • E for enrollee • ER for enrollee's representative or purported representative
V	Was the grievance withdrawn or dismissed?	Enter the disposition of the grievance if the grievance was withdrawn or dismissed: • W for withdrawn • D for dismissed • P if the grievance was processed and not withdrawn or dismissed.
W	Coverage Request Initiated	Was a related coverage request (initial determination or reconsideration) initiated as a result of the complaint/grievance being received? • Y for Yes • N for No
X	Date coverage request was initiated	Enter the date a coverage determination (initial determination or reconsideration) was initiated as a result of the complaint. Enter None if a coverage request was not initiated.

Please use the guidance below for the following record layout:

Universe Table 5: Reopened Part C Determinations (RCD) Record Layout

- Include all organization or reconsidered determinations (for both coverage and payment) the Sponsoring organization reopened and revised during the universe request period.
- The date the Sponsoring organization notified the enrollee and/or provider of a revision (Column ID L) must fall within the universe request period.
- Include only reopenings that were initiated by the Sponsoring organization or an FDR on behalf of the Sponsoring organization. Do not include re-openings that were requested by an enrollee, a provider, an Independent Review Entity (IRE), an Administrative Law Judge (ALJ), or the Medicare Appeals Council (MAC).
- Exclude all requests for Value Added Items and Services.

Column ID	Field Name	Description
A	Enrollee First Name	Enter the first name of the enrollee.
B	Enrollee Last Name	Enter the last name of the enrollee.
C	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001).
F	First Tier, Downstream, and Related Entity	Enter the name of the First Tier, Downstream, and Related Entity (which is any party that enters into a written arrangement, acceptable to CMS, with the Sponsoring organization to provide administrative or health care services to an enrollee under the Part C or D program) that processed the reopening. Enter None if the Sponsoring organization processed the reopening.
G	Case ID (Authorization or Claim Number)	Enter the associated case ID (authorization or claim number) for this re-opening. Enter None if there is no case ID, authorization, claim or other tracking number available.
H	Case Level	Enter the case level associated with the original determination. • Organization Determination or OD • Reconsideration or RC
I	Date of Original Determination	Enter the date of the original determination (decision).
J	Original disposition	Enter the original disposition: • Fully Favorable • Partially Favorable • Adverse
K	Expedited	Was the original case processed under the expedited timeframe? • Enter Y for Yes • Enter N for No
L	Case Type	Enter the type of determination/case: • Service • Claim
M	Status of Treating Provider	Enter the status of the treating provider associated with the reopening:

Column ID	Field Name	Description
		• Contract • Noncontract
N	Date the case was reopened	Enter the date the reopening was initiated by the Sponsor or their FDR.
O	Reason for Reopening	Enter the reason for the reopening: • Clerical Error • Other Error • New and Material Evidence • Fraud or Similar Fault • Other
P	Additional Information	Enter any additional information associated with the reopening, including an issue description or other case information. Enter None if there is no additional information to provide.
Q	Date of Reopening Disposition	Enter the date that the Sponsor notified the enrollee and/or provider of the disposition of the reopening.
R	Reopened disposition	Enter the final disposition following the reopening review: • Fully Favorable • Partially Favorable • Adverse

Audit Field Work Phase

Sample Selection

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

Supporting Documentation Submissions

To facilitate this review, the Sponsoring organization must have access to, and the ability to save and upload screenshots of, supporting documentation and data relevant for a particular case, including, but not limited to:

For initial determinations and reconsiderations:

- The initial organization determination request, payment request (i.e., claim or reimbursement request) or reconsideration 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 Customer Service Representative (CSR) notes and/or documentation of call including date/time stamp of call and call details.
  - If request was received via a chat feature that is available on the sponsoring organization's website, copy of the transcript including date/time stamp.
  - If request was received via an Application Programming Interface (API), documentation of the request transmission to the Sponsoring organization.
  - For all requests, all information received at the time of the request related to what service(s) was being requested and the documentation initially provided to support the request.
- Copy of appointment of representative (AOR) or equivalent written notice, if patient's representative placed request and/or received response, or waiver of liability (WOL) for noncontract provider reconsiderations.
- Copy of all notices, letters, call logs or other documentation showing the Sponsoring organization requested additional information (if applicable) from the requesting provider/physician, including type of communication. If the request was made via phone call, copy of the call log detailing what was communicated to the physician/provider.
- Copy of all supplemental information submitted by the requesting provider/physician or enrollee.
  - If information was received via fax/mail/email, copy of documentation provided including date/time stamp and call details.
  - If information was received via phone, copy of CSR notes and/or documentation of call including date/time stamp.
- Documentation of the decision (approved or denied), including:
  - Documentation showing denial, partial denial, or approval notification to the enrollee and/or their representative and physician/provider, if applicable.
  - Name and title of final reviewer and rationale for the decision, including identification of the clinical criteria used when making the decision.

- Additional documentation may include but is not limited to: Sponsoring organization clinical criteria, Sponsoring organization documents (e.g., EOC); or any other documentation or policies used when considering the request.
- Documentation that internal coverage criteria was created consistent with Medicare rules and based on acceptable evidentiary sources, and copies or links to evidentiary sources if applicable.
- Evidence of any artificial intelligence (AI) used in decision making, including how algorithms or decision trees are created and how they implement criteria within electronic systems.

- For approvals, documentation of effectuation of request, including:
  - Approval in organization determinations/reconsiderations system(s) and evidence of effectuation in Sponsoring organization's claims system clearly showing date/time of approval.
  - Documentation showing approval notification to the enrollee and/or their representative and physician/provider, as applicable.
  - Copy of the written decision letter.
  - If oral notification was given, copy of CSR notes and/or documentation of call.
- For payments, records indicating that payments were made/issued such as EFT records.
- For denials, documentation showing denial notification to the enrollee and/or their representative and provider/physician, if applicable.
  - Copy of written decision letter.
  - If oral notification was given, copy of CSR notes and/or documentation of call.
- For reconsiderations, all documentation outlined for both the original determination and the reconsideration including:
  - Documentation showing reconsideration denial notification to the enrollee and/or their representative and provider/physician, if applicable.
  - If reconsidered case was untimely, documentation showing the Sponsoring organization auto-forwarded the request to the IRE.
- For terminations of post-acute care (SNF, CORF, Home Health):
  - Documentation of all communications sent and received during the post-acute stay with the facility or provider.
  - Documentation of any medical documentation considered during the termination by the Sponsoring organization showing the enrollee no longer meets the level of care necessary for the facility/service
  - Documentation of any decisions related to terminating the care.
  - Documentation of notification of the decision to terminate services including Notice of Medicare Non-Coverage (NOMNC) and if applicable Detailed Explanation of Non-Coverage (DENC).
  - Documentation of any appeals related to the termination, including appeals to the QIO, and any applicable decisions.
- For reopenings:
  - Copy of the original case, including the clinical documentation and decision letter.
  - Copy of case notes as to why the decision was reopened.
  - Copy of any notice sent to the enrollee regarding the reason for the reopening.
  - Copy of all documentation relating to the decision of the reopening and any subsequent notification regarding the decision.
- If applicable, all documentation to support the Sponsoring organization's decision to process an expedited request under the standard timeframe, including any pertinent medical documentation, and any associated notices provided to the enrollee and the requesting provider/physician.
- If applicable, providing timely notification of dismissed requests to enrollees or another party, and informing enrollees and other parties about the right to request IRE review of the dismissed request.
- Annual Notice Of Coverage (ANOC)/EOC.

- Step therapy policies for Part B drugs.
- Copy of overturn notice from IRE/ALJ/MAC.
- Copy of effectuation notice sent to IRE.

For grievances:

- Initial Complaint and any other supplemental documentation explaining the issue:
  - If complaint was received via fax/mail/email, copy of original complaint including date/time stamp of receipt.
  - If complaint was received via phone, copy of CSR notes and/or documentation of call including date/time of call and call details.
- Where applicable, copy of all notices, letters, call logs, or other documentation showing when the Sponsoring organization acknowledged receipt of the grievance to the enrollee, and/or requested additional information from the enrollee and/or their representative, including the date and time of the acknowledgement. If the request was made via phone call, copy of the CSR notes and/or documentation of call, as well as what was communicated to the enrollee.
- Documentation of all supplemental information submitted by enrollee and/or their representative:
  - If information was received via fax/mail/email, copy of documentation provided including date/time stamp of receipt.
  - If information was received via phone, copy of CSR notes and/or documentation of call including date/time of call and call details.
- Documentation showing the steps the Sponsoring organization took to resolve the issue and a description of the final resolution. This documentation may include, but is not limited to, appropriate correspondence with other departments within the organization; referral to the Sponsoring organization's fraud, waste, and abuse department; and outreach to providers.
- Documentation showing the Sponsoring organization's investigation, follow-up steps, and description of the final grievance outcome. Include all notices, letters, and enrollee communications.
- Documentation showing resolution notification to the enrollee and/or their representative:
  - Copy of the written decision letter sent and documentation of date/time letter was printed and mailed.
  - If oral notification was given, copy of CSR notes and/or documentation of call including date/time stamp.
- Documentation that supports a Sponsoring organization's record layout population (e.g. mailroom policies).

CMS may require a Sponsoring organization to produce initial determinations, reconsiderations, and/or overturned decisions made by an outside entity (i.e., IRE, ALJ, or MAC) when that information is related to the selected sample. For example, CMS may require a Sponsoring organization to present data pertaining to an approved prior authorization for Skilled Nursing Facility (SNF) admission when the sample being reviewed is a discharge from a SNF. Similarly, CMS may require a Sponsoring organization to present relevant data pertaining to a denied initial decision when reviewing a reconsideration. CMS may also request claims history or other data to show the enrollee's approved and denied services either prior to or subsequent to the reviewed case.

Sponsoring organizations are expected to submit supporting documentation within two business days of the request unless otherwise specified by CMS. All requested information must be uploaded to the Health Plans Management System (HPMS).

Timeliness Mitigation Analysis

When service level data submissions are used for audits, CMS will analyze submissions to assess timeliness of

determinations. When potential noncompliance is identified in any of the service level data submissions (initial determinations or reconsiderations) related to the timeliness compliance standards in this protocol, the Sponsoring organization must complete and submit a timeliness mitigation analysis. Descriptions and clarifications of what must be included in each submission and data field is outlined in the corresponding excel document. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each column. Sponsoring organizations must provide an accurate and timely mitigation analysis submission within 15 business days of the request. Submissions that do not strictly adhere to the data submission instructions will be rejected.

Timeliness Mitigation Analysis	Scope of Mitigation Analysis Request
ODAG Timeliness Mitigation Tool	CMS will analyze the service level data submissions and submit a list to the Sponsoring organization of all initial determinations and reconsiderations that appear to be untimely. Sponsoring organizations must populate untimely cases with all mitigating information available to demonstrate timeliness (e.g., AOR receipt date, extension information, etc).

Root Cause Analysis Submissions

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

Impact Analysis Submissions

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

Verification of Information Collected

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