ATTACHMENT II

Part D Coverage Determinations, Appeals and Grievances (CDAG) Audit Process and Universe Request

Purpose: To evaluate a Medicare plan's performance in the three areas outlined below related to coverage determinations, appeals, and grievances. The Centers for Medicare & Medicaid Services will perform its audit activities using these instructions (unless otherwise noted).

Review Period: Three (3) month period preceding the date of the audit engagement letter (Month, Day, Year through Month, Day, Year). CMS reserves the right to expand the review period to ensure a sufficient universe size.

Note: The plan is expected to present their supporting documentation during the audit and upload it to the secure site using the designated naming convention within the timeframe specified by the reviewers. If the plan fails to submit the supporting documentation using the designated naming convention and within the timeframe specified by the reviewers, CMS will document this as an observation in the plan's program audit report.

I. Effectuation Timeliness - Coverage Determinations and Appeals (CDA)

1. Select universe and submit to CMS: Sponsor will pull a universe consisting of all coverage determinations and redeterminations, IRE, ALJ and MAC decisions which were approved (i.e., favorable to the beneficiary) during the review period (must include overturns by the IRE, ALJ and MAC). The Plan will designate the type of case (coverage determination, redetermination, or IRE-ALJ MAC) in the designated column of the universe template. The date of the favorable determination should fall within the review period specified above.

   Submit Universe in Attachment II-A1 (**Effectuation Timeliness**). Please note that the universes are to be provided as a whole and not separately for each contract. If the file is too large for Excel, or CSV, a tab delimited text file would also be acceptable.

2. Timeliness test: During the pre-audit period (after universes are received from the Sponsor but prior to the live audit review) CMS will perform an analysis of the submitted universes to determine the percentage timely for categories a, b and c below:

   a. Decision-making timeliness for:
      i. Standard coverage determinations
      ii. Expedited coverage determinations
      iii. Standard redetermination requests
      iv. Expedited redetermination requests

   b. Notification timeliness for:
      i. Standard coverage determinations
      ii. Expedited coverage determinations
      iii. Standard redetermination requests
      iv. Expedited redetermination requests

c. Effectuation timeliness:
   i. Standard coverage determinations
   ii. Expedited coverage determinations
   iii. Standard redetermination requests
   iv. Expedited redetermination requests
   v. Standard IRE, ALJ and MAC overturns/approvals
   vi. Expedited IRE, ALJ and MAC overturns/approvals

The audit team will record the percentage of cases that were timely for each of the metrics listed above. CMS will set three timeliness thresholds for each of the metrics above and sponsors will be scored accordingly. CMS will determine an acceptable threshold for each metric, in which a sponsor above the threshold will generally not be cited a condition. CMS will also set a second threshold for each metric, in which a sponsor falling below this threshold will be cited for a corrective action required (CAR) for unmet timeliness metrics. CMS will set a third threshold for each metric, in which a sponsor falling below this threshold will be cited an immediate corrective action (ICAR) for unmet timeliness metrics.

3. Select 10 Cases: CMS will randomly select 10 cases from the universe categories approved at each of the following levels:
   2 coverage determination cases;
   2 redetermination cases;
   2 cases decided above the sponsor level (IRE, ALJ and MAC); and
   4 cases for non-formulary requests.

   If there are less than 2 cases decided above the sponsor level, CMS will increase the number of coverage determination and redetermination cases to obtain a total sample size of 10.

4. Obtain Evidence: During the live review portion of the audit CMS will verify the accuracy of the dates provided in the universe submission. Obtain evidence from sponsor for each case selected to review for timely notification and effectuation. Sponsor must produce all relevant documentation including, but not limited to:
   - Letters, emails or documents confirming the sponsor's receipt of the request.
   - Notices/letters, or other documentation showing the sponsor requested additional information (if applicable) from the prescriber including date/time of communication.
   - All supplemental information submitted by prescriber including documentation showing when information was received by the sponsor.
   - Notices/letters to beneficiaries or reports or other logs that show when beneficiary was notified of the decision and effectuation was made in the sponsor's systems.

- For approved exception requests, CMS will look for evidence within the sponsor's system that the approval is effective for the remainder of the plan year.
- If applicable, all documentation to support the plan'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.

5. Apply Compliance Standard To Each Case: Apply the following test to each of the 10 cases. For a case to receive a score of "pass", there must be a favorable response to the following question:
   a. Are the dates observed during live audit consistent with the timeliness fields in the universe submission?

      Note: The integrity of the universe will be questioned if the timeliness metrics on 6 or more cases observed during live audit review do not match the metrics provided in the universe. If this occurs CMS will request a new universe to test timeliness. Sponsors providing misleading information to CMS will be referred to the Division of Compliance and Enforcement for a civil monetary penalty. 42 CFR 423.752(c)

2. Sample Case Results: CMS will test each of the 10 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

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

1. Select Universe and submit to CMS: Sponsor will pull a universe consisting of (1) all coverage determinations and redeterminations that were denied (i.e., unfavorable to the beneficiary), including those that were untimely and auto-forwarded; and (2) all IRE decisions that reversed the sponsor's denial for the appropriate time period as set out above in Section I.1.

   Submit Universe in Attachment II-A2 (**Clin DM & CDA Comp**). The Plan will designate the type of case (coverage determination or redetermination) in the designated column of the universe template. Please note that the universes are to be provided as a whole and not separately for each contract. If the file is too large for Excel, or CSV, a tab delimited text file would also be acceptable.

2. Timeliness Test: During the pre-audit period (after universes are received from the Sponsor but prior to the live audit review) CMS will perform an analysis of the submitted universe to determine the percentage timely for categories a), b) and c) below:

a. Decision-making timeliness for:
   i. Standard coverage determinations
   ii. Expedited coverage determinations
   iii. Standard redetermination requests
   iv. Expedited redetermination requests

b. Notification timeliness for:
   i. Standard coverage determinations
   ii. Expedited coverage determinations
   iii. Standard redetermination requests
   iv. Expedited redetermination requests

The audit team will record the percentage of cases that were timely for each of the metrics listed above. CMS will set three timeliness thresholds for each of the metrics above and sponsors will be scored accordingly. CMS will determine an acceptable threshold for each metric, in which a sponsor above the threshold will generally not be cited a condition. CMS will also set a second threshold for each metric, in which a sponsor falling below this threshold will be cited for a corrective action required (CAR) for unmet timeliness metrics. CMS will set a third threshold for each metric, in which a sponsor falling below this threshold will be cited an immediate corrective action (ICAR) for unmet timeliness metrics.

c. IRE auto-forward timeliness (For cases that were untimely in (a)(i)-(a)(iv) above, determine the percentage that were forwarded to the IRE within the required timeframe).

The audit team will record the percentage of cases that were timely in being auto-forwarded to the IRE. CMS will set three timeliness thresholds for IRE auto-forward cases and sponsors will be scored accordingly. CMS will determine an acceptable threshold in which a sponsor above the threshold will generally not be cited a condition for any of the timeless metrics related to IRE auto-forward cases. CMS will also set a second threshold for IRE auto-forward cases, in which a sponsor falling below this threshold will be cited for a corrective action required (CAR) for unmet timeliness metrics related to IRE auto-forward cases. CMS will set a third threshold for IRE auto-forward cases, in which a sponsor falling below this threshold will be cited an immediate corrective action (ICAR) for unmet timeliness metrics related to IRE auto-forward cases.

3. Select 30 Cases: CMS will randomly select 30 cases 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 reversals

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

4. Obtain Evidence (Case Files): During the live review portion of the audit CMS will verify the accuracy of the dates provided in the universe submission. Obtain complete case files from sponsor for each case selected to review for clinical appropriateness of the decision. Sponsor must produce all relevant documentation including, but not limited to:
   - Copy of the initial request made.
   - All notices, letters, or other documentation showing the sponsor requested additional information (if necessary) from the prescriber, including date/time of the communication.
   - All supplemental information submitted by the prescriber including documentation showing when information was received by sponsor.
   - Documentation showing the sponsor's rationale for the decision, including any standard operating procedures or standard decision trees used by clinical personnel.
   - All notices, letters, and communications to the enrollee (and prescriber, if applicable) demonstrating when notification was made.

5. For cases that were auto-forwarded to the IRE, the case file should include documentation showing when the case was forwarded and when the enrollee was notified that the case was sent to the IRE.

6. Apply Compliance Standard To Each Case: Apply the following test to each of the 30 sampled cases. For a case to receive a score of "pass", there must be a favorable response to all of the following questions:
   - Was appropriate notification provided to the enrollee (or representative)?
   - If applicable, was appropriate notification provided to the provider/physician?
   - For initial coverage determination requests that were partially or fully denied for lack of medical necessity – 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?
   - For Redeterminations where the initial Coverage Determination was denied for lack of medical necessity – was the Redetermination made by a physician with expertise in the field of medicine that is appropriate for the drug benefits at issue?; and
   - Did the sponsor appropriately consider clinical information and comply with CMS coverage and notification requirements (e.g., followed all required compendia, followed their CMS approved formulary and coverage criteria, issued a denial notice with appropriate rationale).
   - Are the dates and times observed during live audit consistent with the universe submission?

Note: The integrity of the universe will be questioned if the timeliness metrics on 6 or more cases observed during live audit review do not match the metrics provided in the universe. If this occurs CMS will request a new universe to test timeliness. Sponsors providing misleading information to CMS will be referred to the Division of Compliance and Enforcement for a civil monetary penalty. 42 CFR 423.752(c)

For the cases where the decision making timeframe was not met, did the sponsor auto-forward to the IRE properly?

7. Sample Case Results: CMS will test each of the 30 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

III. Grievances

1. Select Universe and submit to CMS: Sponsor will pull a universe consisting of grievances received (e.g., written correspondence, calls received by customer service representatives, etc.) for the appropriate time period as set out above in Section I.1.

   Submit Universe in Attachment II-A3 (**Grievances**). Please note that the universes are to be provided as a whole and not separately for each contract. If the file is too large for Excel, CSV or a text file would also be acceptable.

2. Select 15 Cases: CMS will select a targeted sample of 15 grievances from the universe which focus on grievances related to drug access or pricing issues.

3. Obtain Evidence: Obtain files from sponsor for each case selected to determine timeliness, appropriate classification and resolution. Plan sponsor must produce all relevant documentation including, but not limited to:
   - Documentation showing when grievance was received.
   - Documentation explaining the issue.
   - Documentation showing the steps the Sponsor took to resolve the issue, including description of the final resolution.
   - All notices, letters, and beneficiary communications demonstrating when resolution notification was made.

4. Apply Compliance Standard To Each Case: Apply the following test to each of the 15 cases. For a case to receive a score of "pass", there must be a favorable response to all of the following questions:
   a. Was the request properly identified as a grievance; and,
   b. Was the enrollee notified of the disposition timely; and,
   c. Did the grievance resolution appropriately address all issues raised in the complaint?

Sample Case Results: CMS will test each of the 15 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.