



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Part D Coverage Determinations, Appeals, and Grievances (CDAG) August 24, 2021

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FINAL MAPD PROGRAM AUDIT & PART C TMP PROTOCOL TRAINING

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Overview

- CDAG Program Audit Protocol
 - Audit Elements Tested
 - Method of Evaluation
- CDAG Program Audit Data Request
 - Review Technical Specifications





Polling Question 1

I have experience participating in a CMS Program Audit.

- A. Yes
- B. No



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CDAG Program Audit Protocol

- The data collection specifications and tools described in the program audit protocols, including the record layout (table) instructions, are used for auditing/monitoring activities and by themselves should not be used to interpret policy. Not all data points within each record are used to determine a Sponsor's compliance with CMS requirements





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CDAG Audit Elements Tested



- Timeliness
- Processing of Coverage Requests
- Classification of Requests
- Administration of Drug Management Program



Universe Integrity Testing

- CMS will select 10 cases from each universe (Tables 1 – 7)
–70 cases total
- CMS will verify the accuracy of data within the universe submissions and will confirm effectuation of approved requests for each of the sampled cases





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Timeliness Audit Element (1 of 5)

Coverage Determination Notification

Standard	Expedited	Payment
<ul style="list-style-type: none"> • 72 hours • Exception <ul style="list-style-type: none"> ✓ 72 hours after receipt of supporting statement ✓ If supporting statement not received after 14 calendar days – 72 hours from end of 14 days after receipt of request 	<ul style="list-style-type: none"> • 24 hours • Exception <ul style="list-style-type: none"> ✓ 24 hours after receipt of supporting statement ✓ If supporting statement not received after 14 calendar days – 24 hours from end of 14 days after receipt of request 	<ul style="list-style-type: none"> • 14 calendar days • Payment ≤ 14 calendar days



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Timeliness Audit Element (2 of 5)

Redetermination Notification

Payment Coverage	Standard	Expedited
<ul style="list-style-type: none"> • 14 calendar days • Payment ≤ 30 calendar days 	<ul style="list-style-type: none"> • 7 calendar days 	<ul style="list-style-type: none"> • 72 hours



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Timeliness Audit Element (3 of 5)

Independent Review Entity (IRE), Administrative Law Judge (ALJ) and Medicare Administrative Contractor (MAC) Overturns

Pre-benefit Standard	Post-service Payment	Pre-benefit Expedited
<ul style="list-style-type: none"> 72 hours 	<ul style="list-style-type: none"> 72 hours Payment within 30 calendar days 	<ul style="list-style-type: none"> 24 hours



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Timeliness Audit Element (4 of 5)

Grievances	
Standard	Expedited
<ul style="list-style-type: none">• 30 calendar days• 44 calendar days with extension	<ul style="list-style-type: none">• 24 hours



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Timeliness Audit Element (5 of 5)

- Auto-Forwarding to Independent Review Entity (IRE)
 - If notification was untimely and auto-forwarding to IRE is required, review to determine if the Sponsor auto-forwarded the case to the IRE
 - In Tables 1-4, review of:
 - Total number of cases
 - Number of cases requiring auto-forwarding
 - Number of cases not auto-forwarded as required





Processing of Coverage Requests – Approvals

- 10 cases selected – represents various types of CDs
- Review for proper notification of the approval decision
- Representative requested: review to determine if notification was sent to the enrollee's representative
- Prescriber requested: review to determine if decision notification was also sent to the prescriber
- Sample selections provided to Sponsor approximately one hour prior to the scheduled webinar
- Review for proper effectuation duration



Processing of Coverage Requests – Denials (1 of 3)

- 30 cases selected – represents various types of CDs
- Protected class drug denials
- Review for proper notification and appropriate consideration of clinical information
- Representative requested: review to determine if notification was sent to the enrollee's representative
- Prescriber requested: review to determine if decision notification was also sent to the prescriber
- Sample selections provided to Sponsor approximately one hour prior to the scheduled webinar



Processing of Coverage Requests – Denials (2 of 3)

- Evidence Sponsor's Medical Director/other appropriate health care professional reviewed request for clinical accuracy
- If Sponsor denies request for expedited determination, CMS will review determination and:
 - Notification to enrollee and prescriber explaining:
 - Request processed using the 72-hour timeframe (standard);
 - Informs enrollee of right to file expedited grievance if s/he disagrees with Sponsor not to expedite;
 - Informs enrollee of right to resubmit a request for expedited determination with prescriber's support; and
 - Provides instructions about Sponsor's grievance process and timeframes



Processing of Coverage Requests – Denials (3 of 3)

- For redeterminations, review for proper evidence that person(s) involved in the coverage determination or at-risk determination did not conduct the redetermination
- If the denial of coverage was based on a lack of medical necessity, the redetermination was made by a physician with expertise in the field of medicine appropriate for the services at issue





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Classification of Requests – Dismissed

- Select up to 10 Cases
 - Review to determine if request was appropriately dismissed
 - Should have been treated as a coverage request or grievance
 - Sample selections provided to Sponsor approximately one hour prior to scheduled webinar





Classification of Requests – Grievances

- Select up to 20 Cases – verbal and written
 - Quality of care, involve multiple issues, do not appear in coverage determination and redetermination universes, misclassified requests
 - Determine if proper notification provided
 - If Sponsor extended deadline, review for documentation stating how delay is in the interest of enrollee
 - Review for written notification to enrollee of delay reason(s)
 - Representative requested: determine if notification was sent to enrollee's representative
 - Sample selections provided to Sponsor approximately one hour prior to scheduled webinar



Administration of Drug Management Program (1 of 2)

- **Select up to 15 Cases**
 - Proper initial written notice to enrollee for at-risk determinations
 - Ensure Sponsor made reasonable efforts to provide the enrollee's prescriber(s) of frequently abused drugs with a copy of the notice
 - Representative requested: determine if notification was sent to enrollee's representative
 - Sample selections provided to Sponsor approximately one hour prior to scheduled webinar



Administration of Drug Management Program (2 of 2)

- If Sponsor determined enrollee is an at-risk beneficiary, determine whether enrollee submitted preferences for prescribers or pharmacies and review for proper second written notice to enrollee
- If Sponsor determined the enrollee is not an at-risk beneficiary, review for proper alternate second written notice to the enrollee
- Sponsor made reasonable efforts to provide enrollee's prescriber(s) of frequently abused drugs with a copy of the notice



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Drug Management Program– Timeliness



- Compliance Standard 1.6: Timeliness conducted at universe level for at-risk determination second notice or alternate second notice
- Compliance Standard 1.11: Timeliness conducted at universe level on standard at-risk determination decisions overturned by the IRE, ALJ or MAC
- Compliance Standard 1.14: Timeliness conducted at universe level on expedited at-risk determination decisions overturned by the IRE, ALJ or MAC



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Classification of Requests

- Compliance Standard 3.1: CMS will review case file documentation to determine if the request was appropriately dismissed and will also review the content of the dismissal notice





Administration of Drug Management Program

- Compliance Standard 4.1: CMS will review case file documentation for proper initial written notice to the enrollee for at-risk determinations
- Compliance Standard 4.2: For cases wherein the Sponsor determined the enrollee is an at-risk beneficiary, CMS will review case file documentation for proper second written notice to the enrollee
- Compliance Standard 4.3: For cases wherein the Sponsor determined the enrollee is not an at-risk beneficiary, CMS will review case file documentation for proper alternate second written notice to the enrollee



Program Audit Data Request

- Sponsors must submit each universe comprehensive of all contracts and Plan Benefit Packages (PBP) identified in audit engagement letter
- Descriptions and clarifications for inclusion are outlined in individual universe record layouts
- Characters are required in all requested fields unless otherwise specified and data must be limited to request specified in each record layout
- Sponsors 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



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Scope of Universe Request

PDP/MAPD Enrollment

< 50,000	≥50,000 but <250,000	≥250,000 but <500,000	≥500,000
✓ Submit 12-week period preceding Audit engagement letter date	✓ Submit 8-week period preceding Audit engagement letter date	✓ Submit 4-week period preceding Audit engagement letter date	✓ Submit 2-week period preceding Audit engagement letter date



Polling Question 2

How many CDAG Record Layouts does the final 2022 protocol include?

- A. 5
- B. 6
- C. 7



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Record Layouts

Record Layouts

Universe Table 1	Standard and Expedited Coverage Determination (CD)
Universe Table 2	Standard and Expedited Coverage Determination Exception Requests (CDER)
Universe Table 3	Payment Coverage Determinations and Redeterminations (PYMT_D)
Universe Table 4	Standard and Expedited Redeterminations (RD)
Universe Table 5	Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)
Universe Table 6	Part D Standard and Expedited Grievances (GRV_D)
Universe Table 7	Comprehensive Addition and Recovery Act (CARA) At-Risk Determination (AR)



Record Layout Instructions

- Requests for multiple drugs made at the same time
- Fields for single request in same time zone
- Universe inclusion based on date of determination
- Column ID used to determine inclusion within the universe request period is noted within the record layout instructions
- Part B Drug Requests must be included based on the way in which the request was processed
- Sponsors may submit data for fields even if not required



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Record Layout Exclusions

- Requests where a decision has not been issued while the Sponsor awaits the appropriate representative documentation
- Requests from members whose coverage is not yet effective as of the date of Engagement Letter





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Field Descriptions



- Dismissed requests: Sponsors may enter ***None***
- *Who made the request?* Field (some tables)

Field Descriptions – Authorization or Claim Number



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AUTHORIZATION OR CLAIM NUMBER	NDC	AOR/EQUIVALENT NOTICE RECEIPT DATE/TIME	TIME THE REQUEST WAS UPGRADED TO EXPEDITED	DATE/TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Sponsor's associated authorization or claim number for the request 	<ul style="list-style-type: none"> Aligns with the field description within the FA protocol May be populated as blank when a blank field is submitted by pharmacy or delegate For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE Sponsors may populate the field as submitted for at-risk redeterminations 	<ul style="list-style-type: none"> No AOR or equivalent written notice received or not required: enter <i>None</i> Dismissed requests, when applicable: enter <i>None</i> Date/time Appointment of Representative (AOR) form or equivalent written notice received by Sponsor Standard cases with timeliness requirements in days, Sponsors may enter a time if desired 	<ul style="list-style-type: none"> Enter <i>None</i> if: <ul style="list-style-type: none"> Initial request made under the expedited timeframe Sponsor chose not to expedite request Request received and processed under standard timeframe 	<ul style="list-style-type: none"> Sponsor not able to successfully provide verbal notice: enter <i>None</i>



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Field Descriptions – NDC

AUTHORIZATION OR CLAIM NUMBER	NDC	AOR/EQUIVALENT NOTICE RECEIPT DATE/TIME	TIME THE REQUEST WAS UPGRADED TO EXPEDITED	DATE/TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Sponsor's associated authorization or claim number for the request 	<ul style="list-style-type: none"> Aligns with the field description within the FA protocol May be populated as blank when a blank field is submitted by pharmacy or delegate For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE Sponsors may populate the field as submitted for at-risk redeterminations 	<ul style="list-style-type: none"> No AOR or equivalent written notice received or not required: enter <i>None</i> Dismissed requests, when applicable: enter <i>None</i> Date/time Appointment of Representative (AOR) form or equivalent written notice received by Sponsor Standard cases with timeliness requirements in days, Sponsors may enter a time if desired 	<ul style="list-style-type: none"> Enter <i>None</i> if: <ul style="list-style-type: none"> Initial request made under the expedited timeframe Sponsor chose not to expedite request Request received and processed under standard timeframe 	<ul style="list-style-type: none"> Sponsor not able to successfully provide verbal notice: enter <i>None</i>



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Field Descriptions – AOR/Equivalent Notice Receipt Date/Time

AUTHORIZATION OR CLAIM NUMBER	NDC	AOR/EQUIVALENT NOTICE RECEIPT DATE/TIME	TIME THE REQUEST WAS UPGRADED TO EXPEDITED	DATE/TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Sponsor's associated authorization or claim number for the request 	<ul style="list-style-type: none"> Aligns with the field description within the FA protocol May be populated as blank when a blank field is submitted by pharmacy or delegate For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE Sponsors may populate the field as submitted for at-risk redeterminations 	<ul style="list-style-type: none"> No AOR or equivalent written notice received or not required: enter <i>None</i> Dismissed requests, when applicable: enter <i>None</i> Date/time Appointment of Representative (AOR) form or equivalent written notice received by Sponsor Standard cases with timeliness requirements in days, Sponsors may enter a time if desired 	<ul style="list-style-type: none"> Enter <i>None</i> if: <ul style="list-style-type: none"> Initial request made under the expedited timeframe Sponsor chose not to expedite request Request received and processed under standard timeframe 	<ul style="list-style-type: none"> Sponsor not able to successfully provide verbal notice: enter <i>None</i>



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Field Descriptions – Time the Request was Upgraded to Expedited

AUTHORIZATION OR CLAIM NUMBER	NDC	AOR/EQUIVALENT NOTICE RECEIPT DATE/TIME	TIME THE REQUEST WAS UPGRADED TO EXPEDITED	DATE/TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Sponsor's associated authorization or claim number for the request 	<ul style="list-style-type: none"> Aligns with the field description within the FA protocol May be populated as blank when a blank field is submitted by pharmacy or delegate For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE Sponsors may populate the field as submitted for at-risk redeterminations 	<ul style="list-style-type: none"> No AOR or equivalent written notice received or not required: enter <i>None</i> Dismissed requests, when applicable: enter <i>None</i> Date/time Appointment of Representative (AOR) form or equivalent written notice received by Sponsor Standard cases with timeliness requirements in days, Sponsors may enter a time if desired 	<ul style="list-style-type: none"> Enter <i>None</i> if: <ul style="list-style-type: none"> Initial request made under the expedited timeframe Sponsor chose not to expedite request Request received and processed under standard timeframe 	<ul style="list-style-type: none"> Sponsor not able to successfully provide verbal notice: enter <i>None</i>



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Field Descriptions – Date/time Oral Notification Provided to Enrollee

AUTHORIZATION OR CLAIM NUMBER	NDC	AOR/EQUIVALENT NOTICE RECEIPT DATE/TIME	TIME THE REQUEST WAS UPGRADED TO EXPEDITED	DATE/TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Sponsor's associated authorization or claim number for the request 	<ul style="list-style-type: none"> Aligns with the field description within the FA protocol May be populated as blank when a blank field is submitted by pharmacy or delegate For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE Sponsors may populate the field as submitted for at-risk redeterminations 	<ul style="list-style-type: none"> No AOR or equivalent written notice received or not required: enter <i>None</i> Dismissed requests, when applicable: enter <i>None</i> Date/time Appointment of Representative (AOR) form or equivalent written notice received by Sponsor Standard cases with timeliness requirements in days, Sponsors may enter a time if desired 	<ul style="list-style-type: none"> Enter <i>None</i> if: <ul style="list-style-type: none"> Initial request made under the expedited timeframe Sponsor chose not to expedite request Request received and processed under standard timeframe 	<ul style="list-style-type: none"> Sponsor not able to successfully provide verbal notice: enter <i>None</i>



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Field Descriptions – Date Written Notification Provided to Enrollee

DATE WRITTEN NOTIFICATION PROVIDED TO ENROLLEE	UM EXCEPTION TYPE	FORMULARY UM TYPE	EXPIRATION DATE OF THE APPROVAL, DATE/TIME EFFECTUATED IN THE SYSTEM
<ul style="list-style-type: none"> • Date written notification of dismissal determination provided to enrollee • No written notification provided: enter <i>None</i> 	<ul style="list-style-type: none"> • If request was not a formulary UM exception or safety edit exception: enter <i>None</i> <ul style="list-style-type: none"> ○ Tiering exception ○ Non-formulary exception ○ Hospice exception • If case was a request to except Prior Authorization UM criteria: enter <i>PA</i> • For request with multiple exception types: enter based on <i>approval or denial reason</i> 	<ul style="list-style-type: none"> • If enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria: enter <i>None</i> • If multiple formulary UM criteria apply: enter <i>applicable criteria based on approval or denial reason</i> • Safety Edit for cases where enrollee appears opioid naïve but wants to show evidence that s/he meets the criteria as not opioid naïve: Table 1 (CD) Sponsors may enter <i>SE</i> 	<ul style="list-style-type: none"> • Partially favorable decisions: enter <i>Denied</i> <ul style="list-style-type: none"> ○ Include data regarding approval/effectuation of favorable portion of the decision



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Field Descriptions – UM Exception Type

DATE WRITTEN NOTIFICATION PROVIDED TO ENROLLEE	UM EXCEPTION TYPE	FORMULARY UM TYPE	EXPIRATION DATE OF THE APPROVAL, DATE/TIME EFFECTUATED IN THE SYSTEM
<ul style="list-style-type: none"> • Date written notification of dismissal determination provided to enrollee • No written notification provided: enter <i>None</i> 	<ul style="list-style-type: none"> • If request was not a formulary UM exception or safety edit exception: enter <i>None</i> <ul style="list-style-type: none"> ○ Tiering exception ○ Non-formulary exception ○ Hospice exception • If case was a request to except Prior Authorization UM criteria: enter <i>PA</i> • For request with multiple exception types: enter based on <i>approval or denial reason</i> 	<ul style="list-style-type: none"> • If enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria: enter <i>None</i> • If multiple formulary UM criteria apply: enter <i>applicable criteria based on approval or denial reason</i> • Safety Edit for cases where enrollee appears opioid naïve but wants to show evidence that s/he meets the criteria as not opioid naïve: Table 1 (CD) Sponsors may enter <i>SE</i> 	<ul style="list-style-type: none"> • Partially favorable decisions: enter <i>Denied</i> <ul style="list-style-type: none"> ○ Include data regarding approval/effectuation of favorable portion of the decision

Field Descriptions – Formulary UM Type



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DATE WRITTEN NOTIFICATION PROVIDED TO ENROLLEE	UM EXCEPTION TYPE	FORMULARY UM TYPE	EXPIRATION DATE OF THE APPROVAL, DATE/TIME EFFECTUATED IN THE SYSTEM
<ul style="list-style-type: none"> • Date written notification of dismissal determination provided to enrollee • No written notification provided: enter <i>None</i> 	<ul style="list-style-type: none"> • If request was not a formulary UM exception or safety edit exception: enter <i>None</i> <ul style="list-style-type: none"> ○ Tiering exception ○ Non-formulary exception ○ Hospice exception • If case was a request to except Prior Authorization UM criteria: enter <i>PA</i> • For request with multiple exception types: enter based on <i>approval or denial reason</i> 	<ul style="list-style-type: none"> • If enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria: enter <i>None</i> • If multiple formulary UM criteria apply: enter <i>applicable criteria based on approval or denial reason</i> • Safety Edit for cases where enrollee appears opioid naïve but wants to show evidence that s/he meets the criteria as not opioid naïve: Table 1 (CD) Sponsors may enter <i>SE</i> 	<ul style="list-style-type: none"> • Partially favorable decisions: enter <i>Denied</i> <ul style="list-style-type: none"> ○ Include data regarding approval/effectuation of favorable portion of the decision

Field Descriptions – Expiration Date of the Approval, Date/Time Effectuated in the System



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DATE WRITTEN NOTIFICATION PROVIDED TO ENROLLEE	UM EXCEPTION TYPE	FORMULARY UM TYPE	EXPIRATION DATE OF THE APPROVAL, DATE/TIME EFFECTUATED IN THE SYSTEM
<ul style="list-style-type: none"> • Date written notification of dismissal determination provided to enrollee • No written notification provided: enter <i>None</i> 	<ul style="list-style-type: none"> • If request was not a formulary UM exception or safety edit exception: enter <i>None</i> <ul style="list-style-type: none"> ○ Tiering exception ○ Non-formulary exception ○ Hospice exception • If case was a request to except Prior Authorization UM criteria: enter <i>PA</i> • For request with multiple exception types: enter based on <i>approval or denial reason</i> 	<ul style="list-style-type: none"> • If enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria: enter <i>None</i> • If multiple formulary UM criteria apply: enter <i>applicable criteria based on approval or denial reason</i> • Safety Edit for cases where enrollee appears opioid naïve but wants to show evidence that s/he meets the criteria as not opioid naïve: Table 1 (CD) Sponsors may enter <i>SE</i> 	<ul style="list-style-type: none"> • Partially favorable decisions: enter <i>Denied</i> <ul style="list-style-type: none"> ○ Include data regarding approval/effectuation of favorable portion of the decision



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Field Descriptions – Date/Time Effectuated in the System

DATE/TIME EFFECTUATED IN THE SYSTEM	DATE/TIME FORWARDED TO IRE	REQUEST DETERMINATION	DATE/TIME OF DETERMINATION
<ul style="list-style-type: none"> No authorization is required: enter <i>None</i> 	<ul style="list-style-type: none"> If request was not forwarded to IRE: enter <i>None</i> 	<ul style="list-style-type: none"> Any request denied in whole or in part: enter <i>Denied</i> Partially approved cases: enter <i>Denied</i> 	<ul style="list-style-type: none"> Date of determination must fall within universe request period Untimely coverage determinations or redeterminations auto-forwarded to IRE: Sponsor may enter <i>date/time case file was closed as untimely/began preparing file for IRE</i>



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Field Descriptions – Date/Time Forwarded to IRE

DATE/TIME EFFECTUATED IN THE SYSTEM	DATE/TIME FORWARDED TO IRE	REQUEST DETERMINATION	DATE/TIME OF DETERMINATION
<ul style="list-style-type: none"> No authorization is required: enter <i>None</i> 	<ul style="list-style-type: none"> If request was not forwarded to IRE: enter <i>None</i> 	<ul style="list-style-type: none"> Any request denied in whole or in part: enter <i>Denied</i> Partially approved cases: enter <i>Denied</i> 	<ul style="list-style-type: none"> Date of determination must fall within universe request period Untimely coverage determinations or redeterminations auto-forwarded to IRE: Sponsor may enter <i>date/time case file was closed as untimely/began preparing file for IRE</i>



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Field Descriptions – Request Determination

DATE/TIME EFFECTUATED IN THE SYSTEM	DATE/TIME FORWARDED TO IRE	REQUEST DETERMINATION	DATE/TIME OF DETERMINATION
<ul style="list-style-type: none"> No authorization is required: enter <i>none</i> 	<ul style="list-style-type: none"> If request was not forwarded to IRE: enter <i>none</i> 	<ul style="list-style-type: none"> Any request denied in whole or in part: enter <i>Denied</i> Partially approved cases: enter <i>Denied</i> 	<ul style="list-style-type: none"> Date of determination must fall within universe request period Untimely coverage determinations or redeterminations auto-forwarded to IRE: Sponsor may enter <i>date/time case file was closed as untimely/began preparing file for IRE</i>



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Field Descriptions – Date/Time of Determination

DATE/TIME EFFECTUATED IN THE SYSTEM	DATE/TIME FORWARDED TO IRE	REQUEST DETERMINATION	DATE/TIME OF DETERMINATION
<ul style="list-style-type: none"> No authorization is required: enter <i>none</i> 	<ul style="list-style-type: none"> If request was not forwarded to IRE: enter <i>none</i> 	<ul style="list-style-type: none"> Any request denied in whole or in part: enter <i>Denied</i> Partially approved cases: enter <i>Denied</i> 	<ul style="list-style-type: none"> Date of determination must fall within universe request period Untimely coverage determinations or redeterminations auto-forwarded to IRE: Sponsor may enter <i>date/time case file was closed as untimely/began preparing file for IRE</i>



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Universe Table 1: CD

- Requests for a single drug involving multiple UM criteria: enter as a single line item
 - Separate line items in CD universe if Sponsor sends separate distinct letters addressing each UM criteria individually





Universe Table 2: CDER

- Request for multiple drugs at the same time: enter each drug in a separate row
- Requests for single drug, multiple UM criteria and exception types: enter as single line item (Universe Table 2 only)
- Multiple exception types, includes tiering exception: reported as a tiering exception
- Include safety edit requests in the CDER universe



Universe Table 3: PYMT_D

- All payment coverage determinations and redetermination requests only reported in Universe Table 3
- Request for multiple drugs made at the same time: enter each drug in a separate row
- Requests for single drug: enter as a single line item
- Payment request: clinical review aspect is not to be reported within any other CDAG tables
 - Report in Table 3 only



Field Descriptions – Date Prescriber Supporting Statement Received



DATE PRESCRIBER SUPPORTING STATEMENT RECEIVED	DATE EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED
<ul style="list-style-type: none"> • Populate based on the type of the request • Payment Coverage Determinations: enter <i>date the prescriber's supporting statement was received</i> • Payment Redeterminations: enter <i>date the prescriber's supporting statement was received</i> 	<ul style="list-style-type: none"> • Date approved payment decision was effectuated in the system 	<ul style="list-style-type: none"> • Date check or reimbursement was provided to the enrollee

- Table 3: PYMT_D



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Field Descriptions – Date Effectuated in the System

DATE PRESCRIBER SUPPORTING STATEMENT RECEIVED	DATE EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED
<ul style="list-style-type: none"> • Populate based on the type of the request • Payment Coverage Determinations: enter <i>date the prescriber's supporting statement was received</i> • Payment Redeterminations: enter <i>date the prescriber's supporting statement was received</i> 	<ul style="list-style-type: none"> • Date approved payment decision was effectuated in the system 	<ul style="list-style-type: none"> • Date check or reimbursement was provided to the enrollee

- Table 3: PYMT_D



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Field Descriptions – Date Reimbursement Provided

DATE PRESCRIBER SUPPORTING STATEMENT RECEIVED	DATE EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED
<ul style="list-style-type: none"> • Populate based on the type of the request • Payment Coverage Determinations: enter <i>date the prescriber's supporting statement was received</i> • Payment Redeterminations: enter <i>date the prescriber's supporting statement was received</i> 	<ul style="list-style-type: none"> • Date approved payment decision was effectuated in the system 	<ul style="list-style-type: none"> • Date check or reimbursement was provided to the enrollee

- Table 3: PYMT_D

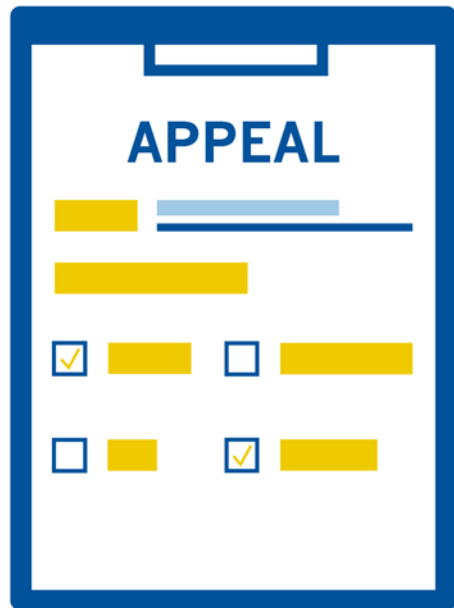


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Universe Table 4: RD (1 of 2)



- If a case with multiple restrictions came in as a single redetermination request list as a single line item in the submitted universe
- If an at-risk redetermination with multiple restrictions came in as separate redetermination requests list as separate line items in the submitted universe



Universe Table 4: RD (2 of 2)

- Single drug request, multiple UM criteria/exception types: entered as a single line item
- Multiple exception types, includes a tiering exception: enter as a tiering exception
- At-risk determination appeals are to be included in Table 4
- CMS will test Sponsors' compliance with auto-forwarding upheld appeals of at-risk determinations to the IRE



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Field Descriptions – Is this a protected class drug?

IS THIS A PROTECTED CLASS DRUG?	IS THIS AN APPEAL OF AN AT-RISK DETERMINATION?	EXCEPTION TYPE	WAS THE COVERAGE DETERMINATION REQUEST DENIED FOR LACK OF MEDICAL NECESSITY?
<ul style="list-style-type: none"> If does not apply for at-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Was appeal of an at-risk determination <ul style="list-style-type: none"> Request for a change in pharmacy and/or prescriber limitations Request for change in the enrollee's at-risk determination status 	<ul style="list-style-type: none"> At-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Based on the initial coverage determination denial for lack of medical necessity

- Table 4: RD



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

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Field Descriptions – Is this an appeal of an at-risk determination?

IS THIS A PROTECTED CLASS DRUG?	IS THIS AN APPEAL OF AN AT-RISK DETERMINATION?	EXCEPTION TYPE	WAS THE COVERAGE DETERMINATION REQUEST DENIED FOR LACK OF MEDICAL NECESSITY?
<ul style="list-style-type: none"> If does not apply for at-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Was appeal of an at-risk determination <ul style="list-style-type: none"> Request for a change in pharmacy and/or prescriber limitations Request for change in the enrollee's at-risk determination status 	<ul style="list-style-type: none"> At-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Based on the initial coverage determination denial for lack of medical necessity

- Table 4: RD



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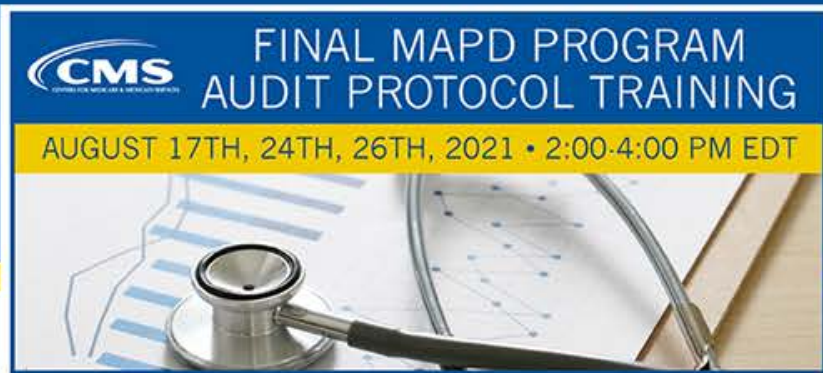


Field Descriptions – Exception Type

IS THIS A PROTECTED CLASS DRUG?	IS THIS AN APPEAL OF AN AT-RISK DETERMINATION?	EXCEPTION TYPE	WAS THE COVERAGE DETERMINATION REQUEST DENIED FOR LACK OF MEDICAL NECESSITY?
<ul style="list-style-type: none"> If does not apply for at-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Was appeal of an at-risk determination <ul style="list-style-type: none"> Request for a change in pharmacy and/or prescriber limitations Request for change in the enrollee's at-risk determination status 	<ul style="list-style-type: none"> At-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Based on the initial coverage determination denial for lack of medical necessity

- Table 4: RD

Field Descriptions – Was the coverage determination request denied for lack of medical necessity?



IS THIS A PROTECTED CLASS DRUG?	IS THIS AN APPEAL OF AN AT-RISK DETERMINATION?	EXCEPTION TYPE	WAS THE COVERAGE DETERMINATION REQUEST DENIED FOR LACK OF MEDICAL NECESSITY?
<ul style="list-style-type: none"> If does not apply for at-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Was appeal of an at-risk determination <ul style="list-style-type: none"> Request for a change in pharmacy and/or prescriber limitations Request for change in the enrollee's at-risk determination status 	<ul style="list-style-type: none"> At-risk redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Based on the initial coverage determination denial for lack of medical necessity

- Table 4: RD



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Field Descriptions – Expiration Date of the Approval

EXPIRATION DATE OF THE APPROVAL	WAS THE COVERAGE DETERMINATION REQUEST DENIED FOR LACK OF MEDICAL NECESSITY?
<ul style="list-style-type: none"> • Exception request: enter <i>expiration date of exception approval</i> • Not an exception request: enter <i>None</i> • Unapproved exception request: enter <i>None</i> • At-risk redeterminations resulting in removal of a restriction authorization currently in place: enter <i>None</i> 	<ul style="list-style-type: none"> • Auto-forwarded cases: enter <i>None</i>

- Table 4: RD

Field Descriptions – Was the coverage determination request denied for lack of medical necessity?



EXPIRATION DATE OF THE APPROVAL	WAS THE COVERAGE DETERMINATION REQUEST DENIED FOR LACK OF MEDICAL NECESSITY?
<ul style="list-style-type: none"> • Exception request: enter <i>expiration date of exception approval</i> • Not an exception request: enter <i>None</i> • Unapproved exception request: enter <i>None</i> • At-risk redeterminations resulting in removal of a restriction authorization currently in place: enter <i>None</i> 	<ul style="list-style-type: none"> • Auto-forwarded cases: enter <i>None</i>

- Table 4: RD



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Field Descriptions – Date Oral Notification Provided to Enrollee

DATE ORAL NOTIFICATION PROVIDED TO ENROLLEE	AOR/EQUIVALENT NOTICE RECEIPT TIME	DATE/TIME WRITTEN NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Standard redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Standard cases: Sponsors may enter <i>None</i> 	<ul style="list-style-type: none"> If case was auto-forwarded and Sponsor did not send written notification to enrollee: enter <i>None</i>

- Table 4: RD



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Field Descriptions – AOR/Equivalent Notice Receipt

DATE ORAL NOTIFICATION PROVIDED TO ENROLLEE	AOR/EQUIVALENT NOTICE RECEIPT TIME	DATE/TIME WRITTEN NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Standard redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Standard cases: Sponsors may enter <i>None</i> 	<ul style="list-style-type: none"> If case was auto-forwarded and Sponsor did not send written notification to enrollee: enter <i>None</i>

- Table 4: RD

Field Descriptions – Date/Time Written Notification Provided to Enrollee



DATE ORAL NOTIFICATION PROVIDED TO ENROLLEE	AOR/EQUIVALENT NOTICE RECEIPT TIME	DATE/TIME WRITTEN NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Standard redeterminations: enter <i>None</i> 	<ul style="list-style-type: none"> Standard cases: Sponsors may enter <i>None</i> 	<ul style="list-style-type: none"> If case was auto-forwarded and Sponsor did not send written notification to enrollee: enter <i>None</i>

- Table 4: RD



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Universe Table 5: EFF_D

- Coverage determinations, redeterminations, or at-risk determinations (fully or partially overturned) by IRE, ALJ or MAC
- Requiring effectuation as pre-benefit, post-service (payment), or at-risk determination
- Exclude any cases that were re-opened by the Sponsor or its first tier, downstream, or related entities



Field Descriptions – Type of Request Reversed by Review Entity



TYPE OF REQUEST REVERSED BY REVIEW ENTITY	DATE/TIME THE OVERTURN DECISION WAS EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED	DRUG NAME, STRENGTH, AND DOSAGE FORM	IS THIS A PROTECTED CLASS DRUG?
<ul style="list-style-type: none"> • Priority determined by how case was received from review entity • If overturn involves both reimbursement and coverage for the same drug going forward: Sponsors report appeal as <i>Standard request for benefits</i> 	<ul style="list-style-type: none"> • Overturn decision not effectuated, or no effectuation required: enter <i>None</i> 	<ul style="list-style-type: none"> • Pre-service requests: enter <i>None</i> <ul style="list-style-type: none"> ○ Coverage determination, redetermination, at-risk determination 	<ul style="list-style-type: none"> • Not applicable: enter <i>None</i> 	<ul style="list-style-type: none"> • Not applicable: enter <i>None</i> <ul style="list-style-type: none"> ○ At-risk appeals, no specific drug under appeal

- Table 5: EFF_D



Field Descriptions – Date/Time the Overturn Decision was Effectuated in the System

TYPE OF REQUEST REVERSED BY REVIEW ENTITY	DATE/TIME THE OVERTURN DECISION WAS EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED	DRUG NAME, STRENGTH, AND DOSAGE FORM	IS THIS A PROTECTED CLASS DRUG?
<ul style="list-style-type: none"> Priority determined by how case was received from review entity If overturn involves both reimbursement and coverage for the same drug going forward Sponsors report appeal as <i>Standard request for benefits</i> 	<ul style="list-style-type: none"> Overturn decision not effectuated, or no effectuation required: enter <i>None</i> 	<ul style="list-style-type: none"> Pre-service requests: enter <i>None</i> <ul style="list-style-type: none"> Coverage determination, redetermination, at-risk determination 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> <ul style="list-style-type: none"> At-risk appeals, no specific drug under appeal

- Table 5: EFF_D



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Field Descriptions – Date Reimbursement Provided

TYPE OF REQUEST REVERSED BY REVIEW ENTITY	DATE/TIME THE OVERTURN DECISION WAS EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED	DRUG NAME, STRENGTH, AND DOSAGE FORM	IS THIS A PROTECTED CLASS DRUG?
<ul style="list-style-type: none"> Priority determined by how case was received from review entity If overturn involves both reimbursement and coverage for the same drug going forward: Sponsors report appeal as <i>Standard request for benefits</i> 	<ul style="list-style-type: none"> Overturn decision not effectuated, or no effectuation required: enter <i>None</i> 	<ul style="list-style-type: none"> Pre-service requests: enter <i>None</i> <ul style="list-style-type: none"> Coverage determination, redetermination, at-risk determination 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> <ul style="list-style-type: none"> At-risk appeals, no specific drug under appeal

- Table 5: EFF_D



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Field Descriptions – Drug Name, Strength, and Dosage Form

TYPE OF REQUEST REVERSED BY REVIEW ENTITY	DATE/TIME THE OVERTURN DECISION WAS EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED	DRUG NAME, STRENGTH, AND DOSAGE FORM	IS THIS A PROTECTED CLASS DRUG?
<ul style="list-style-type: none"> Priority determined by how case was received from review entity If overturn involves both reimbursement and coverage for the same drug going forward: Sponsors report appeal as <i>Standard request for benefits</i> 	<ul style="list-style-type: none"> Overturn decision not effectuated, or no effectuation required: enter <i>None</i> 	<ul style="list-style-type: none"> Pre-service requests: enter <i>None</i> <ul style="list-style-type: none"> Coverage determination, redetermination, at-risk determination 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> <ul style="list-style-type: none"> At-risk appeals, no specific drug under appeal

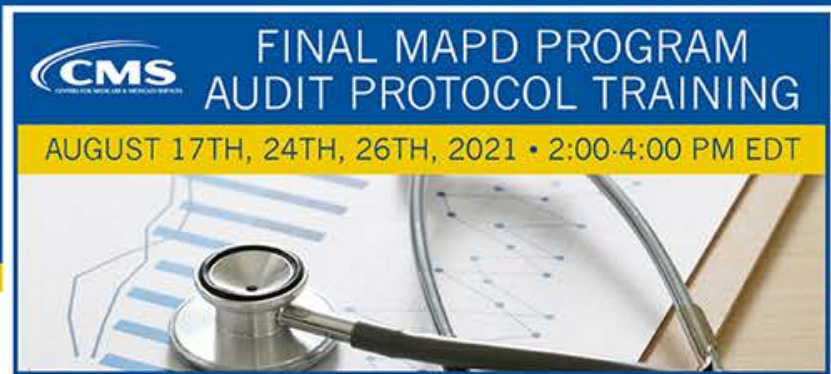
- Table 5: EFF_D

Field Descriptions – Is this a protected class drug?



TYPE OF REQUEST REVERSED BY REVIEW ENTITY	DATE/TIME THE OVERTURN DECISION WAS EFFECTUATED IN THE SYSTEM	DATE REIMBURSEMENT PROVIDED	DRUG NAME, STRENGTH, AND DOSAGE FORM	IS THIS A PROTECTED CLASS DRUG?
<ul style="list-style-type: none"> Priority determined by how case was received from review entity If overturn involves both reimbursement and coverage for the same drug going forward: Sponsors report appeal as <i>Standard request for benefits</i> 	<ul style="list-style-type: none"> Overturn decision not effectuated, or no effectuation required: enter <i>None</i> 	<ul style="list-style-type: none"> Pre-service requests: enter <i>None</i> <ul style="list-style-type: none"> Coverage determination, redetermination, at-risk determination 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> 	<ul style="list-style-type: none"> Not applicable: enter <i>None</i> <ul style="list-style-type: none"> At-risk appeals, no specific drug under appeal

- Table 5: EFF_D



Universe Table 6: GRV_D

- Include request if either the Date oral notification provided to enrollee or the Date written notification provided to enrollee falls within the universe request period
- Grievances with multiple issues must be entered as a single line item
 - Unless Sponsor is treating the issues individually and issued separate notifications
- Withdrawn and dismissed grievances are excluded



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Field Descriptions – Category of the Issue

CATEGORY OF THE ISSUE	GRIEVANCE DESCRIPTION	TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> • Category assigned by the Sponsor <ul style="list-style-type: none"> ○ Based on internal labeling system 	<ul style="list-style-type: none"> • CMS will accept a universe with the character limit greater than 1,800 for this field 	<ul style="list-style-type: none"> • Standard cases or no oral notification provided: enter <i>None</i>

- Table 6: GRV_D



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Field Descriptions – Grievance Description

CATEGORY OF THE ISSUE	GRIEVANCE DESCRIPTION	TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Category assigned by the Sponsor <ul style="list-style-type: none"> Based on internal labeling system 	<ul style="list-style-type: none"> CMS will accept a universe with the character limit greater than 1,800 for this field 	<ul style="list-style-type: none"> Standard cases or no oral notification provided: enter <i>None</i>

- Table 6: GRV_D



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Field Descriptions – Time Oral Notification Provided to Enrollee

CATEGORY OF THE ISSUE	GRIEVANCE DESCRIPTION	TIME ORAL NOTIFICATION PROVIDED TO ENROLLEE
<ul style="list-style-type: none"> Category assigned by the Sponsor <ul style="list-style-type: none"> Based on internal labeling system 	<ul style="list-style-type: none"> CMS will accept a universe with the character limit greater than 1,800 for this field 	<ul style="list-style-type: none"> Standard cases or no oral notification provided: enter <i>None</i>

- Table 6: GRV_D



Polling Question 3

CDAG Table 7 includes all enrollees reviewed under a Drug Management Program (DMP).

- A. Yes
- B. No



Universe Table 7: AR (1 of 2)

- **SUPPORT Act Section 2004**
 - All Part D sponsors must have established DMPs no later than January 1, 2022
- Includes all at-risk and not at-risk determinations
- Each at-risk determination must be listed as its own line item in the submitted universe
- Does not include all enrollees reviewed under a Drug Management Program (DMP)



Universe Table 7: AR (2 of 2)

- Case included
 - If enrollee goes through case management, is not exempt, and at-risk/not at-risk decision is rendered (42 CFR § 423.153(f))
- Case excluded
 - Enrollee is still going through case management and at-risk/not at-risk decision has not been rendered
 - Sponsor determines potentially at-risk beneficiary is exempt through the case management process and did not make an at-risk determination





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Field Descriptions – Request Determination

REQUEST DETERMINATION	DRUG NAME, STRENGTH, AND DOSAGE FORM	CONFIRMATION OF AGREEMENT TO PLACE LIMITATION UPON ENROLLEE
<ul style="list-style-type: none"> Not At-Risk request determinations where no type of at-risk limitation is being imposed upon the beneficiary, reason the coverage limitation was unnecessary does not need to be entered 	<ul style="list-style-type: none"> Drug Name, Strength, and Dosage Form applicable to the specific limitation Sponsor intends to place on beneficiary's access to coverage for frequently abused drugs under the program Intended limitation applies to more than one drug: enter <i>Multiple</i> Intended limitation not related to a specific drug: enter <i>None</i> 	<ul style="list-style-type: none"> Pharmacy advance agreement: enter <i>YPH</i> Provider confirmed limitation: enter <i>YPR</i> Pharmacy <u>and</u> provider confirmed: enter <i>YBO</i>

- Table 7: AR



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Field Descriptions – Drug Name, Strength, and Dosage Form

REQUEST DETERMINATION	DRUG NAME, STRENGTH, AND DOSAGE FORM	CONFIRMATION OF AGREEMENT TO PLACE LIMITATION UPON ENROLLEE
<ul style="list-style-type: none"> Not At-Risk request determinations where no type of at-risk limitation is being imposed upon the beneficiary, reason the coverage limitation was unnecessary does not need to be entered 	<ul style="list-style-type: none"> Drug Name, Strength, and Dosage Form applicable to the specific limitation Sponsor intends to place on beneficiary's access to coverage for frequently abused drugs under the program Intended limitation applies to more than one drug: enter <i>Multiple</i> Intended limitation not related to a specific drug: enter <i>None</i> 	<ul style="list-style-type: none"> Pharmacy advance agreement: enter <i>YPH</i> Provider confirmed limitation: enter <i>YPR</i> Pharmacy <u>and</u> provider confirmed: enter <i>YBO</i>

- Table 7: AR

Field Descriptions – Confirmation of Agreement to Place Limitation Upon Enrollee



REQUEST DETERMINATION	DRUG NAME, STRENGTH, AND DOSAGE FORM	CONFIRMATION OF AGREEMENT TO PLACE LIMITATION UPON ENROLLEE
<ul style="list-style-type: none"> Not At-Risk request determinations where no type of at-risk limitation is being imposed upon the beneficiary, reason the coverage limitation was unnecessary does not need to be entered 	<ul style="list-style-type: none"> Drug Name, Strength, and Dosage Form applicable to the specific limitation Sponsor intends to place on beneficiary's access to coverage for frequently abused drugs under the program Intended limitation applies to more than one drug: enter <i>Multiple</i> Intended limitation not related to a specific drug: enter <i>None</i> 	<ul style="list-style-type: none"> Pharmacy advance agreement: enter <i>YPH</i> Provider confirmed limitation: enter <i>YPR</i> Pharmacy <u>and</u> provider confirmed: enter <i>YBO</i>

- Table 7: AR



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Field Descriptions – Type of At-Risk Limitation

TYPE OF AT-RISK LIMITATION	DATE THE INITIAL WRITTEN NOTIFICATION OF POTENTIAL AT-RISK STATUS WAS PROVIDED TO ENROLLEE/DATE SECOND WRITTEN NOTIFICATION OF AT-RISK DETERMINATION PROVIDED TO ENROLLEE	DATE THE AT-RISK DETERMINATION WAS MADE
<ul style="list-style-type: none"> • Point of Sale Edit • Pharmacy Lock-In • Provider Lock-In • Enter all that apply 	<ul style="list-style-type: none"> • Notification date 	<ul style="list-style-type: none"> • Date at-risk determination was made

- Table 7: AR



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Field Descriptions – Date Written Notification Provided to Enrollee

TYPE OF AT-RISK LIMITATION	DATE THE INITIAL WRITTEN NOTIFICATION OF POTENTIAL AT-RISK STATUS WAS PROVIDED TO ENROLLEE/DATE SECOND WRITTEN NOTIFICATION OF AT-RISK DETERMINATION PROVIDED TO ENROLLEE	DATE THE AT-RISK DETERMINATION WAS MADE
<ul style="list-style-type: none"> • Point of Sale Edit • Pharmacy Lock-In • Provider Lock-In • Enter all that apply 	<ul style="list-style-type: none"> • Notification date 	<ul style="list-style-type: none"> • Date at-risk determination was made

- Table 7: AR



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Field Descriptions – Date the at-risk Determination was Made

TYPE OF AT-RISK LIMITATION	DATE THE INITIAL WRITTEN NOTIFICATION OF POTENTIAL AT-RISK STATUS WAS PROVIDED TO ENROLLEE/DATE SECOND WRITTEN NOTIFICATION OF AT-RISK DETERMINATION PROVIDED TO ENROLLEE	DATE THE AT-RISK DETERMINATION WAS MADE
<ul style="list-style-type: none"> • Point of Sale Edit • Pharmacy Lock-In • Provider Lock-In • Enter all that apply 	<ul style="list-style-type: none"> • Notification date 	<ul style="list-style-type: none"> • Date at-risk determination was made

- Table 7: AR



Impact Analysis Submissions

- When noncompliance is identified, audit Sponsors must submit each requested impact analysis
- Information collected will mirror existing CDAG universe record layouts





FINAL MAPD PROGRAM AUDIT & PART C TMP PROTOCOL TRAINING

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Questions?

- Questions related to the program audit process can be sent to the program audit mailbox at part_c_part_d_audit@cms.hhs.gov.

