Part D Drug Management Program (DMP): Overutilization Monitoring System (OMS) Training

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ROADMAP

1. DMP and OMS Background
2. OMS Process
3. OMS Documents
4. OMS Reports
5. ORF and SRF Submission Process
6. Website Information
7. Validation Reports
8. Q&A

ROADMAP

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BACKGROUND

- Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs).
- CMS established the framework under which Part D sponsors may implement a DMP in the final rule (CMS-4182-F) published in the Federal Register on April 16, 2018 ("final rule").
- DMPs are voluntary under CARA.
- SUPPORT for Patients and Communities Act, enacted on October 24, 2018, requires all Part D sponsors to have a DMP for plan years beginning on or after January 1, 2022.

DMP: OVERUTILIZATION MONITORING SYSTEM (OMS) AND MARx REQUIREMENTS

1. CMS will provide sponsors with DMP quarterly OMS reports of potential at-risk beneficiaries (PARBs) enrolled in their contract who met the Minimum OMS criteria;
2. Sponsors may identify PARBs by applying the Minimum or Supplemental OMS criteria on their own.
3. Part D sponsors will engage in case management of such beneficiaries through contact with their prescribers, if beneficiary does not have an exception, to determine if a beneficiary is at-risk.
4. Within 30 days of the OMS report, Part D sponsors will report to CMS the outcome of their review of each PARB, including if the beneficiary has an exception.
5. Sponsors will submit each beneficiary-level coverage limitation notification and implementation start and end-dates into the Medicare Advantage Prescription Drug (MARx) system within 7 days. MARx UI Role: MCO CARA Status User.
6. The MARx system will notify new Part D sponsors upon an enrollment request if a beneficiary has an active CARA status.

OMS CRITERIA: MINIMUM OMS CRITERIA

During the **6-month** measurement period:

- Use of opioids with average daily Morphine Milligram Equivalent (MME) >=90 mg for any duration and either:
  - 3+ opioid prescribers AND 3+ opioid dispensing pharmacies OR
  - 5+ opioid prescribers (regardless of the number of opioid dispensing pharmacies)
- Prescribers within the same practice are counted as a single prescriber.
- Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

OMS CRITERIA: SUPPLEMENTAL OMS CRITERIA

During the **6-month** measurement period:

- Use of opioids **regardless of the average daily MME** for any duration and either:
  - 7+ opioid prescribers OR
  - 7+ opioid dispensing pharmacies
- Prescribers associated with the same practice are counted as a single prescriber.
- Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

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OPIOID PRODUCTS

What opioid products are **included**?	• Contains an Opioid with a strength > zero
What opioid products are **excluded**?	• Cough and cold products • Opium tinctures • Injectable, external or miscellaneous routes of administration

The Opioid products can be found in the Medication and Code List workbook located on the Patient Safety Website

MME CONVERSION FACTORS

- MME conversion factor (CF) is the amount of opioid product in milligrams (MG) that is equivalent in potency to 1 MG of Morphine, Centers for Disease Control (CDC) Oral MME CFs.
- CDC does not publish a MME CF for Buprenorphine.
- Methadone products use a graduated MME CF based on the amount of methadone available per day.

Methadone (mg)	Conversion Factor
>0,<=20	4
>20, <=40	8
>40, <=60	10
>50	12

MEASUREMENT PERIOD

- Opioid Part D claims with a date of service within the 6-month measurement period.
- Different contracts can contribute to the opioid utilization of a beneficiary.

EXAMPLE CLAIMS:

Measurement Period	Beneficiary ID	Claim	Contract Number	Opioid	Date of Service	Quantity Supplied	Days Supply	Inclusion
1/1/2018 – 6/30/2018	J1	A	S0001	Morphine	12/30/2017	20	5	NO
	J1	B	A0001	Morphine	1/3/2018	10	2	YES
	J1	C	A0001	Methadone	1/3/2018	24	2	YES
	J1	D	A0001	Morphine	1/4/2018	4	1	YES
	J1	E	A0001	Methadone	1/4/2018	10	1	YES
	J1	F	A0001	Buprenorphine	1/5/2018	20	10	YES
	J1	G	C0001	Morphine	06/29/2018	10	5	YES
	J1	H	B0001	Morphine	07/1/2018	20	10	NO

Beneficiary 'J1' has 6 claims with Date of Service within the measurement period from 2 different contracts.

MINIMUM OMS CRITERIA: DAILY DOSE AND MME

Dosage Units per day = Quantity Supplied / Days Supply

Morphine Milligram Equivalent (MME) daily dose= Dosage Units per day x Opioid Strength x MME CF

Daily Dose (mg) per claim (for Methadone) = Dosage Units per day x Opioid Strength

NON METHADONE Opioid Claims:

Claim	Contract Number	Opioid	Date of Service	Days Supply	Quantity Supplied	Dosage Units per day	Opioid Strength	MME CF	MME Daily Dose (MG) per claim
B	A0001	Morphine	1/3/2018	2	10	10/2 = 5	1 MG	1	5*1*1 = 5
D	A0001	Morphine	1/4/2018	1	4	4/1 = 4	1 MG	1	4*1*1 = 4
G	C0001	Morphine	6/29/2018	5	10	10/5 = 2	1 MG	1	2*1*1 = 2
F*	A0001	Buprenorphine	1/5/2018	10	20				

METHADONE Opioid Claims:

Claim	Contract Number	Opioid	Date of Service	Days Supply	Quantity Supplied	Dosage Units per day	Opioid Strength	Daily Dose (MG) per claim
C	A0001	Methadone	1/3/2018	2	24	24/2 = 12	1 MG	12*1
E	A0001	Methadone	1/4/2018	1	10	10/1 =10	1 MG	10*1

MINIMUM OMS CRITERIA: TOTAL DAILY MME

NON METHADONE Opioid Claims:

Claim	MME Daily Dose (MG) per claim	Date of Service	Days Supply		1/1/2018	1/2/2018	1/3/2018	1/4/2018	1/5/2018 to 06/28/2018	6/29/2018	6/30/2018
			On Claim	In measurement period							
B	5*1 = 5	1/3/2018	2	2	0	0	5	5	0	0	0
D	4*1 = 4	1/4/2018	1	1	0	0	0	1	0	0	0
G	2*1 = 2	6/29/2018	**5**	**2**	0	0	0	0	0	2	2
Total Non Methadone Claims Daily MME					**0**	**0**	**5**	**6**	**0**	**2**	**2**

METHADONE Opioid Claims:

Claim	Daily Dose (MG) per claim	Date of Service	Days Supply		1/1/2018	1/2/2018	1/3/2018	1/4/2018	1/5/2018 to 06/30/2018
			On Claim	In measurement period					
C	6/2 = 3	1/3/2018	2	2	0	0	12	12	0
E	10/1=10	1/4/2018	1	1	0	0	0	10	0
Total Methadone Claims Daily MG					**0**	**0**	**12**	**22**	**0**
Total Methadone Claims Daily MME					**0**	**0**	**12* 4 = 48**	**22*8 = 176**	**0**

MINIMUM OMS CRITERIA: AVERAGE MME

SUMMING METHADONE AND NON METHADONE DAILY MME:

	1/1/ 2018	1/2/ 2018	1/3/ 2018	1/4/ 2018	1/5/2018 to 06/28/2018	6/29/ 2018	6/30/ 2018
Total Non Methadone Claims Daily MME	0	0	5	6	0	2	2
Total Methadone Claims Daily MME	0	0	48	176	0	0	0
Total Daily MME	**0**	**0**	**53**	**182**	**0**	**2**	**2**

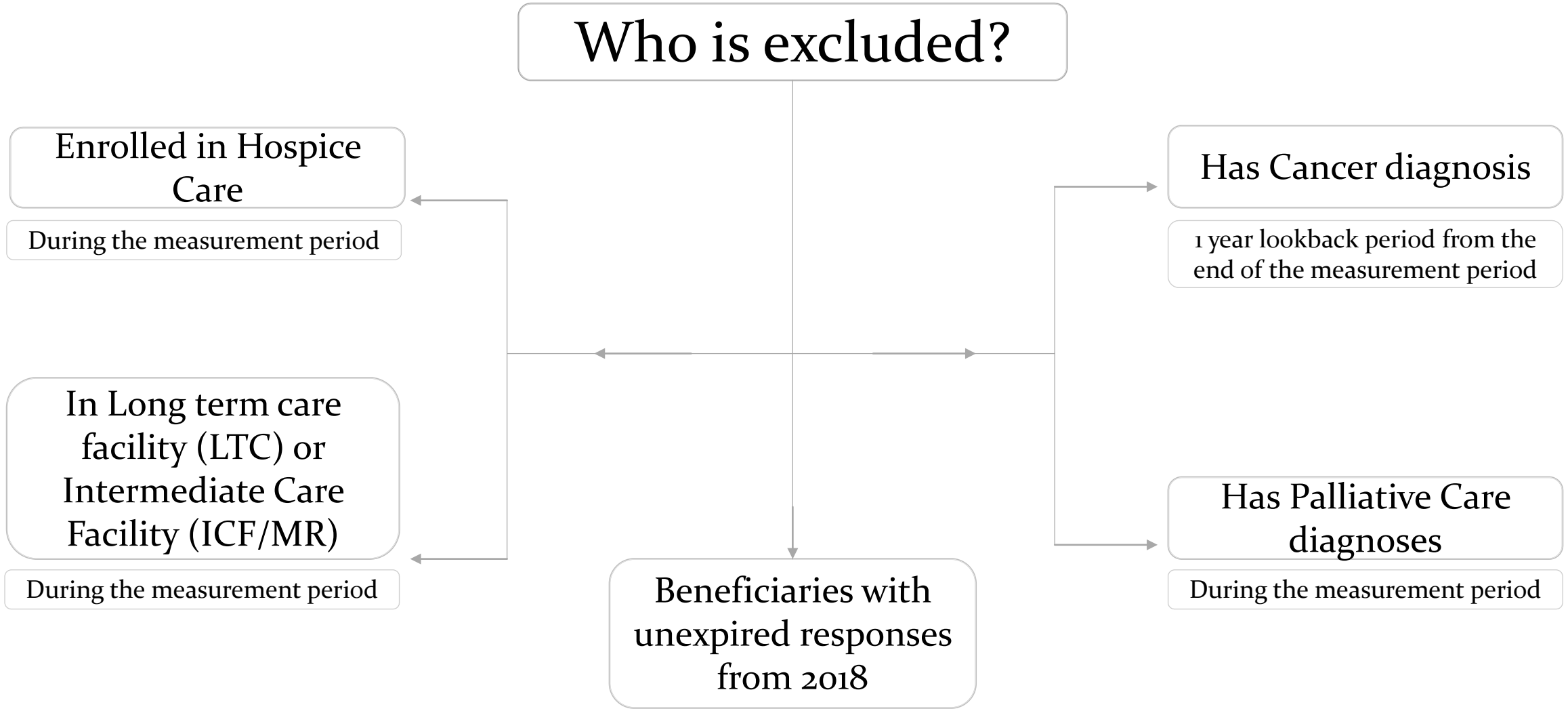
First day of opioid usage	The first day of opioid usage during the measurement period.	1/3/2018
Last day of opioid usage	The last day of opioid usage during the measurement period.	06/30/2018
Total MME	Sum total daily MME during the measurement period.	53+182+2+2 = 239
Duration of Opioid Usage	Total days between and including the first day of opioid usage and last day of opioid usage.	06/30/2018 – 1/3/2018 + 1 = 179
Average MME	Total MME / Denominator Days	239/179 = **1.34**

MINIMUM OMS CRITERIA: PROVIDER COUNTS

Claim	Contract Number	Opioid	Date of Service	Pharmacy ID	Prescriber ID	Group TIN
B	A0001	Morphine	1/3/2018	PHARM01	PRESC01	TIN01
C	A0001	Methadone	1/3/2018	PHARM02	PRESC02	TIN01
D	A0001	Morphine	1/4/2018	PHARM01	PRESC01	TIN01
E	A0001	Methadone	1/4/2018	PHARM02	PRESC02	TIN01
F	A0001	Buprenorphine	1/5/2018	PHARM03	PRESC01	TIN01
G	C0001	Morphine	06/29/2018	PHARM01	PRESC03	TIN03

- Buprenorphine claims are included in total unique providers.
- Individual prescribers with same single organizational Tax Identification Number(TIN) are grouped and counted as one prescriber. In this example, prescriber ID 'PRESC01' and 'PRESC02' are both associated with group TIN 'TIN01', therefore this beneficiary only has 2 unique prescribers.
- Pharmacy IDs are standardized to give preference to the National Provider Identifier (NPI) ID. If NPI is not available then National Council for Prescription Drug Programs (NCPDP) Pharmacy ID is used. If both NPI and NCPDP IDs are unavailable, then pharmacy ID found in the 'service provider' field from the claim is used.

BENEFICIARY EXCLUSIONS



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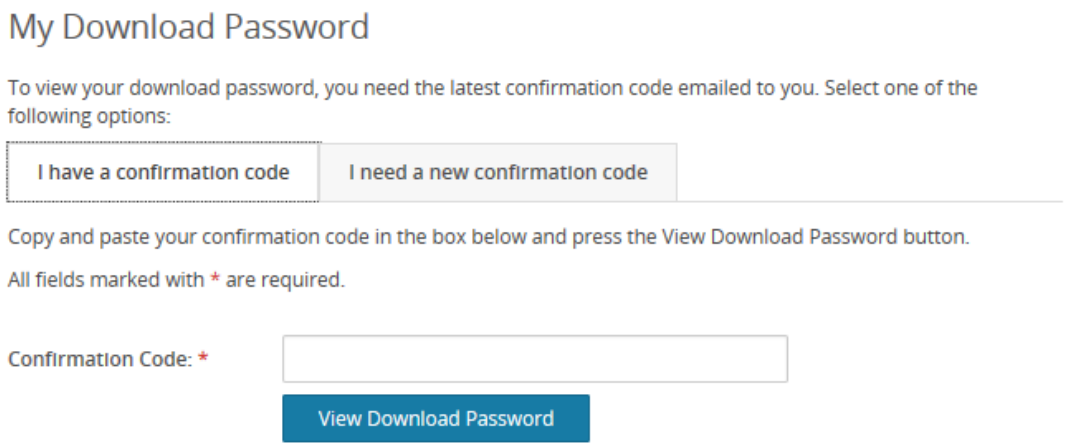
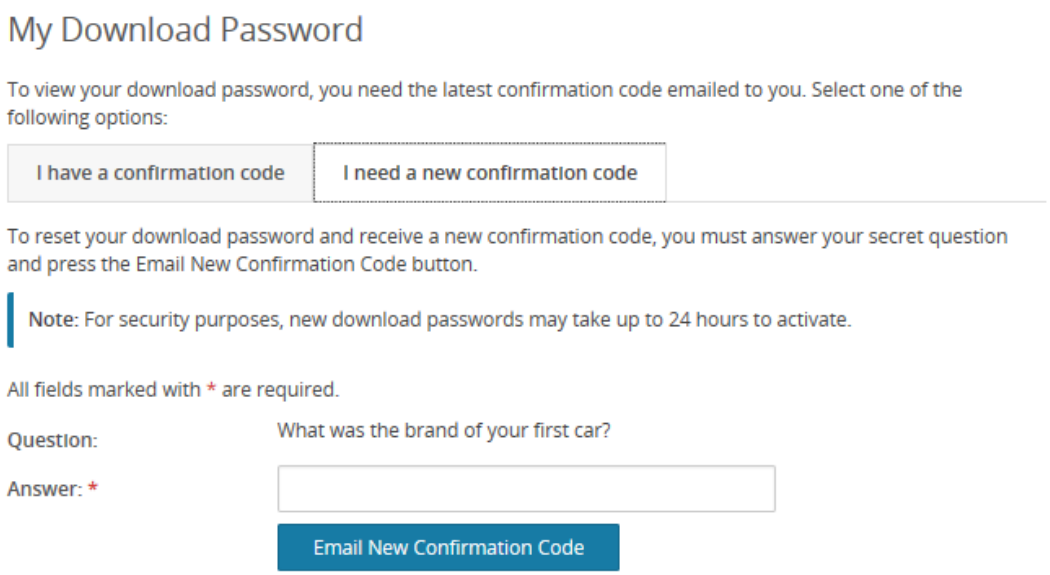
USER ACCESS INSTRUCTIONS

- Before downloading your OMS report packages, you must ensure that you have been made an authorized user for a given contract by the Medicare Compliance Officer (MCO), set up your user account, and acquired your download password.
  - If you are an MCO for this contract, you can log onto the User Security Web Portal (https://partd.programinfo.us/User_Security) to add an existing and/or new user.
  - After being granted web portal access you will receive a welcome email that includes the web portal user guide and more information about acquiring your download password.
  - ***Note:** if you already completed this process on the Patient Safety web portal no further action is required and the steps for changing user access have not changed.

USER ACCESS INSTRUCTIONS

- In order to download the report packages, you must first locate your download password. In order to view your download password, please select the “My Download Password” page (located under “User Settings”) from the menu on the left on the Patient Safety Analysis web portal.



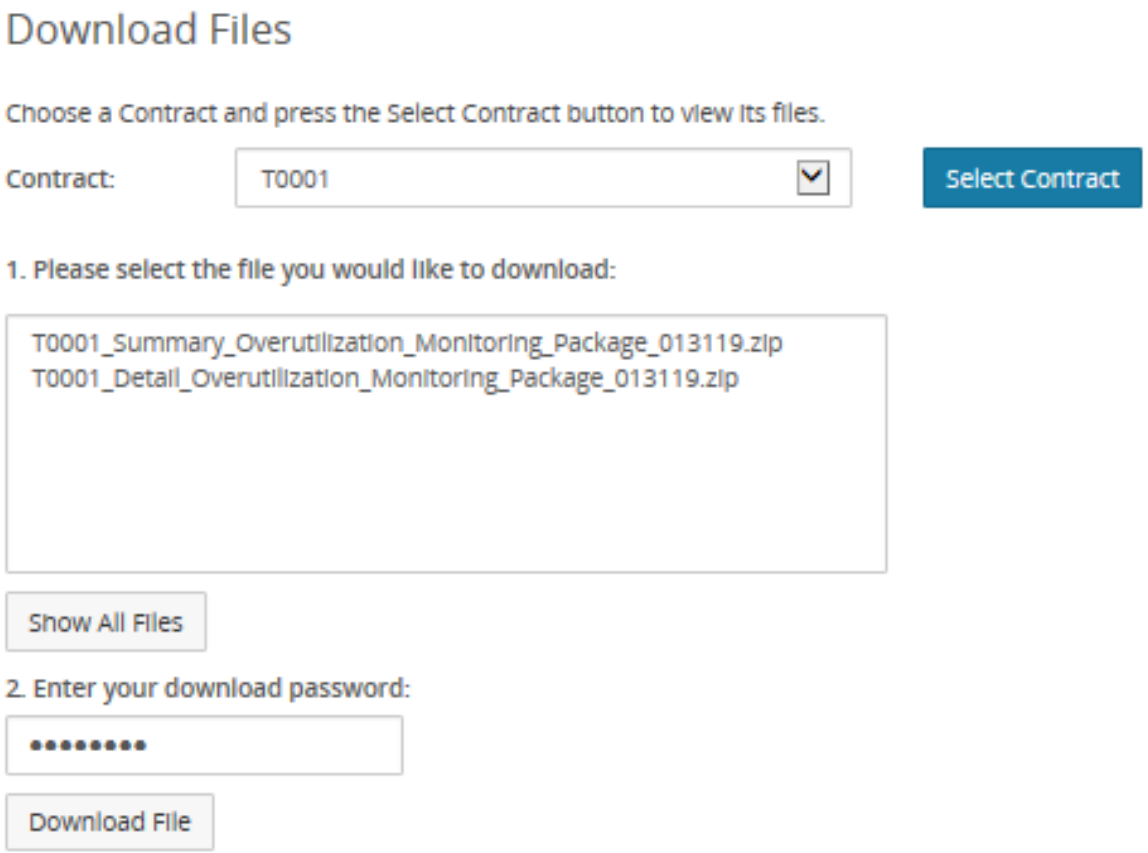


OMS REPORT PACKAGES

- Depending on your user access level, the following types of report packages will be made available each quarter on the Download Files page of the Patient Safety web portal.

OMS PACKAGE	ACCESS LEVEL	INCLUDED FILES
Summary OMS Package	Summary Report access level	• Summary OMS Report (.xlsx) • Sponsor Report Form (SRF) (.xlsx) • OMS User Guide (.pdf) • ORF and SRF Information Workbook (.xlsx)
Detail OMS Package	Summary and Confidential Beneficiary Reports access level	• Detail OMS Report (.xlsx) • OMS Response Form (ORF) – if the contract has open cases for review (.xlsx) • Sponsor Report Form (SRF) (.xlsx) • OMS User Guide (.pdf) • ORF and SRF Information Workbook (.xlsx)

DOWNLOAD INSTRUCTIONS



HELP DOCUMENTS

The following materials are made available on the Help Documents page of the Patient Safety web portal to assist sponsors with understanding their OMS report packages and form submissions:

DOCUMENTS	INFORMATION PROVIDED
OMS User Guide (.pdf)	Comprehensive guide for the Overutilization Monitoring System
ORF and SRF Information Workbook (.xlsx)	Provides additional guidance for successfully submitting the ORF and SRF, including response flowcharts, response code and file layout descriptions, and lists of valid response submission combinations
OMS Medication and Code List (.xlsx)	Comprehensive drug and diagnosis code lists used in OMS reporting
OMS Submission Schedule (.pdf)	Comprehensive list of all report release dates and submission deadlines

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SUMMARY AND DETAIL OMS REPORTS

OMS REPORTS	ACCESS TYPE	INFORMATION PROVIDED
Summary OMS Reports	Summary Report	The Summary OMS Report provides your contract's aggregated statistics
Detail OMS Reports	Summary and Confidential Beneficiary Reports	The Detail OMS Report provides summary and beneficiary-level statistics for your contract, including open and closed case information

CONTRACT SUMMARY TAB

Overall Summary table: Cumulative information about beneficiary cases beginning with the January 2019 posting.

Overall Summary (Beginning January 2019)

Beneficiary Group	Open ORF Cases - Response Expected	Total ORF Cases Reported Since Jan 2019	Total Closed ORF Cases Since Jan 2019	Total SRF Cases since Jan 2019
All Enrollees				
Non-LIS Beneficiaries				
LIS Beneficiaries				

Current Summary Table: Information about beneficiaries in the current measurement period.

Current Summary

Beneficiary Group	Total Part D Enrollees	Total Opioid Utilizers	% of Enrollees who are Opioid Utilizers	Total Open ORF Cases	% of Opioid Users that are Open ORF Cases	Total Open ORF Cases with Concurrent Benzodiazepine and Opioid Use	Total Open ORF Cases with Concurrent High Dose Gabapentin (>2400 mg) and Opioid Use	Total Open ORF Cases with Concurrent Pregabalin and Opioid Use	High Opioid Daily Dose (90 MME) Rate	Total Open SRF Cases
All Enrollees										
Non-LIS Beneficiaries										
LIS Beneficiaries										

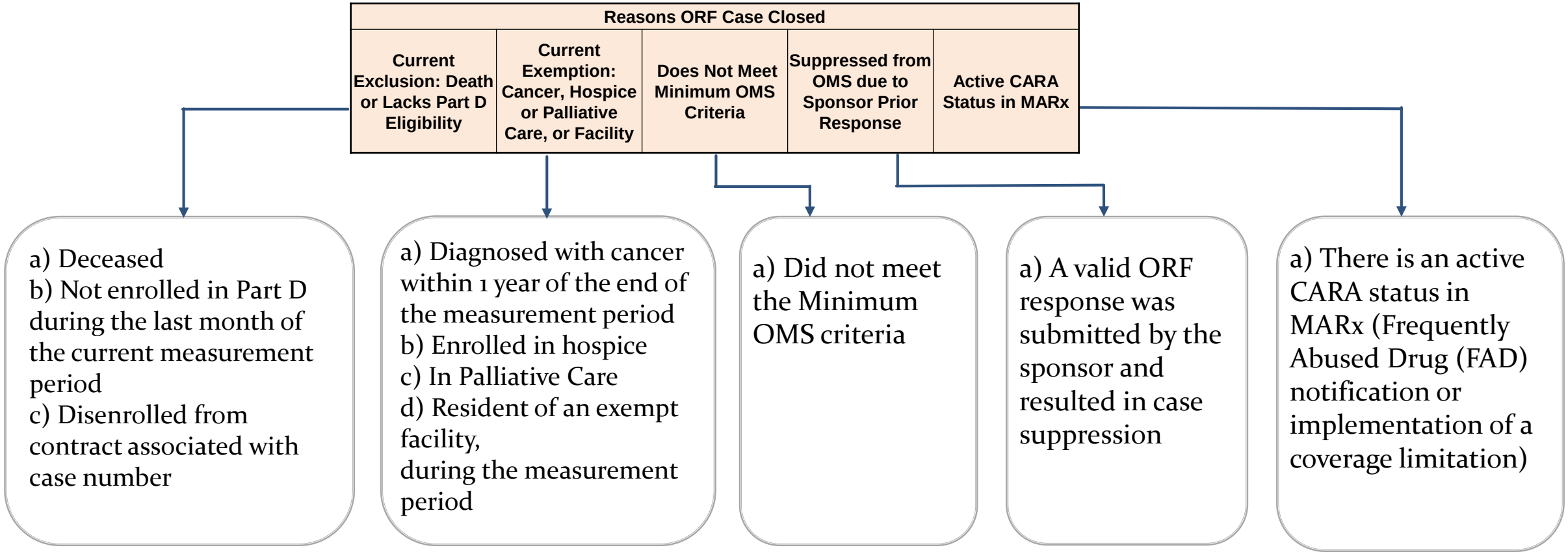
OPEN ORF CASES TAB

Beneficiary Information							Opioid Utilization Information									
Case Number	HICN	MBI	DOB	PBP ID	LIS Status	Date First Reported	Measurement Period	Prior Contracts Contributing to Utilization	Duration of Opioid Use	Total MME	Average Daily MME	Concurrent Benzodiazepine and Opioid Use	Concurrent High Dose Gabapentin (>2400 mg) and Opioid Use	Concurrent Pregabalin and Opioid Use	Number of Pharmacies Contributing to Opioid Claims	Number of Prescribers Contributing to Opioid Claims

- Beneficiary information is provided for each open ORF case.
  - Beneficiary meets Minimum OMS criteria (newly reported or re-identified).
  - ORF case with a previous review status of 'Initial Review in Progress'.
  - ORF case that received either no response or an invalid response.
- Sponsors can use the beneficiary-level fields to identify and review cases.
- Section 3.1.2 in user guide provides detail information about the key elements in Open ORF Cases tab.

CLOSED ORF CASES TAB

A beneficiary can have their ORF case closed for the following reasons:



Note: A beneficiary can have multiple closed reasons.

INTERMISSION

Any questions so far?

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ORF AND SRF

	ORF	SRF
PURPOSE	For Part D sponsors to provide CMS with responses on the status of their review and assessment of all beneficiaries identified by CMS or whose review was reported by the sponsor in the prior report as 'Initial Review in Progress'.	For Part D sponsors to report: • any **internally identified beneficiaries** who meet either the Minimum or *Supplemental OMS criteria** • **newly enrolled PARBs or ARBs for which a sponsor received a TRC of '376'** from the daily transaction reply report • Update any closed or suppressed ORF cases.
DISTRIBUTION & SUBMISSION	• Only sponsors with open cases will receive an ORF in their quarterly Detail Overutilization Monitoring Report package.	• Provided to all sponsors. • All sponsors are required to submit an SRF each quarter, even if there are no internally identified beneficiaries.

***Supplemental OMS criteria:** Use of opioids (regardless of average daily MME) during the most recent 6 months with 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies.

ORF AND SRF

WHERE ARE THEY LOCATED?	ORF: Detail Overutilization Monitoring Report Package SRF: Summary and Detail Overutilization Monitoring Report Packages
WHERE SHOULD THEY BE SUBMITTED?	Each quarter, the ORF and SRF forms must be submitted to the Upload Files page of the Patient Safety web portal.
WHEN IS THE DEADLINE?	• Sponsors must provide responses for open ORF cases and SRF cases **within exactly 30 days of the OMS report release date.** Example: ORF and SRF released with the OMS package on 1/31/19 must be submitted by 3/2/19. • The submission deadline is provided in the email notification and in the **Submission Schedule** on the Help Documents page of the Patient Safety web portal.
HOW SHOULD YOU COMPLETE BOTH FORMS ?	• Both forms should be **populated completely** and **with valid response combinations** for each case. • ORF or SRF with an Overall Form Status of "Complete" could still receive a Validation Status of "Invalid" if the response combinations for one or more cases are invalid.

ORF AND SRF

Example ORF

Contract ID:	
Report Date:	

Overall Form Status	**Incomplete**
# of Cases	**1**
# of Complete Cases	**0**

Name1	I, certify that the following information is accurate to the best of my knowledge

Responder Information		
Position	Email	Phone
Position1	Email@email.com	###-###-####

Case Number	HICN	MBI	DOB	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain	Exemption: Hospice, Palliative or End-of-Life Care	Administrative Exclusion: Deceased	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS Criteria Not Met: MME for Other Reasons	Response Status
T0001_0001	MBI1	HICN1	12/12/1961																**Incomplete**

INITIAL FIELDS TO FILL OUT

- For both the ORF and SRF, sponsors must first fill out the Responder Information portion of the form in the upper left hand corner.

ORF

Contract ID:	
Report Date:	

Overall Form Status	Complete
# of Cases	0
# of Complete Cases	0

Name1	I, certify that the following information is accurate to the best of my knowledge

Responder Information		
Position	Email	Phone
Position1	Email@email.com	###-###-####

SRF

Contract ID:	
Report Date:	

Overall Form Status	Incomplete
# of Cases	0
# of Complete Cases	0

Name1	I, certify that the following information is accurate to the best of my knowledge

Responder Information		
Position	Email	Phone
Position1	Email@email.com	###-###-####

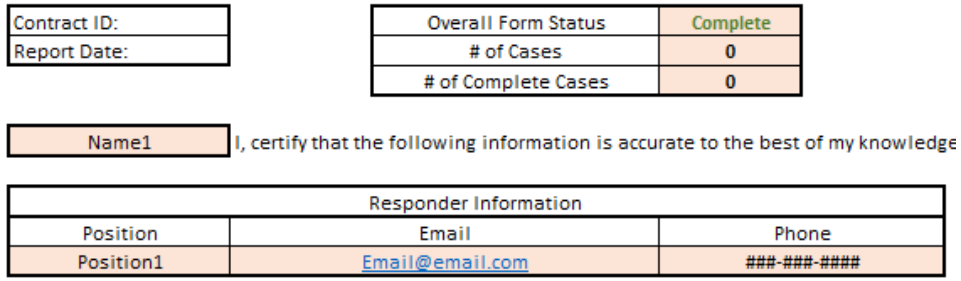
Has the sponsor internally identified any cases?

Y

INITIAL FIELDS TO FILL OUT

- For both the ORF and SRF, sponsors must first fill out the Responder Information portion of the form in the upper left hand corner.

ORF



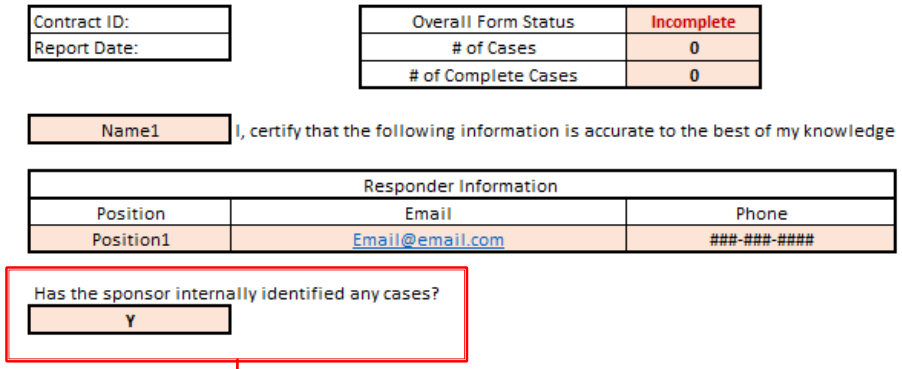
Contract ID:
Report Date:

Overall Form Status	Complete
# of Cases	0
# of Complete Cases	0

Name1	I, certify that the following information is accurate to the best of my knowledge

Responder Information		
Position	Email	Phone
Position1	Email@email.com	###-###-####

SRF



Contract ID:
Report Date:

Overall Form Status	Incomplete
# of Cases	0
# of Complete Cases	0

Name1	I, certify that the following information is accurate to the best of my knowledge

Responder Information		
Position	Email	Phone
Position1	Email@email.com	###-###-####

Has the sponsor internally identified any cases?
Y

Sponsors must also answer the question in Cell B13: 'Has the sponsor internally identified any cases'.

- If 'N', then sponsors must leave the remainder of the SRF blank, save the form to your desktop, and upload the form to the Patient Safety Analysis web portal using the Upload Files page.
- If 'Y', then populate the form with the SRF cases that have been identified using the remainder of this section as a guide.

ORF AND SRF INFORMATION WORKBOOK

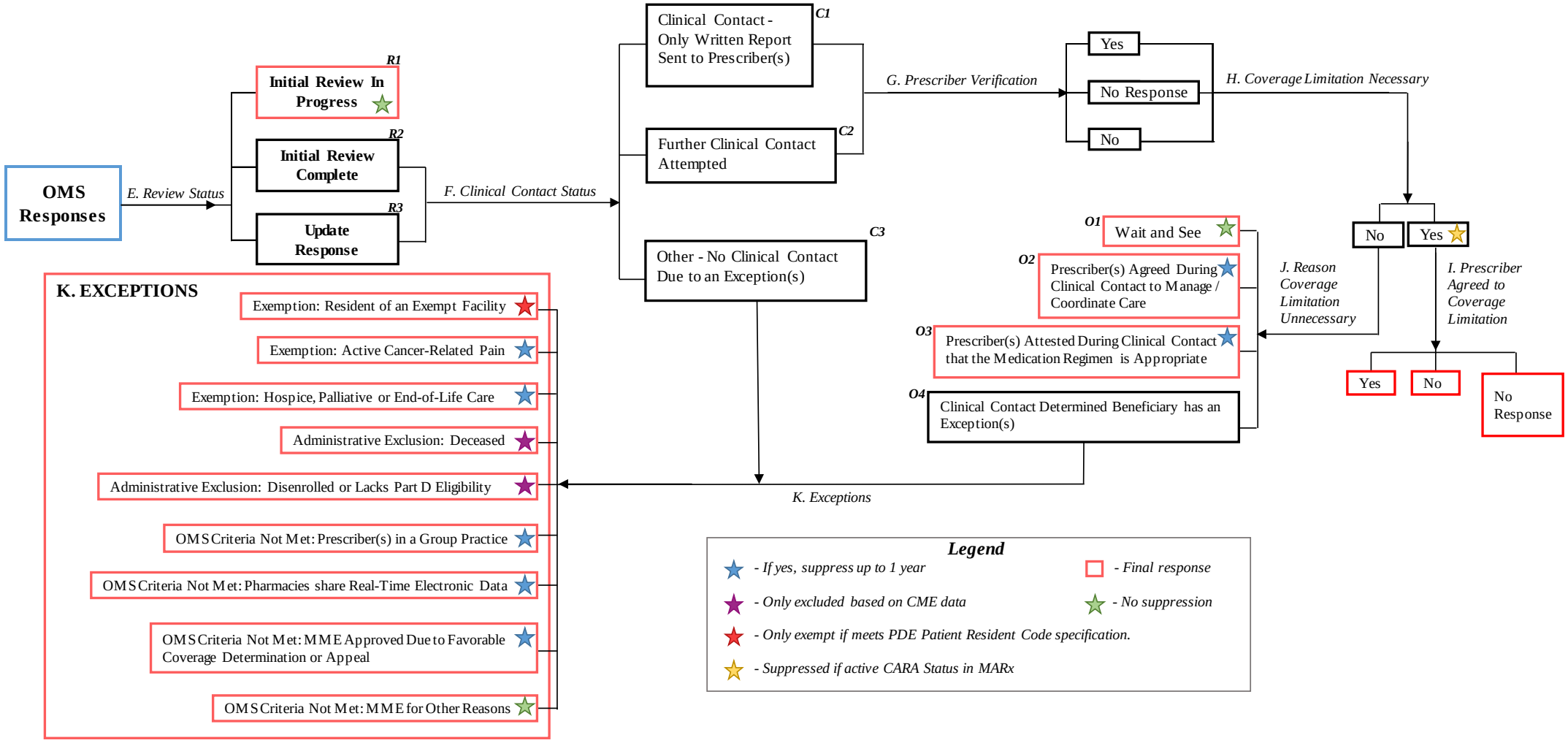
ORF AND SRF INFORMATION WORKBOOK:

Information Provided	• Flowcharts that provide a visual illustration for completing the response forms • Response form layouts with descriptions • Formats for each data element • Full descriptions of the response codes
Locations	• Report Packages • Patient Safety Web Portal -> Help Documents Page • CMS.gov: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

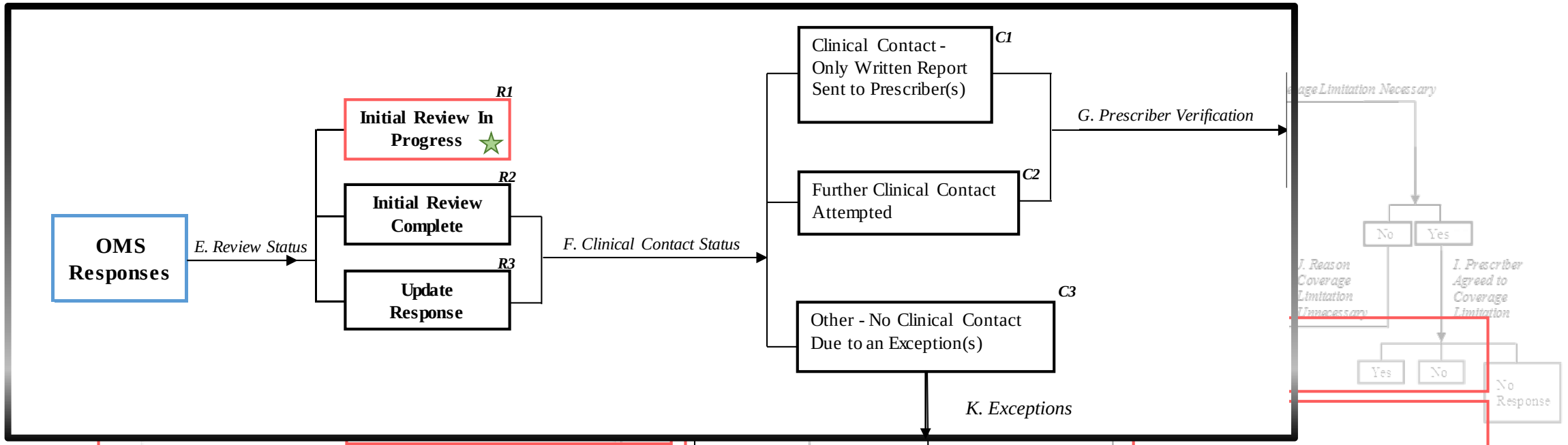
ORF AND SRF INFORMATION WORKBOOK TABS:

ORF Flowchart	This tab depicts the logic tree for the ORF reporting process and all response codes
SRF Flowchart	This tab depicts the logic tree for the SRF reporting process and all response codes
Response File Layout	This tab presents detailed descriptions of each data element as well as each data element's format and possible values
Response Codes	This tab presents detailed descriptions of all ORF and SRF response codes
ORF Valid Cases	This tab presents all possible combinations of response codes that are considered valid for ORF case responses
SRF Valid Cases	This tab presents all possible combinations of response codes that are considered valid for SRF case responses
Error Code Hierarchy	This tab outlines the hierarchy used for all 10 error codes and messages for invalid responses

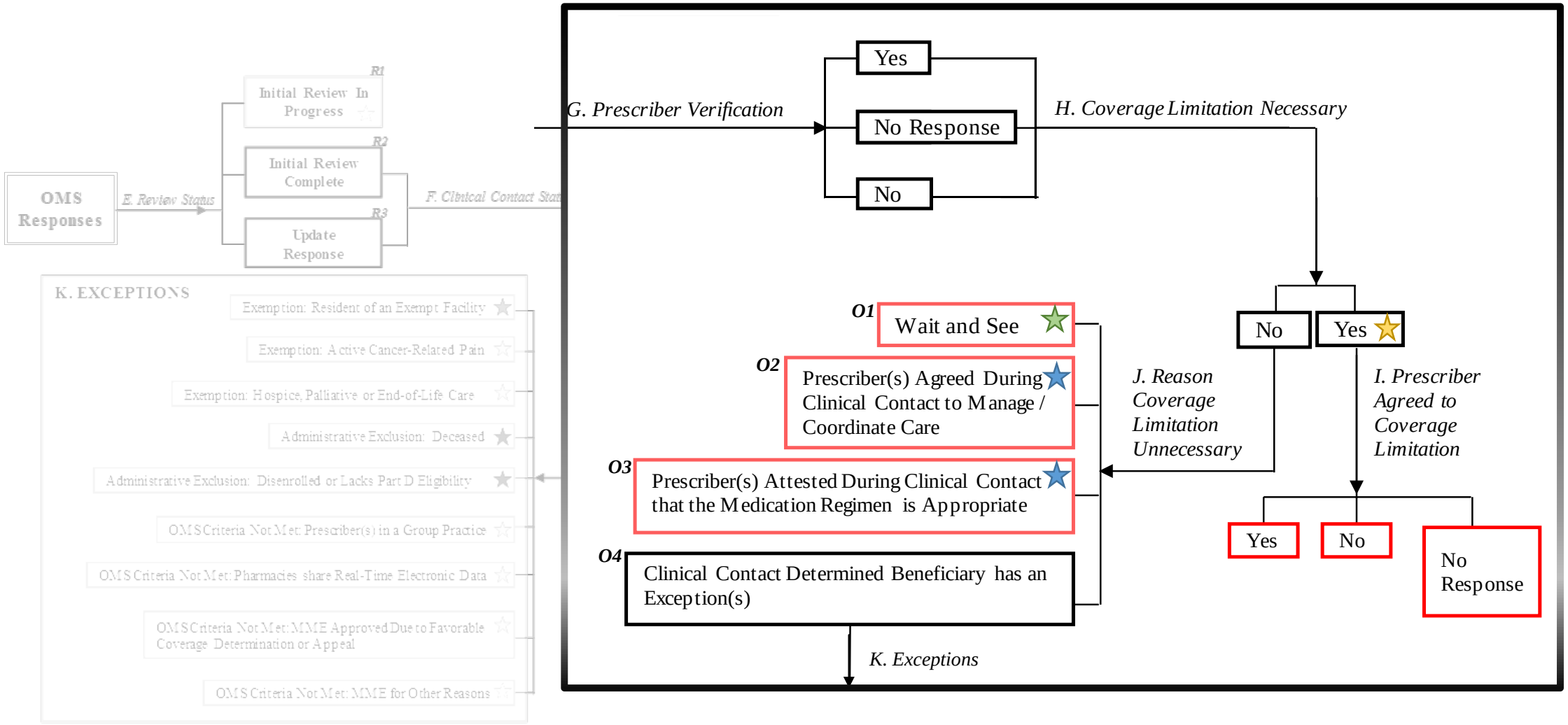
ORF FLOWCHART



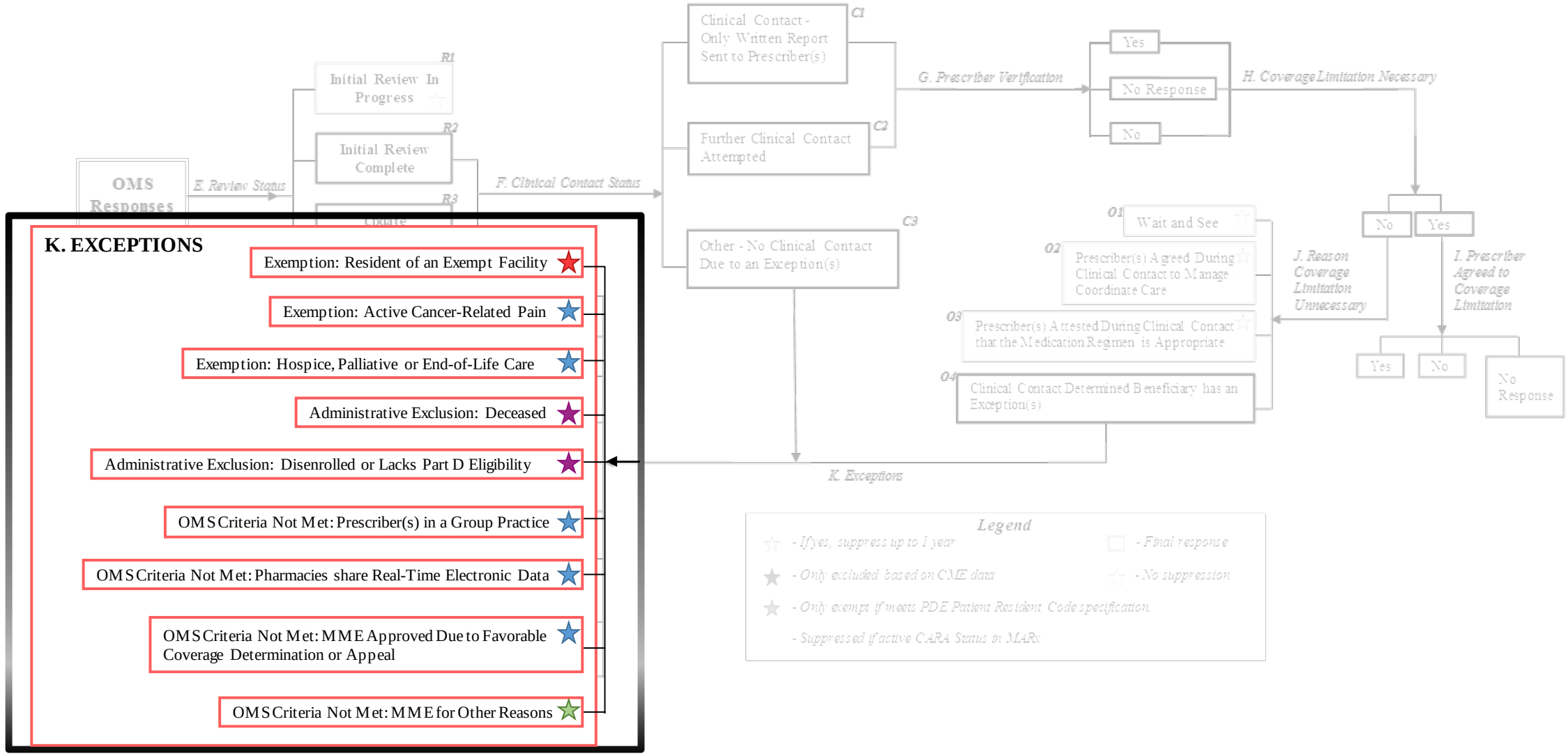
ORF FLOWCHART: ELEMENTS E AND F



ORF FLOWCHART: ELEMENTS G, H, I AND J



ORF FLOWCHART: ELEMENT K



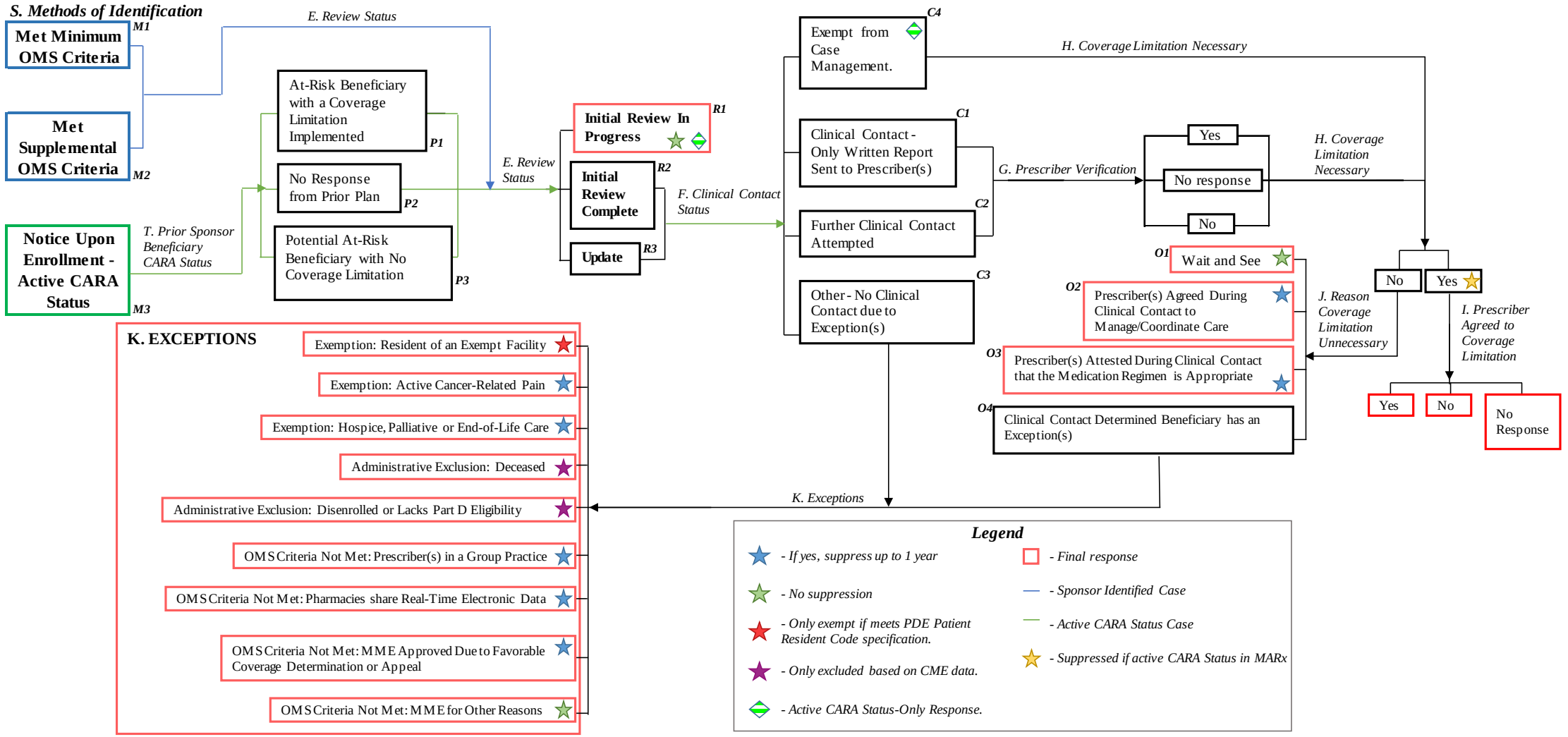
EXCEPTIONS

Element	Exception	Description	Suppression Rule
K1.	Resident of an Exempt Facility	Beneficiary is a resident of a LTC facility, of a facility described in section 1905(d) of the Act, or of another facility for which FADs are dispensed for residents through a single pharmacy.	If last Prescription Drug Event (PDE) Patient Resident Code is 3 or 9.
K2.	Active Cancer-Related Pain	Beneficiary is being treated for active cancer-related pain.	Y=Suppressed up to 1 year, death or disenrollment.
K3.	Hospice, Palliative or End-of-Life Care	Beneficiary has elected to receive hospice care or is receiving palliative or end-of-life care.	Y=Suppressed up to 1 year, death or disenrollment.
K4.	Deceased	Beneficiary is deceased.	Exclude from OMS reporting. Source: Common Medicare Environment (CME).
K5.	Disenrolled or Lacks Part D Eligibility	Beneficiary disenrolled or lacks Part D enrollment.	Exclude from OMS reporting. Source: CME.

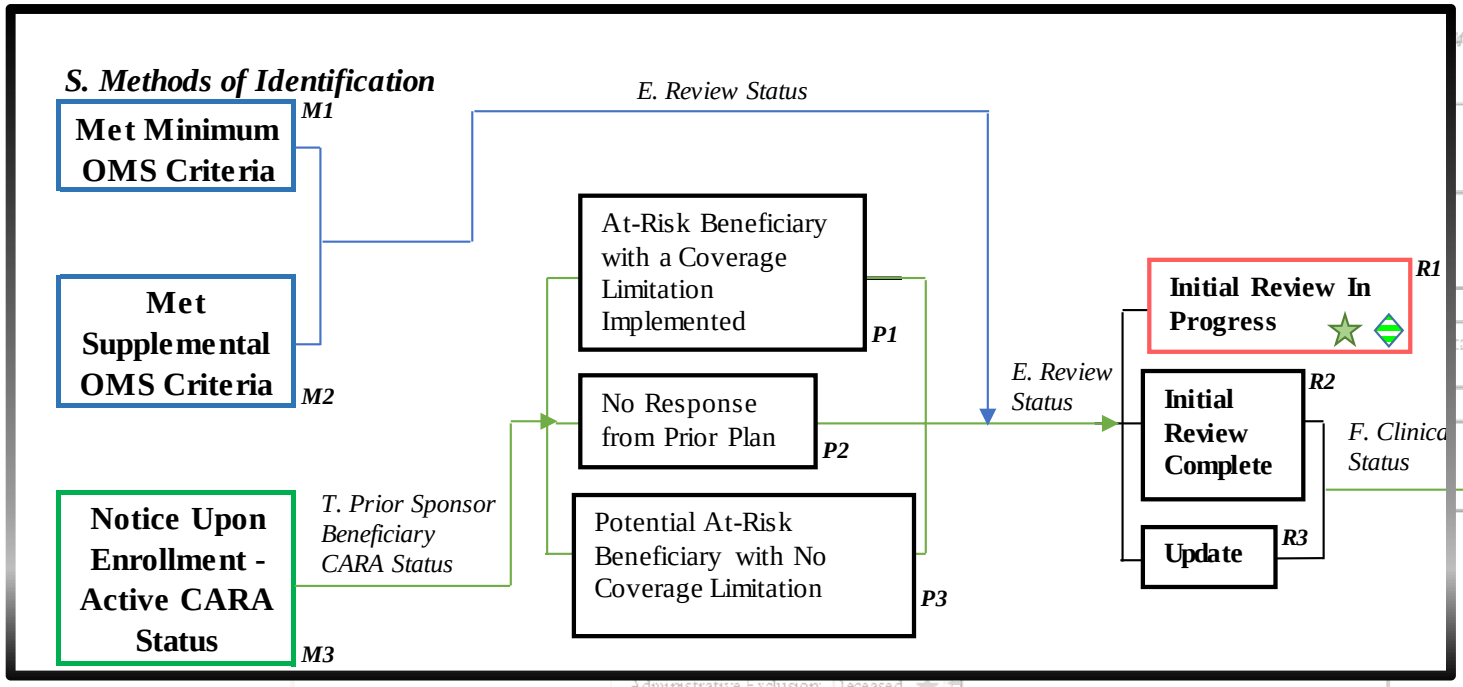
EXCEPTIONS CONTINUED

Element	Exception	Description	Suppression Rule
K6.	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Prescriber criterion not met because several prescribers are within the same group practice and treated as one prescriber.	Y=Suppressed up to 1 year, death or disenrollment.
K7.	OMS Criteria Not Met: Pharmacies share Real-Time Electronic Data	OMS Pharmacy criterion not met because pharmacies with multiple locations that share real-time electronic data are treated as one pharmacy.	Y=Suppressed up to 1 year, death or disenrollment.
K8.	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS MME criterion not met because of a favorable coverage determination or appeal.	Y=Suppressed up to 1 year, death or disenrollment.
K9.	OMS Criteria Not Met: MME for Other Reasons	OMS MME criterion not met for other reasons (e.g., MME is due to appropriate prescription fill overlap, data entry error, an acute/temporary short-term use that has resolved or dosage was reduced).	None

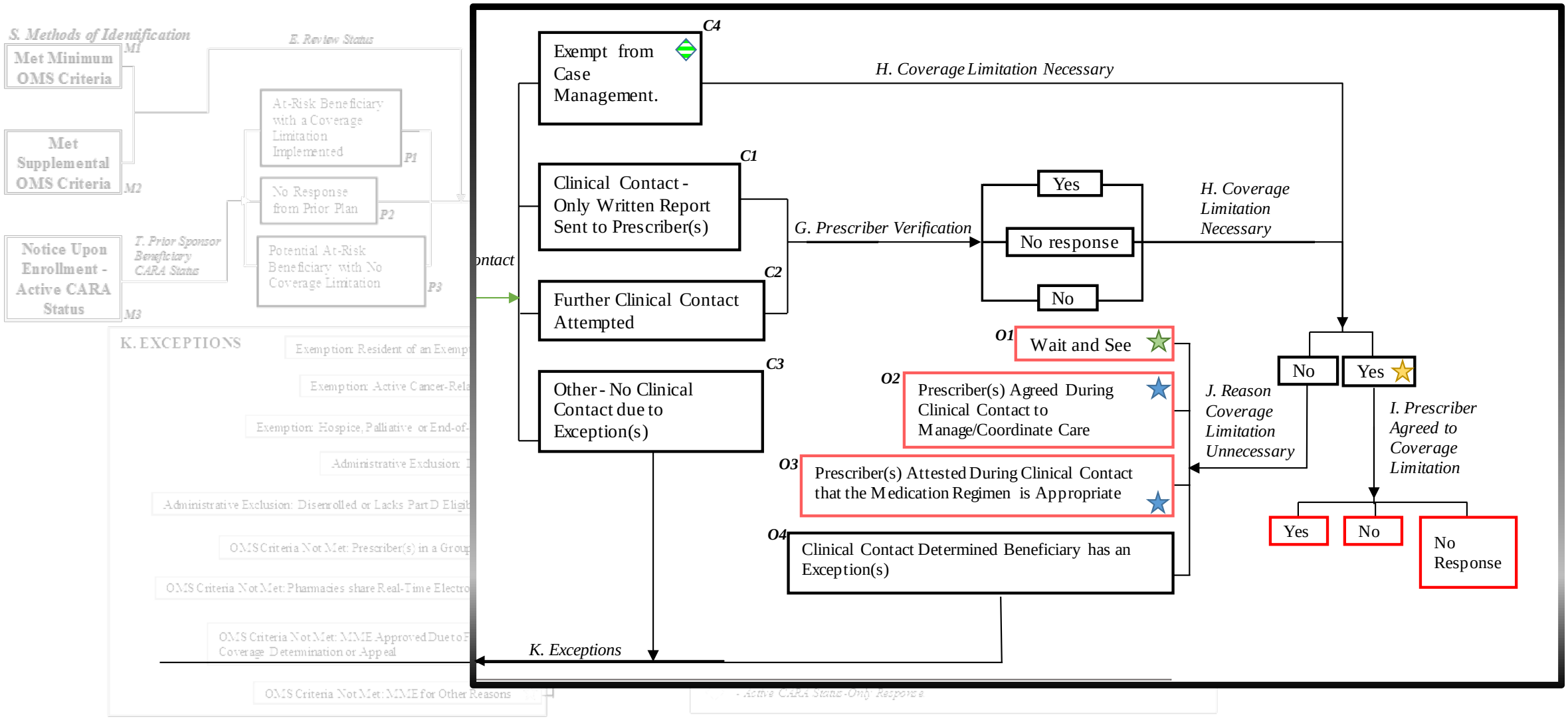
SRF FLOWCHART



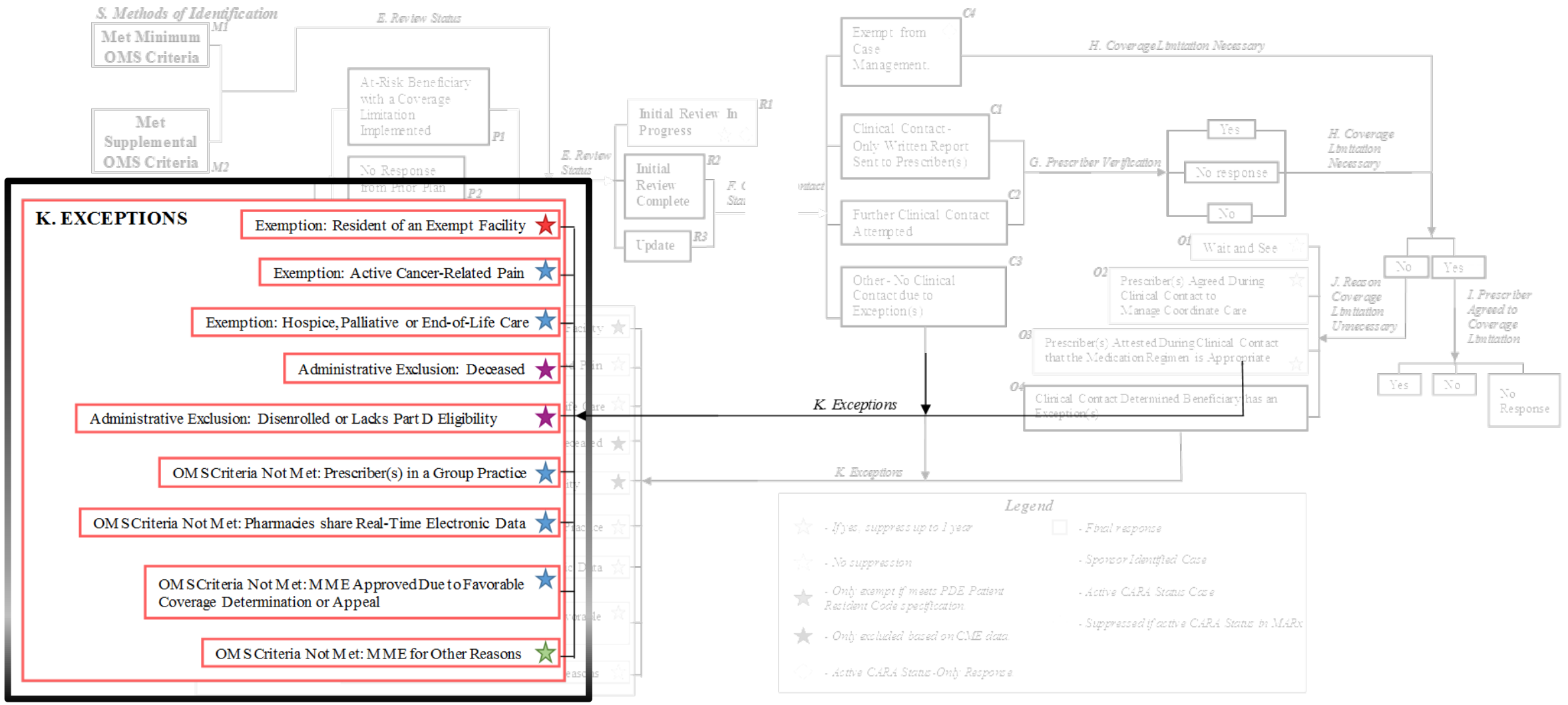
SRF FLOWCHART: ELEMENTS S, T, AND E



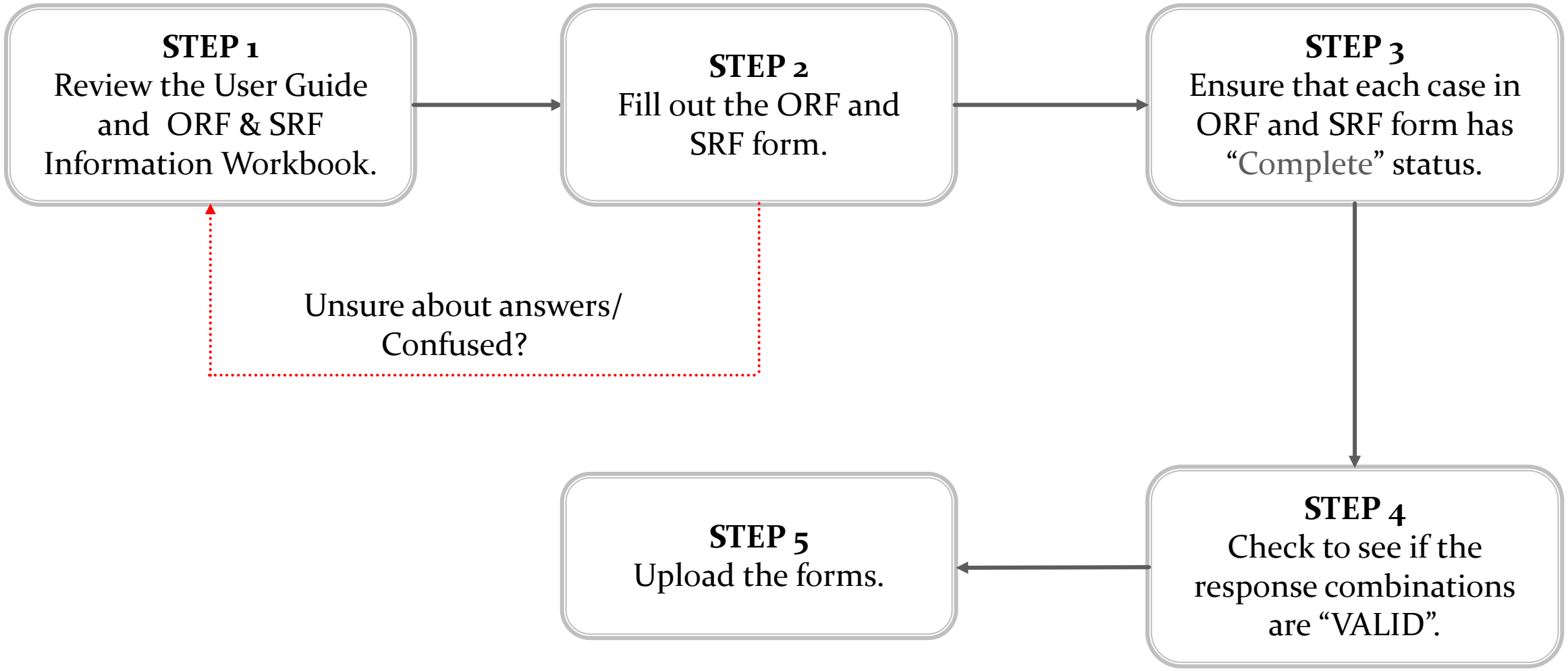
SRF FLOWCHART: ELEMENTS F-J



SRF FLOWCHART: ELEMENT K



HOW TO COMPLETE THE FORMS: OVERVIEW



WHEN IS THE FORM COMPLETE?

Contract ID:	
Report Date:	

Overall Form Status	Complete
# of Cases	5
# of Complete Cases	5

Ensure Statuses are "Complete"

Name1	I, certify that the following information is accurate to the best of my knowledge

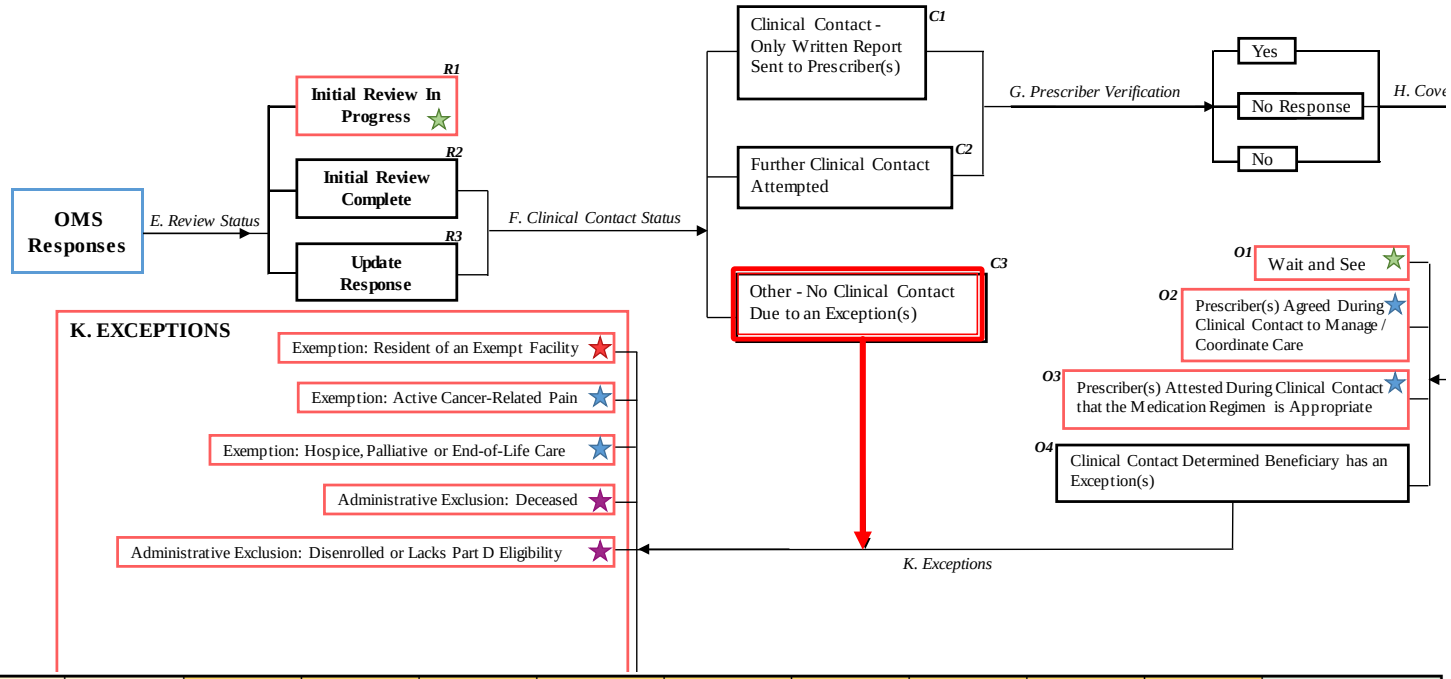
Responder Information		
Position	Email	Phone
Position1	Email@email.com	###-###-####

Case Number	MBI	HICN	DOB	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain	Exemption: Hospice, Palliative or End-of-Life Care	Administrative Exclusion: Deceased	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS Criteria Not Met: MME for Other Reasons	Response Status
T0001_0001	MBI1	HICN1	01/01/65	R2	C2	Y	Y	Y	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Complete
T0001_0002	MBI2	HICN2	01/01/76	R2	C3	NA	NA	NA	NA	N	Y	Y	N	N	N	N	N	N	Complete
T0001_0003	MBI3	HICN3	01/01/47	R1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Complete
T0001_0004	MBI4	HICN4	01/01/67	R2	C1	N	N	NA	O3	NA	NA	NA	NA	NA	NA	NA	NA	NA	Complete
T0001_0005	MBI5	HICN5	01/01/41	R2	C2	N	N	NA	O4	N	Y	N	N	N	N	N	N	N	Complete

SAMPLE RESPONSE QUESTION #1

Q: I chose "C3" for Clinical Contact Status, how do I proceed?

A: Using the **ORF Flowchart** tab in ORF and SRF Information workbook, a sponsor could determine that if the Clinical Contact Status is "C3", then they should proceed to the 'Exceptions'.
Also, the elements that were skipped (*Prescriber Verification, Coverage Limitation Necessary, Prescriber Agreed to Coverage Limitation, and Reason Coverage Limitation Unnecessary*) should all be populated "NA".



ORF FORM:

Case Number	HICN	MBI	DOB	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain	Exemption: Hospice, Palliative or End-of-Life Care	Administrative Exclusion: Deceased	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS Criteria Not Met: MME for Other Reasons	Response Status
T0001_0001	HICN1	MBI1	12/12/1961	R2	C3	NA	NA	NA	NA										Incomplete

SAMPLE RESPONSE QUESTION #2

Q: What does the "Exemption: Resident of an Exempt Facility" mean?

A: Using the **Response File Layouts** tab in ORF and SRF Information workbook, a sponsor could find the description for the element "Exemption: Resident of an Exempt Facility".

RESPONSE FILE LAYOUTS TAB:

ORF			
#	Data Element	Element Description	Format/Value(s)
K1	Exemption: Resident of an Exempt Facility	Beneficiary is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy	CHAR(2) (Y, N, NA)

ORF FORM:

Case Number	HICN	MBI	DOB	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain	Exemption: Hospice, Palliative or End-of-Life Care	Administrative Exclusion: Deceased	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS Criteria Not Met: MME for Other Reasons	Response Status
T0001_0001	HICN1	MBI1	12/12/1961	R2	C3	NA	NA	NA	NA										Incomplete

SAMPLE RESPONSE QUESTION #3

Q: What does the response code "P3" for "Prior Sponsor Beneficiary CARA Status" mean, and which forms is this code used for?

A: Using the **Response Codes** tab, a sponsor could find the definition for the response code "P3", which response form(s) this code is available in, and how to proceed with populating the response form.

RESPONSE CODES TAB:

Element	Code	Response Name	Response Description	Forms Used
T. Prior Sponsor Beneficiary CARA Status *Only applies if the response to S. = M3*	P1	At-Risk Beneficiary with a Coverage Limitation Implemented	Indicates that successful communication was established with the prior Part D sponsor and the beneficiary had an implemented coverage limitation(s) under the prior contract. **Proceed to 'E. Review Status'.**	SRF
	P2	No Response from Prior Plan	Indicates that attempted contact with the prior Part D sponsor was unsuccessful. **Proceed to 'E. Review Status'.**	SRF
	P3	Potential At-Risk Beneficiary with No Coverage Limitation Implemented	Indicates successful communication was established with the prior Part D sponsor and the beneficiary coverage limitation(s) were pending. **Proceed to 'E. Review Status'.**	SRF
	NA	Not Applicable	If 'S. Method of Identification' = 'M1' or 'M2'.	SRF

ORF FORM:

HICN	MBI	DOB	Method of Identification	Prior Sponsor Beneficiary CARA Status	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain	Exemption: Hospice, Palliative or End-of-Life Care	Administrative Exclusion: Deceased	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS Criteria Not Met: MME for Other Reasons	Response Status
HICN1	MBI1	5/6/1967	M3	P3																Incomplete

SAMPLE RESPONSE QUESTION #4

Q: I've populated my case information and the Response Status is "Complete". How do I know if my response combination is valid or invalid?

A: Using the **ORF Valid Cases** tab like an answer key, a sponsor could verify whether the populated responses for each case are valid or not. Please note that a case's response combination can be invalid even when the Response Status is 'Complete'.

ORF Valid Cases

Note: For elements K1-9 where 'Y or N' is a valid responses, at least one element must by 'Y'.

E. Review Status	F. Clinical Contact Status	G. Prescriber Verification	H. Coverage Limitation Necessary	I. Prescriber Agreed to Coverage Limitation	J. Reason Coverage Limitation Unnecessary	K1. Exemption: Resident of an Exempt Facility	K2. Exemption: Active Cancer-Related Pain	K3. Exemption: Hospice, Palliative or End-of-Life Care	K4. Administrative Exclusion: Deceased	K5. Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	K6. OMS Criteria Not Met: Prescriber(s) in a Group Practice	K7. OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	K8. OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	K9. OMS Criteria Not Met: MME for Other Reasons
R2	C2	Y	N	NA	O4	Y or N	Y or N	Y or N	Y or N	Y or N	Y or N	Y or N	Y or N	Y or N

ORF FORM:

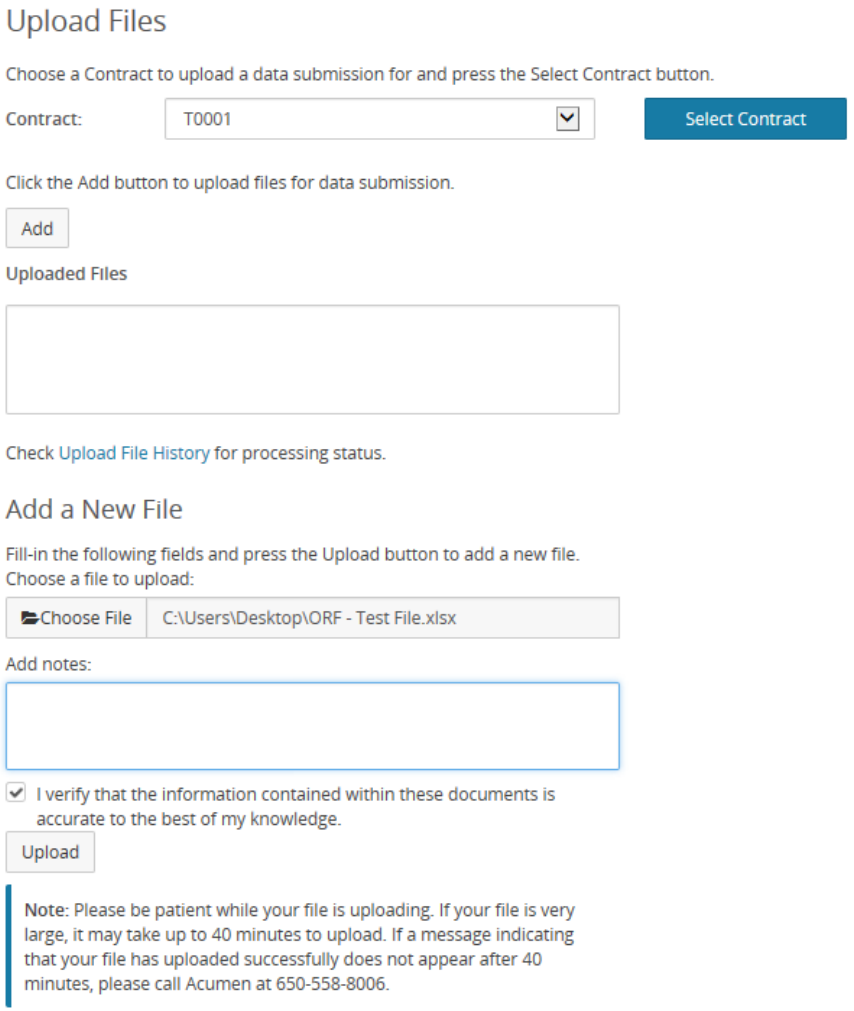
Case Number	HICN	MBI	DOB	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain	Exemption: Hospice, Palliative or End-of-Life Care	Administrative Exclusion: Deceased	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS Criteria Not Met: MME for Other Reasons	Response Status
T0001_0001	HICN1	MBI1	12/12/1961	R2	C2	Y	N	NA	O4	N	Y	Y	N	N	N	N	N	N	Complete

ROADMAP

1. DMP and OMS Background
2. OMS Process
3. OMS Documents
4. OMS Reports
5. ORF and SRF Submission Process
6. **Website Information**
7. Validation Reports
8. Q&A

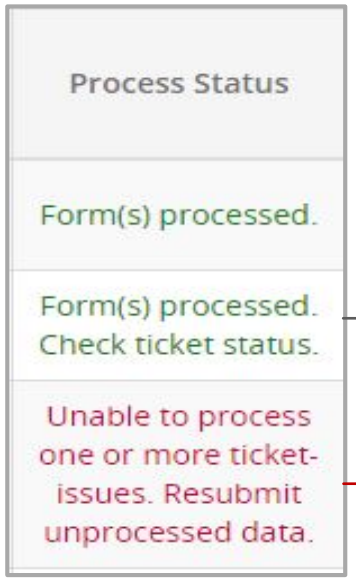
HOW TO UPLOAD THE FORMS?

- Once the forms are ready for submission, save a copy of the file to your desktop, and navigate to the Upload Files page on the web portal.



UPLOAD FILE HISTORY

- Once a form is submitted, the status of the upload can be viewed on the Upload File History page of the web portal.



Please ensure that the Process Status includes "Form(s) Processed"

If the Process Status is unsuccessful, there is an issue with the form that was submitted

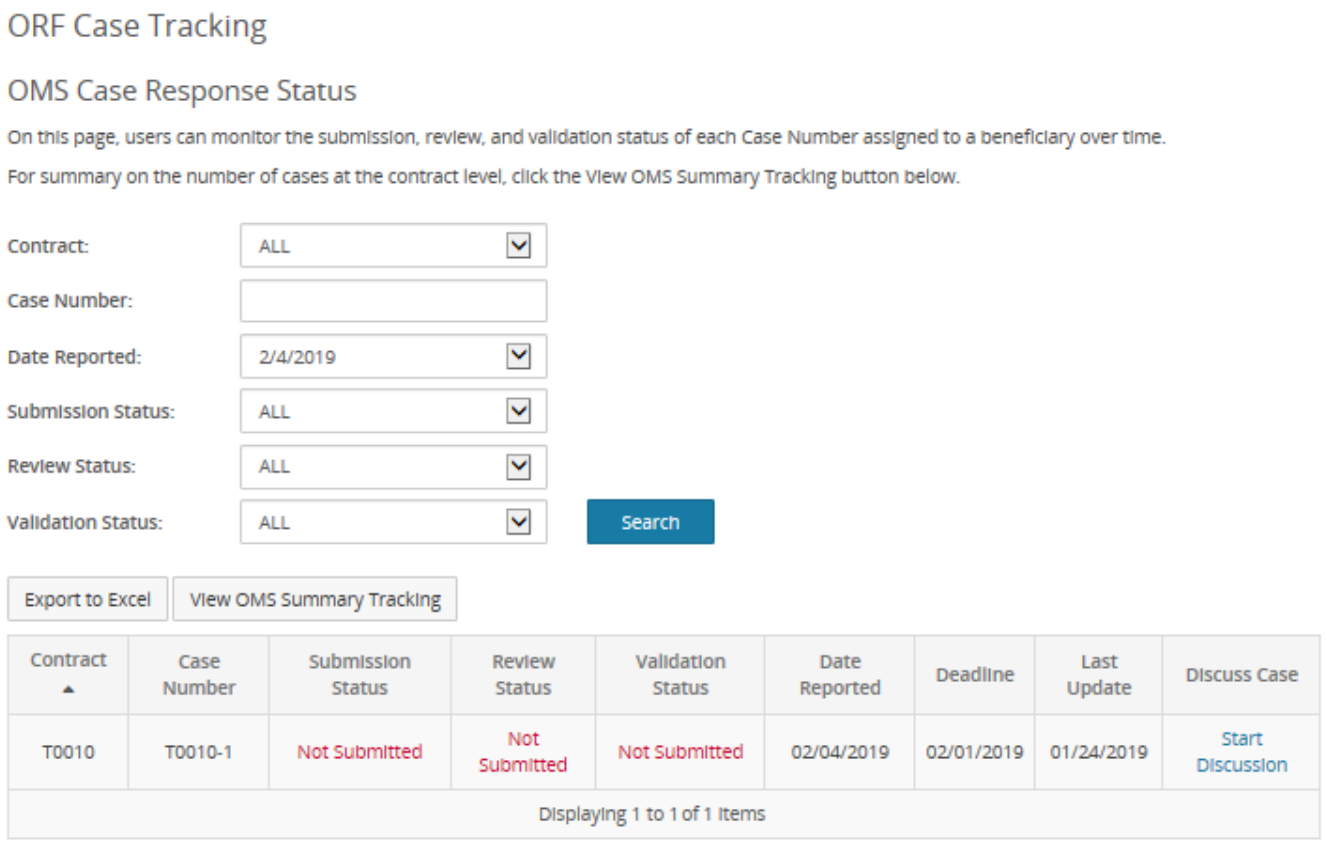
WEB PORTAL CASE STATUS

- Additional information about submissions can be found on the Summary and Case Tracking pages of the web portal.
- On the Case Tracking page, you will find 3 statuses for each case:

STATUS	STATUS DESCRIPTION
Submission Status	'Submitted' or 'Not Submitted'
Review Status	If the 'Submission Status' is 'Submitted', then the 'Review Status' will be populated with the Review Status value from the submitted ORF (R1, R2, or R3)
Validation Status	After the Response Validation Reports are sent out to sponsors, will be updated to 'Valid' or 'Invalid

CASE SUBMISSION STATUS

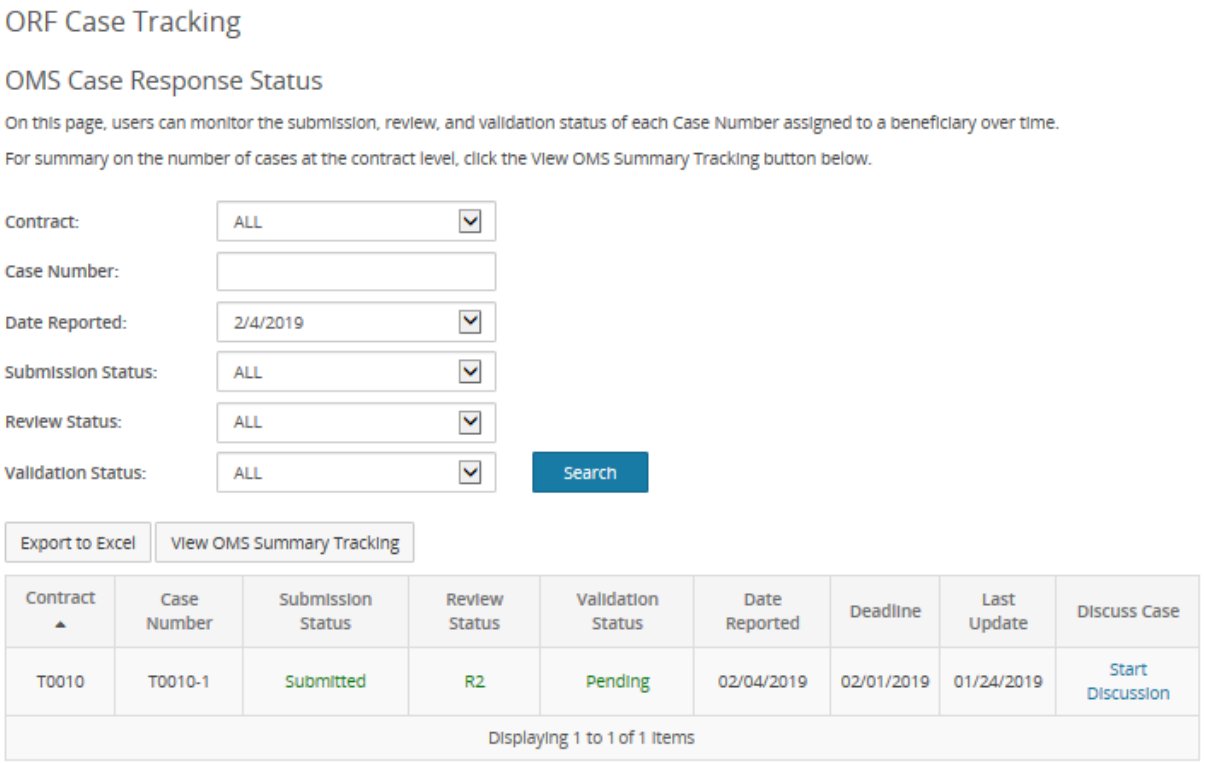
- **Submission Status** – ‘Submitted’ or ‘Not Submitted’



Website Information: Upload Process | **Statuses**

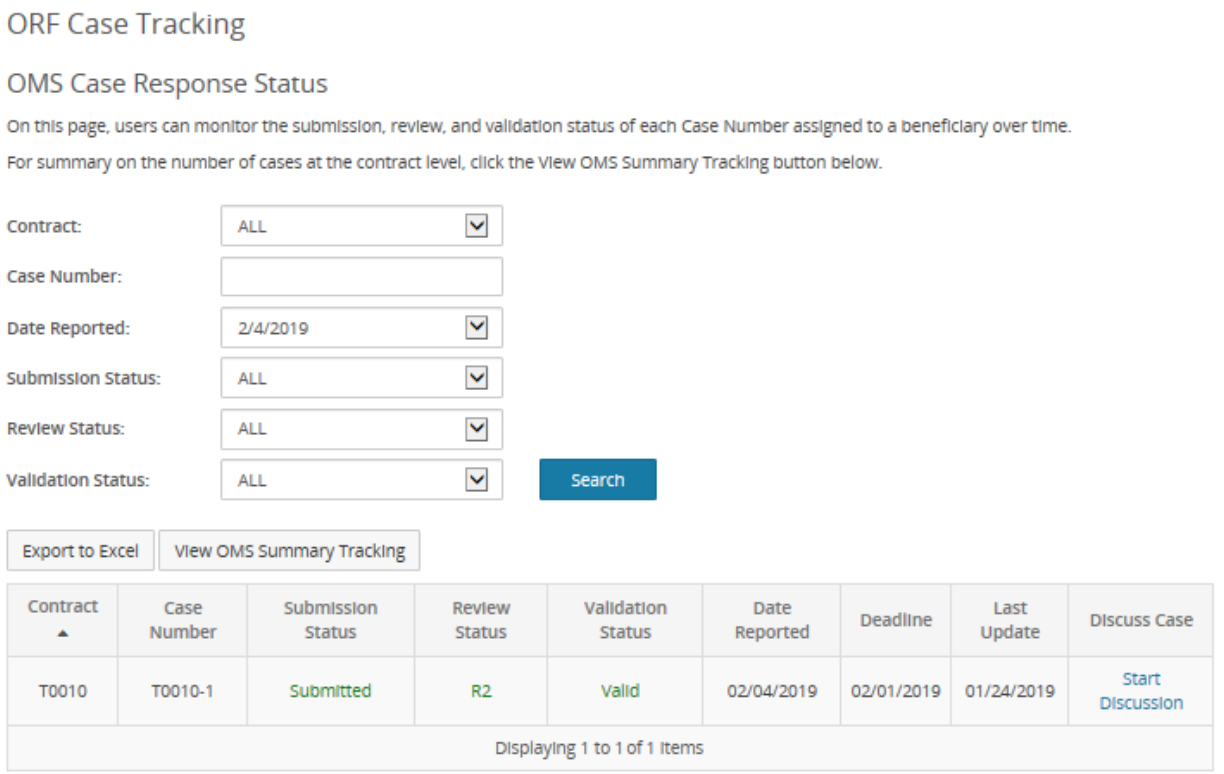
CASE REVIEW STATUS

- **Review Status** – If the 'Submission Status' is 'Submitted', then the 'Review Status' will be populated with the Review Status value from the submitted ORF (R1, R2, or R3).
- Before the validation reports are sent out, the validation status for all completed responses will be 'Pending'.



CASE VALIDATION STATUS

- **Validation Status** – After the Response Validation Reports are sent out to sponsors, this status be updated to 'Valid' or 'Invalid'.



ROADMAP

1. DMP and OMS Background
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RESPONSE VALIDATION REPORT

WHEN IS IT SENT?	The Response Validation Report will be sent to all sponsors that submitted an ORF or SRF **one week after the submission deadline**
WHAT DOES IT CONTAIN?	The Response Validation Report contains the same information as the ORF and SRFs, with three additional columns: • **Validation Status** – this column indicates whether the submitted responses are deemed 'valid' or 'invalid • **Error Code** – if the submitted responses are 'invalid', then the error code will be displayed • **Error Message** – a description of the error code
WHAT HAPPENS TO THE VALIDATION STATUS ON THE WEBSITE?	The website 'validation status' will be updated to reflect the validation status on the report

WHAT HAPPENS TO INVALID RESPONSES?

- Invalid responses will be treated as 'No Response' in the next cycle and may be re-reported to sponsors if no exceptions are met.
- Sponsors who repeatedly submit ORF reports with invalid responses may be subject to a compliance action.
- CMS will evaluate the necessity for any additional re-submission periods.

HOW TO CORRECT ERRORS?

Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R1	C1	N	N	N	O1	N	Y

- Invalid cases will have an 'Error Code' and 'Error Message' populated.
- The cause of the error as stated in the 'Error Message' are highlighted in the subsequent response element columns.
- Note: In the event of an opened ad hoc submission period, always correct and submit your original ORF and SRF for resubmissions, NOT in the 'Response Validation Report'.

ERROR CODE HIERARCHY

Table 12. Validation Error Code Hierarchy

Hierarchy	Error Code	Error Message
1	E1	Both element B (MBI) and C (HICN) are invalid.
2	E2	Prior Sponsor Beneficiary CARA Status (element T) is not populated with 'NA' when Method of Identification (element S) is populated with 'M1' or 'M2'.
3	E3	Prior Sponsor Beneficiary CARA Status (element T) is populated with 'NA' when Method of Identification (element S) is populated with 'M3'.
4	E4	Multiple final response elements populated with non-'NA' responses.
5	E5	All final response elements populated with 'NA'.
6	E6	At least one element is not populated with 'NA' when Review Status (element E) is populated with 'R1'.
7	E7	Elements leading to final response populated incorrectly.
8	E8	At least one exception (elements K.1-9) is populated with 'Y' or 'N' when Clinical Contact Status (element F) is not populated with 'C4' and Reason Coverage Limitation Unnecessary (element J) is not populated with 'O4'.
9	E9	No exceptions (elements K.1-9) are populated with 'Y' when Clinical Contact Status (element F) is populated with 'C3' or Reason Coverage Limitation Unnecessary (element J) is populated with 'O4'.
10	E10	Review Status (element E) is populated with 'R3' for a newly identified case.

- If multiple errors exist, only the error highest on the 'error code hierarchy' will be displayed.

CORRECTION EXAMPLE

Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R1	C1	N	N	N	O1	N	Y

- In this example, the response is flagged with an error code of 'E4', indicating that the 'Invalid' validation status is due to multiple final responses being populated.
- A response of 'R1' (Initial Review In Progress) for the 'Review Status' element, 'N' for the 'Prescriber Agreed to Coverage Limitation' element, 'O1' (Wait and See) for the 'Reason Coverage Limitation Unnecessary' element, and the 'Y' and 'N' responses to the 'Exception' elements are all Final Responses and thus are all highlighted.
- In this example, let's assume that the following actions and determinations were made by the sponsor:
  - Initial review of the case has finished.
  - A written report was sent to the prescriber, but no response was received.
  - The sponsor decided to wait and see if prescriber(s) adjust their management of, and prescriptions for, the beneficiary.

CORRECTION EXAMPLE

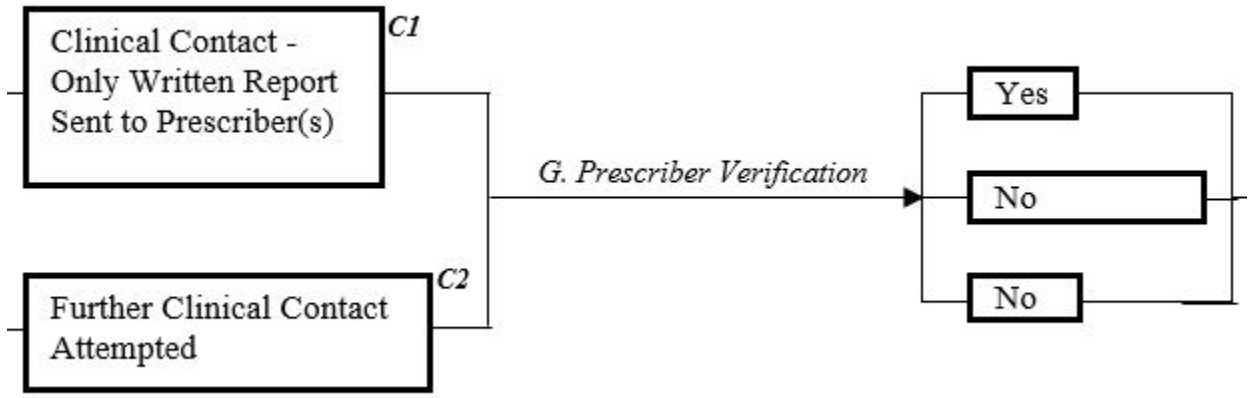
Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R1	C1	N	N	N	O1	N	Y

- The first response, 'R1' (Initial Review In Progress), should be changed to 'R2' (Initial Review Complete) since the sponsor has finished reviewing the case and has decided on a course of action.

CORRECTION EXAMPLE CONTINUED

Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R2	C1	N	N	N	O1	N	Y

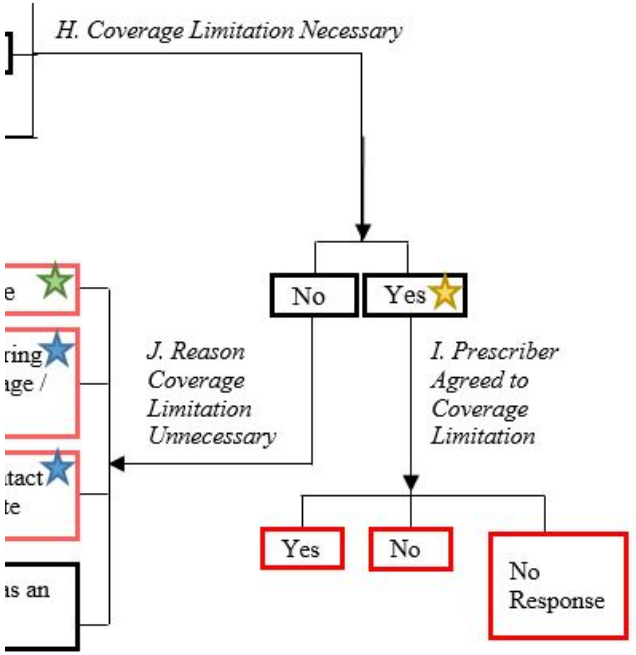
- After correcting the 'Review Status', the next element is correctly populated with 'C1' (Clinical Contact - Only Written Report Sent to Prescriber).
- However, since the prescriber did not respond, the 'Prescriber Verification' element should be populated with 'NR' (No Response).
- Note that this cell was not previously highlighted and a response of 'N' is allowed in combination with 'C1', but 'NR' would be the most correct response.



CORRECTION EXAMPLE CONTINUED

Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R2	C1	NR	N	N	O1	N	Y

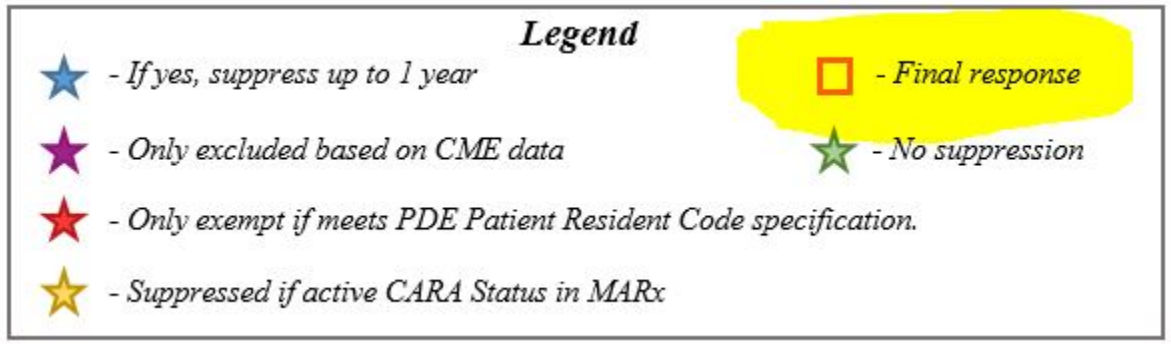
- The 'Coverage Limitation Necessary' was correctly populated with 'N', indicating that the sponsor determined that coverage limitation was unnecessary.
- However, 'Prescriber Agreed to Coverage Limitation' should be 'NA' since the sponsor determined coverage limitation was unnecessary.
- Note: Anytime an element is bypassed on the flowchart, the bypassed element should be populated with 'NA'.



CORRECTION EXAMPLE CONTINUED

Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R2	C1	NR	N	NA	O1	N	Y

- 'Reason Coverage Limitation Unnecessary' is correctly populated with 'O1' (Wait and See).
- Since 'O1' is the final response, all subsequent elements should be populated with 'NA'.



CORRECTION EXAMPLE CONTINUED

Validation Status	Error Code	Error Message	Review Status	Clinical Contact Status	Prescriber Verification	Coverage Limitation Necessary	Prescriber Agreed to Coverage Limitation	Reason Coverage Limitation Unnecessary	Exemption: Resident of an Exempt Facility	Exemption: Active Cancer-Related Pain
Invalid	E4	Multiple final response elements populated with non-'NA' responses.	R2	C1	NR	N	NA	O1	NA	NA

- With all the corrections made, check the 'Valid ORF Cases' tab in the 'ORF and SRF Information' workbook to ensure that all your responses are valid.
- If your response combination is found, then it will be treated as a valid response and will be used in the next OMS cycle.

ORF and SRF Information

ORF Valid Cases

Note: For elements K1-9 where 'Y or N' is a valid responses, at least one element must by 'Y'.

E. Review Status	F. Clinical Contact Status	G. Prescriber Verification	H. Coverage Limitation Necessary	I. Prescriber Agreed to Coverage Limitation	J. Reason Coverage Limitation Unnecessary	K1. Exemption: Resident of an Exempt Facility	K2. Exemption: Active Cancer-Related Pain	K3. Exemption: Hospice, Palliative or End-of-Life Care	K4. Administrative Exclusion: Deceased	K5. Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	K6. OMS Criteria Not Met: Prescriber(s) in a Group Practice	K7. OMS Criteria Not Met: Pharmacies Share Real-Time Electronic Data	K8. OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	K9. OMS Criteria Not Met: MME for Other Reasons
R2	C1	NR	N	NA	O1	NA	NA	NA	NA	NA	NA	NA	NA	NA

OMS AND WEB PORTAL ASSISTANCE

- Improving Drug Utilization Review Controls in Part D

  https://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovContra/RxUtilization.html

- MAPD Plan Communication User Guide (PCUG)

  https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html

- Technical Support

  Email: PatientSafety@AcumenLLC.com

  Phone: (650) 558-8006

- If you have questions related to the Medicare Part D drug management program requirements, send an email with “DMP” in the subject line to CMS at:

  Email: PartD_OM@cms.hhs.gov

ROADMAP

1. DMP and OMS Background
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