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 date of the favorable determination should fall within the review period specified above.

Submit Universe in Attachment II-A (**Effectuation Timeliness Tab**). 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 text file would also be acceptable. The universe should consist of the following:

2. Select 30 Cases: CMS will select a targeted sample of 30 cases from the universe categories approved at each of the following levels:
   - 10 coverage determination cases;
   - 10 redetermination cases; and
   - 10 cases decided above the sponsor level (IRE, ALJ and MAC).

If there are less than 10 cases decided above the sponsor level, CMS will increase the number of coverage determination and redetermination cases to obtain a total sample size of 30.

3. Obtain Evidence: 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.

4. Apply Compliance Standard To Each Case: Apply the following test to each of the 30 cases. For a case to receive a score of "pass", there must be a favorable response to both of the following questions:
    a. Was timely notification provided to the enrollee (or representative) and the prescriber, if applicable (applies to plan level decisions only); and
    b. Was the decision effectuated in the sponsor's system within the applicable effectuation timeframe?
5. 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.

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-A (**Clin DM & CDA Comp Tab**)

2. Select 30 Cases: CMS will select a targeted sample of 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.

3. Obtain Evidence (Case Files): Obtain complete case files from sponsor for each case selected to review for timeliness and 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.
4. 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.
5. 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 #1 and #2 and #3 or #4 of the following questions:
   1. Was timely notification provided to the enrollee (or representative) and prescriber, if applicable; and
   2. 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 reviewed by a physician with expertise in the field of medicine that is appropriate for the drug benefits at issue?; and
   3. 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); or,
   4. For the cases where the decision making timeframe was not met, did the sponsor auto-forward to the IRE properly and within the required timeframe?

6. 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-A (**Grievances Tab**). 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 and appropriate classification. 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?
5. 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.