

MINI-SENTINEL MODULAR PROGRAM 7:

DRUG USE, MEDICAL DIAGNOSES AND MEDICAL PROCEDURES BEFORE AND AFTER AN EXPOSURE OR EVENT OF INTEREST

Documentation version 5.0

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Mini-Sentinel is a pilot project sponsored by the <u>U.S. Food and Drug Administration (FDA)</u> to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Mini-Sentinel is one piece of the <u>Sentinel</u> <u>Initiative</u>, a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance. Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise. The Mini-Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223200910006I.



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Modification History

Version	Date	Modification	Ву
5.0	12/17/2013	• Up-versioned to due to major program release of mp7_5.0.	Mini-Sentinel Operations Center
4.0	8/19/2013	 Added Macro parameter "COVERAGE" Added Query File parameters "ENRDAYS", "ENRDAYSBF", and "ENRDAYSAF" Added Incident Query File parameters "CARESETTING" and "PRINCIPAL" Added SING option for Query File Parameter "WASHTYP" and removed MULT option 	Mini-Sentinel Operations Center
3.0	5/16/2013	 Revised the way the MP7 matches codes of interest to allow either exact code match and/or wildcard match in Query and Incident Query Files. Added optional Output Table Selection module to instruct the MP7 to preserve only certain output tables in the final output library. 	Mini-Sentinel Operations Center
2.0	11/9/2012	Original published version	Mini-Sentinel Operations Center



I. OVERVIEW

Mini-Sentinel modular programs (MPs) allow rapid implementation of standard queries across the Mini-Sentinel Distributed Database (MSDD). MPs are designed to run against the Mini-Sentinel Common Data Model (MSCDM).¹ They are written in SAS and can be customized using various parameter settings that define exposures, outcomes, date ranges, age ranges, and other implementation details. This document describes the key program specifications and main assumptions underlying each of the query parameters for Modular Program 7 (MP7) version 5.0. Program specification requirements, formats, and default values of all parameters are defined. A sample program specification is provided along with output from a sample scenario.

II. TERMINOLOGY

For simplicity, the phrase "exposure(s) and/or event(s) of interest" is used throughout this document to broadly represent exposure to a medical product and/or the occurrence of a medical procedure or diagnosis. Exposures and events of interest are defined using any set of outpatient pharmacy dispensings, diagnosis codes, and procedure codes found in the MSCDM.

The term "claim" is used throughout the document to represent either an outpatient pharmacy dispensing or medical encounter/record with any of the codes for the exposure(s) and event(s) of interest.

The term "member" is used to represent an individual with relevant enrollment and other criteria (as specified by the MP parameters). A member can be further defined as a "user" if evidence of the exposure(s) or event(s) of interest is observed.

A "scenario" is used to refer to a set of parameters and criteria used to execute the MP. The term "requester" refers to an individual (or group of individuals) who has issued the MP request and defined the scenarios. The term "request programmer" refers to the individual creating the request Input Files and executing the MP.

The "index date" refers to a requester defined date (either based on a calendar date or the occurrence of an exposure or event of interest) that is used to define a pre- and post-index date period. The "pre-index period" is a requester defined length of time before the index date; the "post-index period" is a requester defined length of time after the index date.

The execution of MP7 allows information to be generated for multiple scenarios at the same time. Results from all scenarios are included in the MP output tables and can be differentiated using "query group names" defined by the requester. This document describes the process for testing one scenario.

III. PROGRAM SUMMARY

MP7 is used to query the MSDD to describe the use of outpatient pharmacy medication(s), or occurrence of medical diagnoses and/or medical procedure(s) in a pre-defined period before and after an index date. The index date can be characterized by drug, diagnosis and/or procedure codes, or

¹ See <u>http://www.mini-sentinel.org/data_activities/</u> for more information about the MSCDM.



defined with respect to a calendar date corresponding to either a target age anniversary or a predefined date.

The requester has the flexibility to fix the number of drug, diagnosis and/or procedure codes that MP7 will tabulate pre- and post-index date (*e.g.*, 10 most frequent, 50 most frequent, etc.). Furthermore, the requester can provide NDC, procedure and/or diagnosis code mappings to tabulate results according to specific code groupings (*e.g.*, by generic name or drug class for NDCs). Figure 1 summarizes the design of MP7.



Figure 1: Summary of MP7 Design

For example, the program can be used to identify the top 50 most frequent NDC, top 10 most frequent procedure, and top 25 most frequent diagnosis codes observed in the 180 days pre and 365 days post the first AMI diagnosis in the 01/01/2007 to 12/31/2009 period. MP7 could also be used to retrieve the 100 most frequent diagnoses in the 365 days following a member's 65th birthday. In MP7, only the first prevalent and first incident index dates will be chosen to avoid overlapping pre- and post-index date characterization periods. That is, a member can have at most two index dates, one prevalent and one incident.

MP7 requires the specification of several parameters to define a scenario. These include program parameters that specify a request identifier, run identifier, query period, age range(s), coverage type requirements, and enrollment criteria. The names of input files (built as SAS datasets) containing several other parameters used to identify the index date, pre- and post-index date lookup period(s), and code mappings must also be specified.

One input file is the <u>Query File</u> that defines the index date (based on exposures and events of interest) and the pre- and post-index periods. The second file is the <u>Incident Query File</u>; it is optional and is used to refine how incident exposures and events are defined. The <u>NDC Code Map File</u>, <u>Procedure Code Map File</u>, and <u>Diagnosis Code Map File</u> define the code mappings to tabulate results according to specific drug, procedure, and diagnosis codes, respectively. The last file is the <u>Output Table Selection File</u>, which defines the relevant output files to generate for a request. All parameters and input file specifications are described in <u>Section IV</u>.



IV. PROGRAM PARAMETER AND INPUT FILE SPECIFICATIONS

A. PROGRAM PARAMETER SPECIFICATIONS

There are several main program parameters that may be specified. These include a request identifier, run identifier, start and end dates for the query identification period, age stratifications, coverage type requirements, an allowed enrollment gap used to create continuous enrollment periods, and six input files (the <u>Query File</u>, <u>Incident Query File</u>, <u>NDC Code Map File</u>, <u>Procedure Code Map File</u>, <u>Diagnosis Code Map File</u>, and <u>Output Table Selection File</u>). Table 1 contains detailed specifications for each of these required parameters.

Parameter	Field Name	Description
Request	REQUESTID	Details: a request identifier. The identifier is appended to all output file names.
Identifier		
		Note 1: must be 5 characters in length. The REQUESTID should start with "mpr"
		and include two additional digits with the assigned request number.
		Defined hu Dequest programmer
		Input type: Request programmer
		Format: Alphanumeric
		Example: REOLIESTID=mpr01
Run Identifier	RUNID	Details: a run identifier to denote each execution of the program. The identifier is
Kurrachtner		appended to all output file names.
		Note 1: must be 3 characters in length. The RUNID should start with "r" and
		include two additional digits with the assigned execution number.
		Defined by: Request programmer
		Input type: Required
		Format: Alphanumeric
		Example: RUNID=r01
Enrollment	ENROLGAP	Details: sets the number of days that will be bridged between two consecutive
Gap		enrollment periods to create a "continuously enrolled" period. For example, if
		ENROLGAP=30 and a member is eligible for medical coverage in periods 1/1/2007-
		3/27/2007 and 4/1/2007-12/21/2007 (<i>i.e.</i> , a 4-day gap between two consecutive
		enrollment episodes), the member will be considered continuously enrolled from
		1/1/2007 to 12/21/2007. In this example, a gap of greater than 30 days will result
		and hew enrollment period, and all the days in the gap will be considered un-
		en oned.
		Note: An enrollment gap of 45 days is recommended for most requests.
		Defined by: Requester
		Input type: Required
		Format: Numeric

Table 1: Main Program Parameter Specification



Parameter	Field Name	Description
		Example: ENROLGAP=45 (gaps less than or equal to 45 days will be "bridged" to
		form one "continuously enrolled" sequence)
User-Defined	COVERAGE	Details: an optional parameter to allow medical and drug coverage type
Coverage Type		requirements to be user-defined and not CODETYPE dependent.
Requirement		
		Valid values are:
		 M: only enrollment spells with at least medical coverage should be considered by the MP algorithm
		 D: only enrollment spells with at least drug coverage should be considered by the MP algorithm
		• MD: only enrollment spells with both medical and drug coverage should be considered by the MP algorithm (default value)
		Note 1: the type of coverage is enforced for both the washout period and continuous enrollment days requirements (see WASHPER, WASHPERBFAF, ENRDAYS, ENRDAYSBF, and ENRDAYSAF parameters in the <u>Query File</u> section).
		Note 2: if the COVERAGE value is left blank, or contains invalid values (i.e., values other than "M", "D", or "MD"), the MP algorithm will consider only enrollment spells with both medical and drug coverage by default.
		Defined by: Requester
		Input type: Optional (default value is MD)
		Format: SAS character \$2
		Example: MD
Query Start Date	QUERYFROM	Details: date for the start of the query identification period. If QUERYFROM =03/01/2008, only claims with a service date on or after this date will be considered.
		Defined by: Requester
		Input type: Required
		Example: $OUERYEROM = 03/01/2008$
Ouerv End	OUERYTO	Details: date for the end of the guery identification period. If
Date		QUERYTO=03/31/2009, claims after this date will not be considered.
		Defined by: Requester
		Input type: Required
		Format: mm/dd/yyyy
		Example: QUERYTO=03/31/2009
Query File	QUERYFILE	Details: name of the SAS dataset defining the query exposure(s)/event(s) of
		interest, target anniversary date, or fixed calendar date (<i>i.e.</i> , the index date). It
		also lists the codes that define each exposure/event of interest (not applicable for
		extension, must be entered. For specific details on the content of this file, see



Parameter	Field Name	Description
		Section IV.B.
		Named by: Request programmer
		Input type: Required
		Format: .sas7bdat or .cport file format
		Example: QUERYFILE=query.sas7bdat or query.cport
Incident Query	INCQUERYFILE	Details: name of the SAS dataset refining the incident exposure/event
<u>File</u>		definition(s). It contains additional codes and various parameters to further refine
		how incidence of each exposure/event must be defined. The file name, including
		its extension, must be entered. For specific details on the content of this file and
		for an example of when this file is used and how it is different from the QUERYFILE,
		see <u>Section IV.B</u> .
		Named by: Request programmer
		Input type: Optional
		Format: sas7bdat or coort file format
		Example: INCOLIERYELLE=incquery sas7bdat or incquery coort
NDC Code Man		Details: The name of the sas7bdat or coort dataset identifying the NDC
File	NDCCODEMIA	lookun/code manning file. The file name including its appropriate extension must
		be entered. For specific details on the content of this file see Section IV B
		be entered. For specific details of the content of this file see <u>section w.b</u> .
		Named by: Request programmer
		Input type: Ontional
		Format: sas7bdat or coort file format
		Example: NDCCODEMAP=ndc_lookup_table sas7bdat or ndc_lookup_table coort
Procedure		Details: The name of the sas7bdat or coort dataset identifying the procedure
Code Man File		lookun/code manning file. The file name including its appropriate extension must
		be entered. For specific details on the content of this file see Section IV B
		be entered. For specific details of the content of this file see <u>section (A.B.</u> .
		Named by: Request programmer
		Input type: Optional
		Format: .sas7bdat or .cport file format
		Example: PROCCODEMAP=px lookup table.sas7bdat or px lookup table.cport
Diagnosis Code	DIAGCODEMAP	Details: The name of the .sas7bdat or .cport dataset identifying the diagnosis
Map File		lookup/code mapping file. The file name including its appropriate extension must
		be entered. For specific details on the content of this file see Section IV.B.
		Named by: Request programmer
		Input type: Optional
		Format: .sas7bdat or .cport file format
		Example: DIAGCODEMAP=dx_lookup_table.sas7bdat or dx_lookup_table.cport
Output Table	OUTTABLESFILE	Details: name of the SAS dataset defining the output table(s) to be preserved in
Selection File		the output folder. The file name, including its extension, must be entered. For
		specific details on the content of this file, see Section IV.B.
		Named by: Request programmer



Parameter	Field Name	Description	
		Input type: Optional	
		Format: .sas7bdat or .cport file format	
		Example: OUTTABLESFILE = output.sas7bdat or output.cport	
Age Groups	AGESTRAT	Details: age group categories for reporting. Specifying this parameter will (1)	
		restrict to certain age groups and (2) specify how age groups will be stratified in	
		the result tables. For example, to have results stratified by 20-year increments for	
		members 40-99 years of age, AGESTRAT=40-59 60-79 80-99 would be entered.	
		Note 1: age is determined at the index date.	
		Note 2: various units of time can be used. Valid values are:	
		• D: days	
		• W: weeks	
		• Q : quarters	
		• M: months	
		• Y: years (default value)	
		Note 3: lower value is binding. If AGESTRAT=0-5 5-10, then all 5 year olds will be	
		placed in the second age group. If AGESTRAT=0-5 6-10, then all 5 year olds will be	
		placed in the first age group.	
		For example, to have results stratified by 6-month increments for the first two	
		years of life and then by 2-year increments until the age of 6, AGESTRAT = 00M-	
		05M 06M-11M 12M-17M 18M-23M 02Y-03Y 04Y-05Y needs to be entered.	
		Defined by: Requester	
		Input type: Optional (default value is 00-01 02-04 05-09 10-14 15-18 19-21 22-44	
		45-64 65-74 75+ in years)	
		Format: AA-AA BB-BB ZZ-ZZ	
		Example: AGESTRAT=40-59 60-79 80-99	

B. INPUT FILE SPECIFICATIONS

In addition to the main program parameters, several required and optional parameters need to be specified in the Input Files.

1. Query File

The <u>Query File</u> is required. It contains the comprehensive set of codes used to define the exposure(s) and event(s) of interest (*i.e.*, index date). National Drug Codes (NDCs), ICD diagnosis and procedure codes, or Healthcare Common Procedure Coding System (HCPCS) codes can be used to define the exposures and/or events; they can be defined using any mix of allowed code types. Target age anniversary and specific calendar date can also be used in the <u>Query File</u>.

The structure of the <u>Query File</u> must reflect how codes should be queried to define an exposure or event of interest. The GROUP field is used to group all codes pertaining to a given exposure/event of interest.



For example, a group for "Index1" could define an exposure (index date) by the occurrence of any NDC for oral forms of anti-diabetic medications, a group for "Index2" by a mix of NDC and HCPCS codes for certain insulin products and another group for "Index3" by only those NDCs for a recently approved oral form of anti-diabetic medication. Table 2 below describes the specifications for the <u>Query File</u>.

Parameter	Field Name	Description
Name of	GROUP	Details: standardized name used to refer to a query
Query Group		GROUP for the index date.
		Note: multiple query groups can be defined within the
		same <u>Query File</u> . In this case all index dates are queried
		independently and results are reported separately and
		labeled using each query GROUP name specified.
		Named by: Request programmer
		Input type: Required
		Format: Alphanumeric; SAS character \$30; no special
		characters (e.g., commas, periods, hyphens, etc) allowed,
		and underscores must be used to mark spaces.
		Example: Index1
Code	CODECAT	Details: type of each code category value included in the
Category		CODETYPE field (below) of this file.
		Valid values include:
		AN: Target age anniversary
		DT: Fixed calendar date
		• RX: NDC code
		DX: Diagnosis code
		• PX: Procedure code
		Note: If a GROUP includes either CODECAT=AN or DT, it
		cannot include any other CODECAT values by definition.
		Defined by: Requester
		Input type: Required
		Format: SAS character \$2.
		Example: DX
Query Group	CODETYPE	Details: type of each code value included in the CODE field
Code Type		(below) of this file.
		Valid values include:
		If CODECAT = AN^{1}
		• Y: age anniversary specified in years
		- i. age anniversary specified in years

Table 2: Query File Specification



Parameter	Field Name	Description
		• M: age anniversary specified in months
		• Q: age anniversary specified in guarters
		• W: age anniversary specified in weeks
		•
		• D: age anniversary specified in days
		•
		If CODECAT = RX:
		• 09 : 9 digits NDC
		• 11 : 11 digits NDC
		If CODECAT = DX:
		• 09 : ICD-9-CM
		• 10 : ICD-10-CM
		• 11 : ICD-11-CM
		• OT : Other
		$\frac{\text{If CODECAT = PX:}}{\text{CODECAT = PX:}}$
		• 10: ICD-10-CM
		• 11: ICD-11-CM
		• C4 : CPT-4 (i.e., HCPCS Level I)
		• HC: HCPCS (I.e., HCPCS Level II)
		• H3: HCPCS Level III
		• C2: CPT Category II
		• C3: CPT Category III
		• RE : Revenue
		• LO: Local homegrown
		• O T: Other
		Note 1: This parameter is not used when CODECAT = DT
		and should be left blank.
		Defined by: Requester, with support from the Mini-
		Sentinel Operations Center (MSOC) as needed
		Input type: Required
		Format: Alphanumeric; SAS character \$2.
		Example: 09
Query Codes	CODE	Details: for CODECAT=RX, DX, or PX, the requester should
of Interest		input the NDC, diagnosis and/or procedure code values
		used to determine the index date.
		For CODECATEAN, the requester should input the desired
		age in the unit specified in CODETYPE.
		For CODECAT=DT, the requester should input the calendar



Parameter	Field Name	Description
		date in the format mm/dd/yyyy.
		Note 1: Codes are matched using exact values (<i>i.e.</i> , 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (<i>e.g.</i> , querying "250*0" would be used to find any ICD-9-CM diagnosis codes for diabetes type II, or "250*" to find ICD-9-CM diagnosis codes for all diabetes codes that start with "250").
		Note 2 : For NDCs, either 9 or 11 digit codes can be entered.
		Note 3: remove decimal points in the code value.
		Note 4 : CODETYPE/CODECAT must be consistent with the expected format of the CODE value (<i>e.g.</i> , MP7 will not find any valid matches in the data for CODECAT=RX, CODETYPE=11, and a 9-digit NDC value).
		Note 5 : Duplicate CODECAT-CODETYPE-CODE- CARESETTING-PRINCIPAL combinations are removed by the MP7 algorithm.
		Defined by: Requester, with support from the MSOC as needed Input type: Required Format: Alphanumeric; SAS character \$11. Example1 (CODECAT=NDC; CODETYPE=11): 12345678911 Example2 (CODECAT=AN; CODETYPE=Y): 65 Example3 (CODECAT=DT): 01/01/2001
Query Care Setting	CARESETTING	Details: contains the care settings considered when CODECAT= PX or DX. This parameter is not relevant for CODECAT=AN, DT, or RX. If all care settings are wanted, leave the field blank.
		The following are valid entries; all entries must be quoted and separated by a space:
		 IP: inpatient hospital stays IS: non-acute institutional stays ED: emergency department visits AV: ambulatory visits OA: other ambulatory visits.
		Note: Request programmer should set CARESETTING to



Parameter	Field Name	Description
		missing for CODECAT=AN, DT, or RX, as the Care Setting
		option does not apply.
		Defined by: Requester
		Input type: Optional (may be left missing if all care settings
		are required)
		Format: Alphanumeric; SAS character \$20.
		Example: 'IP' 'ED'
Query	PRINCIPAL	Details: specifies whether only principal diagnoses are
Principal		considered when CODECATE DX. If PRINCIPAL is set equal
Diagnosis		to YES, only principal diagnoses in the IP and ED settings
Indicator		will be chosen. However, if PRINCIPAL is set equal to NO,
		This parameter is not relevant for CODECAT- AN DT RX
		or PX: for these PRINCIPAL should be set to NO
		of TX, for these, TRINCH AL should be set to NO.
		Defined by: Requester
		Input type: Required (should always be set to NO when
		CODECAT ≠DX)
		Format: Alphanumeric; SAS character \$3.
		Example: NO
Most	TOPDRUG	Details: number of NDC codes (or groupings) to keep in
Frequent		the ranking output files. See <u>Section IV.B</u> for more
Drugs		information on NDC groupings.
Pre/Post		
Index		Note: Each GROUP can only have one unique TOPDRUG
		value.
		Defined hv: Requester
		Input type: Required
		Format: Numeric
		Example: 20
Most	TOPPROC	Details: number of procedure codes (or groupings) to keep
Frequent		in the ranking output files. See Section IV.B for more
Procedures		information on procedure groupings.
Pre/Post		
Index		Note : Each GROUP can only have one unique TOPPROC
		value.
		Defined has Desured as
		Defined by: Requester
		Format: Numeric
		Fxample: 20
Most	TOPDIAG	Details: number of diagnosis codes (or grounings) to keep
Frequent		in the ranking output files. See Section IV.B for more
Diagnoses		information on diagnosis groupings.



Parameter	Field Name	Description
Pre/Post		
Index		Note : Each GROUP can only have one unique TOPDIAG value.
		Defined by: Requester
		Input type: Required
		Format: Numeric
		Example: 20
Query	WASHTYP	Details: defines whether the incident index date claim
Incidence		must be the first one in the member's entire available
Туре		Relevant for the incident cohort only.
		As detailed in <u>Section V.C</u> , the incidence type can take the following values:
		• MIN: minimum incidence identifies and reports metrics only for the first valid incident claim during the query period, but uses ALL observed claims - even those before the query period start date - to define incidence. That is, incidence is the first exposure during the query period with no evidence of prior exposure using all available data.
		• SING : single incidence identifies and reports metrics only for the <i>first</i> valid incident index claim during the query period, and uses claims observed during the specified WASHPER days to determine incidence. That is, incidence is defined as the first index claim during the query period with no evidence of prior exposure during WASHPER days.
		Note 1: MIN setting should be used with caution as interpretation is complex. A claim that meets the MIN criteria must occur during the query period and cannot be preceded by a disqualifying claim at any time during enrollment; that is, the lookback period to define incidence is not limited to the washout period. See <u>Section</u> <u>V.C</u> for details.
		Note 2: For CODECAT=AN or DT, set WASHTYP = MIN. The program will automatically force this value as defensive coding.
		Note 3 : Each GROUP can only have one unique WASHTYP value.



Parameter	Field Name	Description
		Defined by: Requester
		Input type: Required
		Format: Alphanumeric; SAS character \$4; case sensitive
		(upper case only).
		Example: SING
Query	WASHPER	Details: length of washout period in days. Relevant for the
Washout		incident cohort only. The washout period is the period of
Period		time before an incident index date during which a member
		cannot have any evidence of exposure(s)/event(s) of
		interest used to define the index date or any other
		exposure(s)/event(s) specified in the <u>Incident Query File</u> .
		Note 1 : WASHPER is required and used in conjunction with WASHTYP.
		Note 2: Request programmer should set WASHPER=0 for
		CODECAT=AN or DT, as WASHPER does not apply. The
		program will automatically force this value as defensive
		coding.
		Note 3 : Each GROUP can only have one unique WASHPER value.
		Note 4: the MP algorithm may use days before QUERYFROM to determine if continuous enrollment and incidence criteria are met.
		Note 5 : in conjunction with the ENROLGAP, COVERAGE, and ENRDAYS parameters, the WASHPER parameter is used to ensure that appropriate enrollment requirements are met for the incident cohort. Since at least WASHPER days of enrollment must be found prior to index date for the incident cohort, the ENRDAYS parameter value is only binding if ENRDAYS > WASHPER. If enrollment requirements prior to index date are not met, claim incidence cannot be determined and the claim is excluded from <i>incident</i> output metrics.
		Defined by: Requester
		Input type: Required
		Format: Numeric
		Example: 183
Minimum	ENRDAYS	Details: number of days of continuous enrollment required
Enrollment		before the occurrence of an incident claim used to define
Requirement		the index date. By default, the MP algorithm will
for Incident		automatically require WASHPER days of continuous
Cohort Entry		enrollment before an incident index date-defining claim.



Parameter	Field Name	Description
		Since at least WASHPER days of enrollment must be found
		prior to index date for the incident cohort, the ENRDAYS
		parameter value is only binding if ENRDAYS > WASHPER.
		Note 1 : if specified must be the same within a given query
		GROUP.
		Note 2 : in conjunction with the ENROLGAP, COVERAGE,
		and WASHPER parameters, this parameter is used to
		ensure that appropriate enrollment requirements are met
		for the <i>incident</i> cohort. If enrollment requirements prior to
		index date are not met, claim incidence cannot be
		determined and thus the claim is excluded from <i>incident</i>
		output metrics. For the prevalent cohort, ENRDAYS of
		continuous enrollment before index date is not required .
		Named hv: Requester
		Input type: Optional
		Format: Numeric
		Example: 365
Pre-Index	ENRDAYSBF	Details: number of days of continuous enrollment required
Period		before an index date claim to include the claim in
Enrollment		prevalent or incident output metrics.
Requirement		
		Note 1: if specified must be the same within a given query
		GROUP.
		Note 2: if ENRDAYSBE days of continuous enrollment is not
		found before an index date claim, the claim is excluded
		from output metrics. This applies to both prevalent and
		incident index date claims.
		Note 3: for incident and prevalent index date claims, the
		MP algorithm will automatically require WASHPERBFAF
		days of continuous enrollment before the index date
		claim. Since at least WASHPERBFAF days of enrollment
		must be found prior to index date claims, the ENRDAYSBF
		parameter value is only binding if ENRDAYSBF >
		WASHPERBFAF.
		Named by: Requester
		Input type: Optional
		Format: Numeric
		Example: 365
Post-Index	ENRDAYSAF	Details: number of days of continuous enrollment required
Period		after an index date claim to include the claim in prevalent
Enrollment		or incident output metrics.



Parameter	Field Name	Description
Requirement		
		Note 1 : if specified must be the same within a given query GROUP.
		Note 2: if ENRDAYSAF days of continuous enrollment is not found after an index date claim, the claim is excluded from output metrics. This applies to both prevalent and
		incident index date claims.
		Named by: Requester
		Input type: Optional
		Format: Numeric
Due la devi	DAVODE	Example: 365
Date Lookup Period	DATSBE	the pre-index period.
		Note 1 : Each GROUP can only have one unique DAYSBF value.
		Note 2: codes identified during the pre-index period must occur during a valid enrollment span. The program does not, by default, require continuous enrollment during the pre-index period. Enrollment requirements must be specified by the requester using the ENRDAYS and ENRDAYSBF parameters.
		Defined by: Requester Input type: Required Format: Numeric Example: 183
Post Index	DAYSAF	Details: number of days after index date used to define
Date Lookup Period		the post-index period.
		Note 1 : Each GROUP can only have one unique DAYSAF value.
		Note 2: codes identified during the post-index period must occur during a valid enrollment span. The program does
		not, by default, require continuous enrollment during the
		post-index period. Enrollment requirements must be
		specified by the requester using the ENRDAYS and ENRDAYSAF parameters.
		Defined by: Requester
		Input type: Required
		Format: Numeric
		Example: 183



Parameter	Field Name	Description
Pre/Post	WASHTYPBFAF	Details: determines the number of incident pre/post index
Index Date		period codes (or code groupings) that are included in
Incidence		output metrics and defines how incidence is evaluated.
Type		Specific to each GROUP.
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
		WASHTYPBFAF can take the following values:
		 MIN: identifies and reports metrics only for the first valid incident pre/post code (or code grouping) during the query period, and uses ALL previously observed codes- even those before the query period start date - to determine incidence. That is, a pre/post period code is considered incident if it is the first pre/post code during the member's entire available history. MULT: identifies and reports metrics for all valid incident pre/post codes (or code groupings) during the query period, and uses codes observed during the specified WASHPERBFAF days to determine incidence.
		incidence.
		Note 1: Each GROUP can only have one unique
		WASHTYPBFAF value.
		Defined by: Requester
		Input type: Required
		Format: Character \$4.
Due (De et		Example: MULI
Index Date	WASHPERBFAF	period code incidence when WASHTYPBFAF=MULT.
		Note 1 : length of WASHPERBFAF must be the same within a given query GROUP.
		Note 2 : WASHPERBFAF is required and used in conjunction with WASHTYPBFAF.
		Defined by: Pequester
		Input type: Required
		Format: Numeric
		Fxample: 365
Pre/Post	ΡΒΙΝΟΙΡΑΙ ΒΕΔΕ	Details: specifies if only principal diagnoses are included in
Index Date		the pre- and post-index date frequencies. If
Principal		PRINCIPALBEAF is set equal to YES, only principal diagnoses
Diagnosis		in the IP and ED settings will be considered. However, if



Parameter	Field Name	Description
Indicator		PRINCIPALBFAF is set equal to NO, all diagnoses for the
		specified care settings will be chosen.
		Note: Each GROUP can only have one unique
		PRINCIPALBFAF value.
		Defined by: Requester
		Formati Alphanumarici SAS charactor \$2
		Frample: NO
Pre/Post		Details: specifies which care settings are included in the
Index Date		pre- and post-index date diagnosis frequencies. If all care
Care Setting		settings are wanted, leave the field blank.
for Diagnoses		
C C		The following are valid entries; all entries must be in single
		quotes and separated by a space:
		IP: inpatient hospital stays
		IS: non-acute institutional stays
		ED: emergency department visits
		AV: ambulatory visits
		OA: other ambulatory visits
		Note: Each CROUR can only have one unique
		Defined by: Requester
		Input type: Optional (may be left blank if all care settings
		are required)
		Format: Character \$20.
		Example: 'IP' 'ED' 'OA'
Pre/Post	PROCCARESETTINGBFAF	Details: specifies which care settings are included in the
Index Date		pre- and post-index date procedure frequencies. If all care
Care Setting		settings are wanted, leave the field blank.
for		The falls for the second distribution of the second s
Procedures		The following are valid entries; all entries must be in single
		quotes and separated by a space:
		• IP: inpatient hospital stays
		• IS: non-acute institutional stays
		ED: emergency department visits
		AV: ambulatory visits
		OA: other ambulatory visits
		Note: Each GROUP can only have one unique
		PROCCARESETTINGBFAF value.



Parameter	Field Name	Description
		Defined by: Requester Input type: Optional (may be left missing if all care settings are required) Format: Character \$20. Example: 'IP' 'ED' 'OA'
Number of Blackout Days Post-Index Date	BLACKOUTAF	 Details: the day on which the post-index period begins, relative to the index date. For example, if BLACKOUTAF is set to 0, the post-index period will begin on the index date. If BLACKOUTAF is set to 10, the post-index period will begin on the 10th day following the index date. Note 1: Each GROUP can only have one unique BLACKOUTAF value. Note 2: the pre-index period can never include the index date. Defined by: Requester Input type: Required Format: Numeric
		Example: 10
Length of NDC used in Output Tables	NDCLENGTHBFAF	 Details: Length of NDC used in output tables. If a length of 9 is specified, pre/post-index NDC codes will be truncated after the 9th digit before being processed. Note: Each GROUP can only have one unique NDCLENGTHBFAF value. Defined by: Requester
		Input type: Required
		Example: 9
Length of ICD- 9 Diagnosis Codes used in Output Tables	DIAGLENGTHBFAF	 Details: Length of ICD-9 diagnosis codes used in output tables if no <u>Diagnosis Code Map File</u> is specified. For example, if a length of 3 is specified, pre/post-index diagnosis codes will be truncated after the 3rd digit before being processed. Note 1: Each GROUP can only have one unique DIAGLENGTHBFAF value.
		Note 2: The value of DiagLengthBfAf is only binding if the requester does not include a <u>Diagnosis Code Map File</u> .
		Defined by: Requester Input type: Required



Parameter	Field Name	Description
		Format: Numeric
		Example: 3

2. Incident Query File

The <u>Incident Query File</u> is optional. By default, for a given query group MP7 uses the list of codes included in the <u>Query File</u> to determine the incident status of the index date for the exposure(s) and event(s) of interest. The <u>Incident Query File</u> is used to define incidence based on an additional set of codes than those used to define the index exposure and/or event of interest. For example, the requester may be interested in examining drug use before and after Diagnosis A, but wants all members with new Diagnosis A to be free of Diagnosis A, B, and C in the 183 days before the Diagnosis A index date. Codes for Diagnoses B and C would, therefore, be included in the <u>Incident Query File</u> to further define incident Diagnosis A.

The MP7 <u>Incident Query File</u> allows inclusion of the following code types: National Drug Codes (NDCs), ICD diagnosis and procedure codes, and/or Healthcare Common Procedure Coding System (HCPCS) codes. Table 3 contains detailed specifications for the <u>Incident Query File</u>.

Name of GROUP Details: standardized name used to refer to a query GROUP for	
Query Group exposure(s)/event(s) of interest to be queried.	
Note : must match GROUP values from the <u>Query File</u> .	
Named by: Request programmer	
Input type: Required	
Format: Alphanumeric: SAS character \$30: no special characters (e.g., commas	s.
periods, hyphens, etc) allowed, and underscores must be used to mark spaces.	
Example: Index1	
Incident Code CODECAT Details: type of each code category value included in the CODETYPE field (belo	w)
Category of this file.	
Valid values include:	
RX: NDC	
DX: Diagnosis code	
PX: Procedure code	
Defined hu Dequestor	
Defined by: Requester	
Format: SAS character \$2	
Format: SAS character 52.	
Insident CODETVEE Details: type of each code value included in the CODE field (below) of this file	
Query Group Valid values include:	
Code Type	

Table 3: Incident Query File Specification



Parameter	Field Name	Description
		If CODECAT = RX:
		• 09 : 9 digits NDC
		• 11 : 11 digits NDC
		If CODECAT = DX:
		• 09 : ICD-9-CM
		• 10 : ICD-10-CM
		• 11: ICD-11-CM
		• OT: Other
		If CODECAT = PX:
		• 09: ICD-9-CM
		• 10 : ICD-10-CM
		• 11: ICD-11-CM
		• C4 : CP1-4 (i.e., HCPCS LI)
		• HC: HCPCS (i.e., HCPCS L II)
		• H3: HCPCS Level III
		• C2: CPT Category II
		• C3: CPT Category III
		• RE : Revenue
		• LO: Local homegrown
		• OI : Other
		Defined by: Requester, with support from the MSOC as needed
		Input type: Required
		Format: Alphanumeric; SAS character \$2.
		Example: 09
Incident Only	CODE	Details: NDC, diagnosis and/or procedure code values used to refine the incident
Query Codes		definition for the index exposure(s)/event(s) of interest.
		Note 1: Codes are matched using evact values (i.e., 2 digit code lookup requires
		an exact 3-digit code match) Wildcard match (*) functionality is also available
		$(e_{a_{1}})$ querving "250*0" would be used to find any ICD-9-CM diagnosis codes for
		diabetes type II. or "250*" to find ICD-9-CM diagnosis codes for all diabetes
		codes that start with "250").
		Note 2 : For NDCs, either 9 or 11 digit codes can be entered.
		Note 3: remove decimal points in the code value.
		Note 4 : CODECAT/CODETYPE must be consistent with the expected format of
		the CODE value (<i>e.g.</i> , MP7 will not find any valid matches in the data for
		CODECAT=RX, CODETYPE=11, and a 9-digit NDC value).
		Note 5: Duplicate CODECAT-CODETYPE-CODE-CARESETTING-PRINCIPAL
		combinations are removed by the MP7 algorithm.



Parameter	Field Name	Description
		Defined by: Requester, with support from MSOC as needed Input type: Required Format: Alphanumeric; SAS character \$11 Example: 12345678922
Incident Query Care Setting	CARESETTING	Details: contains the care settings considered when CODECAT= PX or DX. This parameter is not relevant for CODECAT=AN, DT, or RX. If all care settings are wanted, leave the field blank.
		The following are valid entries; all entries must be quoted and separated by a space:
		 IP: inpatient hospital stays IS: non-acute institutional stays ED: emergency department visits AV: ambulatory visits OA: other ambulatory visits. Note: Request programmer should set CARESETTING to missing for CODECAT=AN, DT, or RX, as the Care Setting option does not apply. Defined by: Requester Input type: Optional (may be left blank if all care settings are required) Format: Alphanumeric; SAS character \$20. Example: 'IP' 'ED'
Incident Query Principal Diagnosis Indicator	PRINCIPAL	 Details: specifies whether only principal diagnoses are considered when CODECAT= DX. If PRINCIPAL is set equal to YES, only principal diagnoses in the IP and ED settings will be chosen. However, if PRINCIPAL is set equal to NO, all diagnoses for the specified care settings will be chosen. This parameter is not relevant for CODECAT= AN, DT, RX, or PX; for these, PRINCIPAL should be set to NO. Defined by: Requester Input type: Required (should always be set to NO when CODECAT ≠DX) Format: Alphanumeric; SAS character \$3. Example: NO

3. NDC Code Map File

The NDC Code Map File is optional and defines how output is presented for the pre- and post-index period. It allows the grouping of NDC codes into generic name and drug class defined groups. When this file is used, the pre/post-index date dispensings are processed according to the generic name and drug class groups. A "_notfound_" category is created for dispensings that do not map to the codes in the NDCCODEMAP file. If the file is not specified, the NDC results will show the numeric NDC according to the length specified in the NDCLengthBfAf field of the Query File. For example, if no NDC Mapping File is provided and NDCLengthBfAf=9, then all valid NDC codes will be truncated to nine digits and



aggregated. Results will show the most frequent 9-digit NDCs. Generic drug/class names or descriptions will not be included in the output, but can be added later by the MSOC. Table 4 contains detailed specifications for the <u>NDC Code Map File</u>.

Parameter	Field Name	Description
NDC	NDC	Details: NDC code values for the generic name or drug class described
		below.
		Defined by: Requester, with support from MSOC as needed
		Input type: Required
		Format: SAS character \$11.
		Example: 11122233344
Generic	GENERICNAME	Details: the unique generic name assigned to one or more NDCs.
Name		
		Defined by: Requester, with support from MSOC as needed
		Input type: Optional (may be left missing if DRUGCLASS is completed)
		Format: SAS character \$30.
		Example: WARFARIN
Drug Class	DRUGCLASS	Details: the unique drug class assigned to one or more NDCs.
		Defined by: Requester, with support from MSOC as needed
		Input type: Optional (may be left missing if GENERICNAME is
		completed)
		Format: SAS character \$70.
		Example: ANTIFUNGAL

Table 4: NDC Code Map File Specification

4. Procedure Code Map File

The <u>Procedure Code Map File</u> is optional and defines how output is presented for the pre- and postindex period. It allows the grouping of procedure codes into general procedure name groups. When this file is used, the pre/post-index date procedure codes are processed according to the general procedure name groups. A "_notfound_" category is created for codes that do not map to the codes in the <u>Procedure Code Map file</u>. If the file is not specified, results will show counts for the alphanumeric procedure codes with no other identifying information such as procedure names or descriptions. In that case three output tables will be produced: one each for ICD, HCPCS, and CPT procedures. Table 5 contains detailed specifications for the <u>Procedure Code Map File</u>.

Parameter	Field Name	Description
Procedure	PX_CODETYPE	Details: type of each code value included in the PX field of this file.
Code Type		
		• 09: ICD-9-CM
		• 10 : ICD-10-CM
		• 11 : ICD-11-CM

Table 5: Procedure Code Map File Specification



Parameter	Field Name	Description
		• C4 : CPT-4 (i.e., HCPCS LI)
		HC: HCPCS (i.e., HCPCS L II)
		H3: HCPCS Level III
		C2: CPT Category II
		C3: CPT Category III
		• RE : Revenue
		LO: Local homegrown
		• OT : Other
		Defined by: Requester, with support from MSOC as needed
		Input type: Required
		Format: SAS character \$2.
		Example: HC
Procedure	РХ	Details: procedure code values for the general name described below.
		Defined by: Requester, with support from MSOC as needed
		Input type: Required
		Format: SAS character \$11.
		Example: J7602
General	GENERALNAME	Details: the unique general name assigned to one or more procedure
Name		codes.
		Defined by: Requester, with support from MSOC as needed
		Input type: Required
		Format: SAS character \$30.
		Example: HIP_REPLACEMENT

5. Diagnosis Code Map File

The <u>Diagnosis Code Map File</u> is optional and defines how output is presented for the pre- and post-index period. It allows grouping of diagnosis codes into general diagnosis name groups. When this file is used, the pre/post-index date diagnosis codes are processed according to the general diagnosis name groups. A "_notfound_" category is created for codes that do not map to the codes in the <u>Diagnosis Code Map</u> File. If the file is not specified, the diagnosis code results will show the alphanumeric diagnosis codes according to the length specified in the DiagLengthBfAf field of the <u>Query File</u>. For example, if no <u>Diagnosis Code Map File</u> is provided and DiagLengthBfAf=3, then all valid diagnosis codes will be truncated to three digits and aggregated. Results will show the most frequent 3-digit diagnosis codes. Disease/condition names or descriptions will not be included. The value of DiagLengthBfAf is only binding if the requester does not include a <u>Diagnosis Code Map File</u>. Table 6 contains detailed specification for the <u>Diagnosis Code Map File</u>.

Parameter	Field Name	Description
Diagnosis	DX_CODETYPE	Details: type of each code value included in the DX field (below) of this
Code Type		file.

Table 6: Diagnosis Code Map File Specification



Parameter	Field Name	Description			
		• 09 : ICD-9-CM			
		• 10 : ICD-10-CM			
		• 11 : ICD-11-CM			
		• OT: Other			
		Defined by: Requester, with support from MSOC as needed			
		Input type: Required			
		Format: SAS character \$2.			
		Example: 09			
Diagnosis	DX	Details: diagnosis code values for the general name described below.			
		Defined by: Requester, with support from MSOC as needed			
		Input type: Optional			
		Format: SAS character \$11.			
		Example: 410			
General	GENERALNAME	Details: the unique general name assigned to one or more diagnosis			
Name		codes			
		Defined by: Requester, with support from MSOC as needed			
		Input type: Required			
		Format: SAS character \$30.			
		Example: ACUTE_MI			

6. Output Table Selection File

The <u>Output Table Selection File</u> is optional. It is used to instruct the MP algorithm to preserve only a subset of all output tables generated by one run of the MP. If defined, it contains parameters used to specify which output tables generated by the MP should be kept in the output folder of the MP run.

Unlike other MP input files, the GROUP field is not part of the set of required parameters. One instance of the OUTTABLESFILE input file can be used for multiples runs of the MP no matter what GROUP values are used.

There are four parameters that must be specified, all by the request programmer. Moreover, the input file must contain one line for each of the output files generated by each run of MP7. Table 7 contains detailed specifications for the <u>Output Table Selection File</u>, and a template is provided in <u>Section X</u>.

Parameter	Variable Name	Description
Name of Table in	DOCTABNAME	Details: contains the name of the table as specified in the MP
MP		documentation.
Documentation		
		Note: this is not the actual name used inside the program but
		corresponds to the name as listed in the documentation.



Parameter	Variable Name	Description			
		Named by: Request programmer			
		Input type: Optional, for reference only, dropped at the start of the			
		MP execution.			
		Format: Alphanumeric; SAS character \$30.			
		Example: Table1			
Description of	DOCTABDESCR	Details : contains the description of the table as specified in the			
Table in MP		table titles of the modular program documentation.			
Documentation					
		Named by: Request programmer			
		Input type : Optional, for reference only, dropped at the start of the MP execution.			
		Format: Alphanumeric; SAS character \$150.			
		Example: Counts of Members, Incident Claims, Total Dispensings			
		and Days of Supply			
Name of Table	TABNAME	Details: contains the name of the table generated by the modular			
Generated by MP		program.			
		Note 1: must be entered in lower case.			
		Note 2: this is the actual table name used inside the program.			
		Named by: Request programmer			
		Input type: Required			
		Format: Alphanumeric: SAS character \$10.			
		Examples: table1, table11			
Table Inclusion	TABREQUIRED	Details: indicates whether TABNAME must be preserved. Valid			
Indicator		values are:			
		• Y: preserve table in output			
		• N: remove table from output			
		Note 1: if the value specified is not "Y" or "y" then the table will be			
		removed.			
		Named by: Request programmer			
		Input type: Required			
		Format: Alphanumeric; SAS character \$1.			
		Example: Y			

V. KEY DEFINITIONS

A. ENROLLMENT TYPE REQUIREMENTS

All claims used by the MP algorithm to select members of interest must occur during valid enrollment periods. All requirements used to build valid enrollment periods are fully customizable using a set of requester-defined input parameters.



First, the main COVERAGE parameter allows the requester to select the type of coverage required for each run of the MP based on whether medical, drug, or both medical and drug coverage are required during all enrollment periods. The default option is to require both medical and drug coverage.

Continuous enrollment periods are then constructed by bridging all enrollment records of the correct coverage type. That is, using the main ENROLGAP parameter, two (or more) consecutive enrollment periods separated by (no more) than ENROLGAP days are bridged together to form a longer, continuous enrollment episode of the relevant coverage type. Such continuous enrollment episodes are then used to confirm whether claims with query codes of interest and other characteristics can be used toward identification of claims.

There are several enrollment requirements that can be specified for both the prevalent and incident cohorts (all are defined in the <u>Query File</u>).

For the prevalent cohort, a member must have the following to be included in output metrics:

- At least ENRDAYSBF or WASHPERBFAF days (whichever is greater) of continuous enrollment before the index date. These parameters are used to ensure that continuous enrollment requirements during the pre- index period are met (i.e., the member is enrolled for a user-defined number of days during the pre-index period).
- At least ENRDAYSAF days of continuous enrollment after the index date. This parameter is used to ensure that continuous enrollment requirements during the post- index period are met (i.e., the member is enrolled for a user-defined number of days during the post-index period).

In addition to the prevalent cohort requirements, the following enrollment requirements must be met for a member to be included in output metrics for the incident cohort:

• At least ENRDAYS or WASHPER days (whichever is greater) of continuous enrollment before the index date. Note that the value of ENRDAYS and WASHPER days is only binding if greater than the value of ENRDAYSBF or WASHPERBFAF.

B. PREVALENCE-BASED COHORT

The <u>prevalence-based cohort</u> is composed of all members who have at least one claim that qualifies as an exposure/event of interest during the query period who meet pre/post index period enrollment requirements, delimited by the QUERYFROM to QUERYTO dates as illustrated in Figure 2.







In Figure 2, CLAIM 1 represents a valid prevalent code that meets all enrollment criteria. If the index date is defined as a calendar date corresponding to either a target age anniversary or a pre-defined date, the <u>prevalence-based cohort</u> is composed of all members who meet the enrollment criteria on the assigned index date.

C. INCIDENCE-BASED COHORT

If the index date is defined as a calendar date corresponding to either a target age anniversary or a predefined date, the <u>incidence-based cohort</u> is composed of a subgroup of the <u>prevalence-based cohort</u> that meets incident cohort enrollment criteria of at least ENRDAYS or WASHPER days (whichever is greater) of continuous enrollment before the index date. As no drug, diagnosis, or procedure is used to define the index date, neither the minimum nor single incidence type options apply in these situations.

For index dates not defined as a calendar date, the <u>incidence-based cohort</u> is a subset of the <u>prevalence-based cohort</u> that represents members who meet the incident cohort enrollment criteria and the incidence definition during the query period. When generating metrics for the <u>incidence-based cohort</u>, the MP7 algorithm allows members to have either the minimum or single incidence option.

1. Minimum Incidence (MIN) for Index Date

Under the minimum incidence option, members can have only one incident claim during the query period and that claim must be the first one observed for that member in all enrollment periods of relevant type (see Section V.A) in their entire history. Minimum incidence is thus defined as evidence of one query group claim observed during the query period that satisfies the following three conditions. This option should be used with caution as interpretation can be complex. (*i.e.*, incidence is a function of the length of the member's available enrollment history).

- 1. Member is continuously enrolled at least ENRDAYS, ENRDAYSBF, WASHPER, or WASHPERBFAF days (whichever is greater; specified in the <u>Query File</u>) before the index date.
- 2. Member is continuously enrolled at least ENRDAYSAF days (specified in the <u>Query File</u>) after the index date.
- 3. Member has no evidence of another claim with a Query Group code or <u>Incident Query File</u> code during any considered enrollment period before the index claim date. That is, the MP7 algorithm queries the set of data available before the index claim date (regardless of the specified Query Period) to ensure that no claim with a Query Group code or <u>Incident Query File</u> code is observed during enrollment periods under consideration.

2. Single Incidence (SING) for Index Date

Under the single incidence option, members can have only one incident claim during the query period, and the claim must meet the following incidence conditions:

- 1. Member is continuously enrolled at least ENRDAYS, ENRDAYSBF, WASHPER, or WASHPERBFAF days (whichever is greater; specified in the <u>Query File</u>) before the index date.
- 2. Member is continuously enrolled at least ENRDAYSAF days (specified in the <u>Query File</u>) after the index date.
- 3. Member has no evidence of a claim with a Query Group code or <u>Incident Query File</u> code during the WASHPER days prior to the claim index date.
- 4. Claim is the first claim meeting conditions 1-3 during the query period.



3. Examples

For simplicity, all figures assume that relevant enrollment criteria have been met.

Figure 3 illustrates how the MP7 algorithm identifies a claim using the minimum incidence option.



Figure 3: Incident Index Claim Identification Using the Minimum Incidence Option

In the scenario depicted in Figure 3, ENRSTART indicates the member's start of enrollment in drug and/or pharmacy benefits (depending on enrollment criteria). Claim 1 is selected as the incident claim in this scenario, as the member satisfies enrollment criteria and has no query group claim ever before Claim 1. Claims 2 and 3 also satisfy the enrollment period conditions, but prior claims exclude them from being considered incident under the minimum incidence option. In addition, the program will only consider the first valid incident claim as the index date claim.

Figure 4 depicts a scenario where a member does not have an incident claim under the minimum incidence option.





In this scenario, Claim 1 is not considered incident since it did not occur within the query period. While claims 2, 3, and 4 satisfy enrollment conditions, the presence of Claim 1 prior to the query period, but during the member's enrollment history, excludes these as incident claims under the minimum incidence option.

Figure 5 illustrates how the MP7 algorithm identifies a claim using the single incidence option.





In Figure **5**, Claim 2 is considered incident using the single incidence option since a washout period free of any claim (query group or from the incident list) is observed during the query period and it satisfies enrollment conditions. Claims 3 and 4 are not considered incident because the program will only consider the first valid incident claim as the index date for each member. Claim 1 is not considered incident because it does not occur during the query period.

D. PRE- AND POST-INDEX CODE SELECTION

Once the index date claim is identified, NDC, procedure, and diagnosis codes in the pre- and post-index periods are evaluated. By default, the MP7 algorithm will output metrics on all codes of interest observed during the pre- and post-index period. In addition, requesters can require that only incident codes that occur during the pre/post period are considered. The requester can define incidence in two ways:

1. Minimum Incidence Option (MIN) for Pre- and Post-index Period Codes

The minimum incidence option instructs the MP algorithm to only include a code (or code group) once during the pre/post index period. The code must be the first observed in the member's entire available enrollment history.

2. Multiple Incidence Option (MULT) for Pre- and Post-index Period Codes

The multiple incidence option instructs the MP algorithm to include all codes (or code groups) in the pre/post index period that meet washout period requirements (defined as WASHPERBFAF days free of the code (or code group) of interest).

3. Examples

Figure 6 illustrates how the MP identifies pre- and post-index code using the minimum option.





In the scenario depicted in Figure 6, Code 1 and Code 2 are for identical NDCs. ENRSTART indicates the member's start of enrollment in drug and/or pharmacy benefits (depending on coverage and enrollment type requirements). Code 1 would be selected as a pre- index date period incident code as the member does not have a claim with the same code before Code 1. Code 2 would not be counted due to the prior same NDC Code 1.

Figure 7 illustrates how a member does not have a pre- or post-index incident code under the minimum option.





Figure 7: No Pre- or Post-Index Period Incident Code Using the Minimum Option

In the scenario depicted in Figure 7, ENRSTART indicates the member's start of enrollment in drug and/or pharmacy benefits (depending on coverage type and enrollment requirements). If CODEs 1, 2, and 3 are identical NDCs, CODE 2 and CODE 3 would NOT qualify as pre- or post-index period incident codes due to the prior CODE 1. CODE 1 is not considered because it occurred before the pre-index period. Figure 8 illustrates how the MP7 algorithm identifies pre- and post-index codes using the multiple option.



Figure 8: Pre- or Post-Index Period Incident Code Identification Using the Multiple Option

In the scenario depicted in Figure 8, ENRSTART indicates the member's start of enrollment in drug and/or pharmacy benefits (depending on coverage and enrollment type requirements). CODE 2 is selected as a pre-index period code because it is observed during the pre-index period and meets washout period requirements. CODEs 3 and 4 are selected as a incident post-index period codes since both are observed in the post-index period and meet washout period requirements.

VI. DENOMINATORS

MP7 output tables include metrics on denominators associated with each result stratum. Denominator metrics include (1) count of members and (2) eligible member days. These metrics are different for the <u>prevalence-based</u> vs. <u>incidence-based cohort</u>. The members included in any denominator metrics are all the "eligible" members, *i.e.*, members who can potentially be identified by the MP algorithm as contributing an index date (either prevalent or incident) for the exposure(s)/event(s) of interest defined in the query group.

VII. PROGRAM STEPS

The general program steps are:

- 1. Process input files
- 2. Extract medical claims from the diagnosis and procedure files



- 3. Recode claims that occurred during an inpatient stay as inpatient
- 4. Extract drug claims from the outpatient pharmacy file
- 5. Extract enrolled members at target age date or fixed calendar date
- 6. Combine all extraction files into a "Master File" to create index dates for each query groupmember combination
- 7. Reconcile enrollment episodes (gaps in enrollment less than ENROLGAP and correct coverage type)
- 8. For each query group claim and member, assess prevalent and incident status and extract all claims of interest during the query period
- 9. For each query group claim and member, keep only the first prevalent and the first incident claim
- 10. Compute denominator member counts and days exposed for each query group
- 11. Calculate age and identify sex for each cohort member
- 12. For eligible members, extract dispensing, diagnosis, and procedures in the pre/post-index date periods.
- 13. For each query: if a NDC, diagnosis, and/or procedure code mapping file is present, map the raw claim codes to these files; extract valid claims in the pre/post-index date periods and keep one unique claim per day and assess prevalent and incident status of these claims; and calculate and output the top counts datasets
- 14. Create output tables for both prevalent and incident members along with denominators and exposed days

VIII. PROGRAM EXECUTION

When implementing modular programs within the MSDD, the Mini-Sentinel Operations Center (MSOC) uses a uniform folder structure across Data Partners to facilitate communications between MSOC and Data Partners and to streamline file management. Each request distributed by MSOC is assigned a unique Request ID. Upon receipt of the request, Data Partners create a folder named after the Request ID and several subfolders to organize program inputs and outputs. One of the folders contains output to be sent to MSOC and another contains intermediate files that remain with the Data Partner, but could be used to facilitate follow-up queries if necessary. Appropriate retention policies apply.

Table 8 defines the local environment variables that must be initialized by the user to execute the program (*i.e.*, defined by the Data Partner before execution of the program). Please note that these values cannot be left blank. Each Data Partner is required to enter user inputs at the beginning of the SAS Program sent with each request. These inputs are unique to each Data Partner.

Label	Field Name	Description
Data Partner ID	DPID	Enter the two character partner ID.
Site ID of Data Partner	SITEID	Enter the two character Site ID.
Enrollment Table Name	ENRTABLE	Enter the name of the MSCDM Enrollment table.
Demographics Table Name	DEMTABLE	Enter the name of the MSCDM Demographics table.
Dispensing Table Name	DISTABLE	Enter the name of the MSCDM Dispensing table.
Diagnosis Table Name	DIATABLE	Enter the name of the MSCDM Diagnosis table.
Procedure Table Name	PROCTABLE	Enter the name of the MSCDM Procedures table.

Table 8: Environment Variable Definitions



Label	Field Name	Description
Encounter Table Name	ENCTABLE	Enter the name of the MSCDM Encounter table.
Libname of the MSCDM	INDATA	Enter the path where the MSCDM data is saved.
Input file folder	INFOLDER	Enter the path where the input files will be saved.
Output file folder	MSOC	Enter the path where the shared output tables will be saved.
Dataset file folder	DPLOCAL	Enter the path where the local SAS datasets will be saved.

IX. OUTPUT TABLES

The number of output tables created by MP7 is dependent on parameters specified. This section describes all tables that may be created by the program, and when they are generated.

A. PREVALENT AND INCIDENT INDEX DATE SUMMARY TABLES (PTABLES AND ITABLES)

The first set of tables includes the prevalent and incident index date summary tables. These tables provide information on the number of pre- and post-index date claims identified and the number of members with an index claim identified. The PTABLEs provide information for prevalence-based index dates; the ITABLEs provide information for incidence-based index dates. There are four similar PTABLEs and four similar ITABLEs created, each stratified by a different metric:

- PTable1 (prevalence-based index date, metrics stratified by Group)
- PTable2 (prevalence-based index date, metrics stratified by Group and Year)
- PTable3 (prevalence-based index date, metrics stratified by Group, Year and Month)
- PTable4 (prevalence-based index date, metrics stratified by Group, Sex and Age Group)
- ITable1 (incidence-based index date, metrics stratified by Group)
- ITable2 (incidence-based index date, metrics stratified by Group and Year)
- ITable3 (incidence-based index date, metrics stratified by Group, Year and Month)
- ITable4 (incidence-based index date, metrics stratified by Group, Sex and Age Group)

Table 9 provides a data dictionary for each output variable included in the PTABLEs and ITABLEs.

Output	Output Variable Name	Valid Values	Source / Comments
Eligible Members	Denominator	0+	Prevalent : All members eligible for pharmacy and/or medical benefits for at least one day in the QUERYFROM to QUERYTO period. Incident : All members that can potentially have an incident query group index date in the QUERYFROM to QUERYTO period.

Table 9: Prevalent Index Date Summary Table (PTABLE) Data Dictionary



Output	Output Variable	Valid Values	Source / Comments
Eligible Days	MemberDays	0+	Prevalent: Total number of days in the QUERYFROM to QUERYTO period where members are eligible for pharmacy and/or medical benefits.Incident: Total number of days in the QUERYFROM to QUERYTO period where members can potentially have an incident query group index date.
Claim Type	ClaimType	 MAP_RXGEN MAP_RXCLS RX09 MAP_DX DX3 MAP_PX RX_09 PX_C4 PX_HC 	Type of pre/post index date claim.
Prevalent Claims Pre-Index	PrevClaimsCountBf	0+	Number of prevalent claims prior to the index date.
Prevalent Unique Codes Pre-Index	PrevUCodeCountBf	0+	Number of unique prevalent claim codes prior to the index date.
Prevalent Users Pre-Index	PrevUPatCountBf	0+	Number of unique members having prevalent claims prior to the index date.
Prevalent Claims Post-Index	PrevClaimsCountAf	0+	Number of prevalent claims after the index date.
Prevalent Unique Codes Post-Index	PrevUCodeCountAf	0+	Number of unique prevalent claim codes after the index date.
Prevalent Users Post-Index	PrevUPatCountAf	0+	Number of unique members having prevalent claims after the index date.
Incident Claims Pre-Index	IncClaimsCountBf	0+	Number of incident claims prior to the index date.
Incident Unique Codes Pre-Index	IncUCodeCountBf	0+	Number of unique incident claim codes prior to the index date.
Incident Users Pre-Index	IncUPatCountBf	0+	Number of unique members having incident claims prior to the index date.
Incident Claims Post-Index	IncClaimsCountAf	0+	Number of incident claims after the index date.
Incident Unique Codes Post-Index	IncUCodeCountAf	0+	Number of unique incident claim codes after the index date.
Incident Users Post-Index	IncUPatCountAf	0+	Number of unique members having incident claims after the index date.

Below is sample output and output interpretation for PTABLE1 (metrics for a prevalence-based index date stratified by Group).



Group	Eligible Members	Member Days	Users	Claim Type
DX1	4,098,941	2,738,173,177	84,472	MAP_DX
DX1	4,098,941	2,738,173,177	84,472	MAP_PX
DX1	4,098,941	2,738,173,177	84,472	MAP_RXCLS
DX1	4,098,941	2,738,173,177	84,472	MAP_RXGEN

PTARIF1 -	Prevalent Index	Date Summary	v Table, by	v GROUP (nart 1)
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PTABLE1 - Prevalent Index Date Summary Table, by GROUP (part 2)

Prevalent Claims Pre-Index	Prevalent Unique Codes Pre-Index	Prevalent Users Pre-Index	Prevalent Claims Post- Index	Prevalent Unique Codes Post- Index	Prevalent Users Post-Index
82,211	4,260	17,743	585,759	7,912	84,472
29,160	319	17,606	151,062	870	83,265
218,812	1,499	42,082	256,238	1,517	50,436
218,812	1,499	42,082	256,238	1,517	50,436

PTABLE1 - Prevalent Index Date Summary Table, by GROUP (part 3)

Incident Claims	Incident Unique	Incident Users	Incident Claims	Incident Unique	Incident Users
Pre-Index	Codes Pre-Index	Pre-Index	Post-Index	Codes Post-Index	Post-Index
63,144	4,114	16,979	509,287	7,842	84,338
10,132	305	8,131	79,325	863	51,929
57,808	1,290	26,298	103,594	1,332	40,925
57,808	1,290	26,298	103,594	1,332	40,925

<u>First Row Interpretation of PTABLE1</u>: Within the QUERYFROM to QUERYTO period, 84,472 members had at least one diagnosis in the group DX1, the first of which is the index claim date for each member. For these 84,472 members, 17,743 users had a total of 82,211 prevalent claims in the pre-index period. Of these 82,211 prevalent claims, 4,260 are unique codes. All of these 84,472 members had at least one claim in the post-index period for a total of 585,759 prevalent claims in the post-index period. Of these 585,759 prevalent claims, 7,912 are unique codes.

Also for these 84,472 members, 16,979 users had an incident claim for a total of 63,144 incident claims in the pre-index period. Of these 63,144 incident claims, 4,114 are unique codes.

For these 84,472 members, 84,338 had at least one incident claim in the post-index period for a total of 585,759 prevalent claims in the post-index period. Of these 509,287 incident claims, 7,842 are unique codes. Finally, 4,098,941 members could potentially have had an index date for any diagnosis or procedure in group DX1 for a total days exposed of 2,738,173,177 (member days). Members contribute to the prevalent denominator value if they possess at least one day of enrollment during the query period.



B. MOST FREQUENT CLAIMS BY TOTAL CODE COUNT (_BYCODECOUNT TABLES)

The second set of tables includes the most frequent claims by total code count tables. These tables contain the most frequent pre- and post- index date claims according to the number of code or mapping group occurrences (as specified by the requester in the TOPDIAG, TOPPROC, and TOPDRUG parameters in the <u>Query File</u>). The number and name of the _ByCodeCount tables produced by MP7 depends on the type of codes requested (e.g., if TOPDRUG, TOPDIAG and/or TOPPROC are requested) and whether a mapping file is specified:

If TOPDRUGs are requested (TOPDRUG >0), and a <u>NDC Code Map File</u> is provided, the program will output:

- MAP_RXGEN_ByCodeCount (counts by generic name)
- MAP_RXCLS_ByCodeCount (counts by drug class)

If TOPDRUGs are requested (TOPDRUG>0), and a <u>NDC Code Map File</u> is *not* provided, the program will output:

• RX09_ByCodeCount (counts by NDC)

If TOPPROCs are requested (TOPPROC >0), and a <u>Procedure Code Map File</u> is provided, the program will output:

• MAP_PX_ByCodeCount (counts by procedure code name)

If TOPPROCs are requested (TOPPROC >0), and a <u>Procedure Code Map File</u> is *not* provided, the program will output:

- PX09_ByCodeCount (counts by ICD9-Procedure code)
- PXC4_ByCodeCount (counts by CPT code)
- PXHC_ByCodeCount (counts by HCPCS code)

The output will list the top TOPPROC ICD-9 procedure codes, CPT codes, and HCPCS codes separately.

If TOPDIAGs are requested (TOPDIAG >0), and a <u>Diagnosis Code Map File</u> is provided, the program will output:

• MAP_DX_ByCodeCount (counts by general diagnosis name)

If TOPDIAGs are requested (TOPDIAG >0), and a <u>Diagnosis Code Map File</u> is *not* provided, the program will output:

• DX03_ByCodeCount (counts by 3-digit ICD-9 diagnosis code)

While up to five _ByCodeCount tables can be generated for a single request, all have the same table structure. Table 10 provides a data dictionary for each output variable included in the _ByCodeCount tables. While not explicitly shown in the data dictionary, all tables include year, year/month, age, and sex stratifications.



Output	Output Variable Name	Valid Values	Source / Comments
Index date and pre/post claim incidence/prevalence	Combination	II IP PI	II=Incident index date with incident pre/post claims
combination		РР	IP=Incident index date with prevalent pre/post claims
			PI=Prevalent index date with incident pre/post claims
			PP=Prevalent index date with prevalent pre/post claims
Pre- or Post-Index Claim	InDaysBf	0 1	0 = Post-index claims indicator
			1 = Pre-index claims indicator
Code	DX3, GeneralName PX, GeneralName NDC9, DrugClass, GenericName	NDC, CPT, HCPCS, DX codes	The code type depends on the presence of mapping files and the output file name. It can be a NDC code, a CPT code, a generic name, etc. depending on the file generated.
Code Count	CodeCount	0+	Number of pre- or post- index date claims for a code.
User Count	PatCount	0+	Number of pre- or post- index date members having a given code.
Rank	Rank	1+	Upper bound is dependent on the number specified in TOPDRUG, TOPDIAG, or TOPPROC in the <u>Query File</u> .

Table 10: Most Frequent Claims by Total Code Count Table (_ByCodeCount) Data Dictionary

Below is sample output and output interpretation for MAP_RXCLS_ByCodeCount. The sample depicts the top two most frequent NDCs overall for the pre- and post-index period for an index date based on a diagnosis code for the GROUP 'DX1'.

Table 11: MAP_RXCLS_ByCodeCount – Most Frequent Claims by Total Code Count



Group	Combination	Pre or Post Index	Drug Class	Code	User Count	Rank
		-		Count		-
DX1		0	ACETAMINOPHEN	5033	5033	1
DX1	П	0	IBUPROFEN	3559	3559	2
DX1	П	1	ACETAMINOPHEN	1445	1445	1
DX1	П	1	AZITHROMYCIN	1365	1365	2
DX1	IP	0	ACETAMINOPHEN	9063	7028	1
DX1	IP	0	OXYCODONE HCL	8667	7084	2
DX1	IP	1	ACETAMINOPHEN	6032	4719	1
DX1	IP	1	LANSOPRAZOLE	5201	4990	2
DX1	PI	0	ACETAMINOPHEN	5253	5253	1
DX1	PI	0	IBUPROFEN	3721	3721	2
DX1	PI	1	ACETAMINOPHEN	1483	1483	1
DX1	PI	1	AZITHROMYCIN	1392	1392	2
DX1	РР	0	ACETAMINOPHEN	9362	7240	1
DX1	PP	0	OXYCODONE HCL	9014	7368	2
DX1	РР	1	ACETAMINOPHEN	6245	4850	1
DX1	РР	1	LANSOPRAZOLE	5335	5121	2

<u>First Row Interpretation of MAP_RXCLS_ByCodeCount</u>: There were 5033 incident claims and incident users of ACETAMINOPHEN during the post-index date period for an incident DX1 index date. As the ACETAMINOPHEN group had the largest count of claims, it is ranked number one.

C. MOST FREQUENT CLAIMS BY TOTAL MEMBER COUNT (_BYPATCOUNT TABLES)

The third set of tables includes the most frequent claims by total member count tables. These tables contain the most frequent pre- and post-index date codes or mapping groups according to the number of members having the code or mapping group occurrence (as specified by the requester in the TOPDIAG, TOPPROC, and TOPDRUG parameters in the <u>Query File</u>). The number and name of the _ByPatCount tables produced by MP7 depends on the type of codes requested (i.e., if TOPDRUG, TOPDRUG, and/or TOPPROC are requested) and whether a mapping file is specified:

If TOPDRUGs are requested (TOPDRUG >0), and a <u>NDC Code Map File</u> is provided, the program will output:

- MAP_RXGEN_ByPatCount (counts by generic name)
- MAP_RXCLS_ByPatCount (counts by drug class)

If TOPDRUGs are requested (TOPDRUG>0), and a <u>NDC Code Map File</u> is *not* provided, the program will output:

• RX09_ByPatCount (counts by NDC)

If TOPPROCs are requested (TOPPROC >0), and a <u>Procedure Code Map File</u> is provided, the program will output:

• MAP_PX_ByPatCount (counts by procedure code name)



If TOPPROCs are requested (TOPPROC >0), and a <u>Procedure Code Map File</u> is *not* provided, the program will output:

- PX09_ByPatCount (counts by ICD9-Procedure code)
- PXC4_ByPatCount (counts by CPT code)
- PXHC_ByPatCount (counts by HCPCS code)

The output will list the top TOPPROC ICD-9 procedure codes, CPT codes, and HCPCS codes separately.

If TOPDIAGs are requested (TOPDIAG >0), and a <u>Diagnosis Code Map File</u> is provided, the program will output:

• MAP_DX_ByPatCount (counts by general diagnosis name)

If TOPDIAGs are requested (TOPDIAG >0), and a <u>Diagnosis Code Map File</u> is *not* provided, the program will output:

• DX03_ByPatCount (counts by 3-digit ICD-9 diagnosis code)

While up to five _ByPatCount tables can be generated for a single request, all have the same table structure. In fact, all _ByPatCount tables are identical in structure to the _ByCodeCat tables. Please reference the Table 9 data dictionary for additional information on output variables. As a reminder, while not explicitly shown in the Table 9 data dictionary, all tables include year, year/month, age, and sex stratifications.

D. MEMBER COUNTS BY CODE FREQUENCY (_BYUCODECOUNT TABLES)

The fourth set of tables includes the member counts by unique code frequency tables. These tables contain counts of members by unique code frequency during the pre- and post-index period (e.g., the number of members with one unique code in the period, the number of members with two unique codes in the period, etc.). The number and name of the _ByUCodeCount tables produced by MP7 depends on the type of codes requested (e.g., if TOPDRUG, TOPDIAG and/or TOPPROC are requested) and whether a mapping file is specified:

If TOPDRUGs are requested (TOPDRUG >0), and a <u>NDC Code Map File</u> is provided, the program will output:

- MAP_RXGEN_ByUCodeCount (counts by generic name)
- MAP_RXCLS_ByUCodeCount (counts by drug class)

If TOPDRUGs are requested (TOPDRUG>0), and a <u>NDC Code Map File</u> is *not* provided, the program will output:

• RX09_ByUCodeCount (counts by NDC)

If TOPPROCs are requested (TOPPROC >0), and a <u>Procedure Code Map File</u> is provided, the program will output:



• MAP_PX_ByUCodeCount (counts by procedure code name)

If TOPPROCs are requested (TOPPROC >0), and a <u>Procedure Code Map File</u> is *not* provided, the program will output:

- PX09_ByUCodeCount (counts by ICD9-Procedure code)
- PXC4_ByUCodeCount (counts by CPT code)
- PXHC_ByUCodeCount (counts by HCPCS code)

If TOPDIAGs are requested (TOPDIAG >0), and a <u>Diagnosis Code Map File</u> is provided, the program will output:

• MAP_DX_ByUCodeCount (counts by general diagnosis name)

If TOPDIAGs are requested (TOPDIAG >0), and a <u>Diagnosis Code Map File</u> is *not* provided, the program will output:

• DX03_ByUCodeCount (counts by 3-digit ICD-9 diagnosis code)

While up to five _ByUCodeCount tables can be generated for a single request, all have the same table structure. Table 12 provides a data dictionary for each output variable included in the _ByUCodeCount tables. While not explicitly shown in the data dictionary, all tables include year, year/month, age, and sex stratifications.

Output	Output Variable	Valid Values	Source / Comments
	Name		
Index date and	Combination	11	II=Incident index date with incident
pre/post claim		IP	pre/post claims
incidence/prevalence		PI	
combinations		РР	IP=Incident index date with
			prevalent pre/post claims
			PI=Prevalent index date with
			incident pre/post claims
			PP=Prevalent index date with
			prevalent pre/post claims
Pre or Post Index	InDaysBf	0	0 = Post-index claims indicator
Claim		1	1 = Pre-index claims indicator
Unique Code Count	UCodeCount	0+	Number of unique codes of interest
			found in a member's pre/post
			index date period
Unique Code Count	FrequencyCount	0+	Number of members with the
Frequency			specific Unique Code Count during
			the pre/post index period

Table 12: Member Counts by Code Frequency (_ByUCodeCount) Data Dictionary

Below is sample output and output interpretation for MAP_RXGEN_ByUCodeCount.

Group	Combination	Pre or Post Index	Unique Code	Unique Code
		Claim	Count	Count Frequency
DX1	II	0	1	14,716
DX1	II	0	2	10,381
DX1	Ш	0	3	6258
DX1	II	0	4	3,617
DX1	II	0	5	2,022
DX1	II	0	6	1,214
DX1	II	0	7	692
DX1	II	0	8	382
DX1	П	0	9	213
DX1	II	0	10	152
DX1	II	0	11	86
DX1	11	0	12	53

Table 13: MAP_RXGEN_ByUCodeCount – Member Counts by Code Frequency

<u>Interpretation of MAP_RXGEN_ByUCodeCount</u>: For Row 1, a total of 14,716 members had exactly one incident code of interest during the post-index date period for an incident index claim of DX1. For Row 2, a total of 10,381 members had exactly two unique incident codes of interest during the post-index date period for an incident index claim of DX1.

X. EXAMPLE

Tables 14-18 below show partially-populated examples of the Query, NDC Map, Procedure Map, Diagnosis Map, and Output Table Selection files used to create the output described in <u>Section IX</u>:

Group	SubGroup	CodeCat	CodeType	Code	Enrdays	EnrdaysBf	EnrdaysAf	WashPer	WashTyp
DX1	Diagnosis1	DX	09	4321	183	183	183	183	Mult
DX1	Diagnosis2	DX	09	59971	183	183	183	183	Mult

Table 14: Example of <u>Query File</u> (Part 1)

Table 14:	Example	of Query	y File	(Part 2)
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CareSetting	Principal	TopDrug	TopDiag	TopProc	DaysBf	DaysAf	WashPerBfAf	WashTypBfAf
'IP' 'ED'	NO	10	10	10	30	30	183	Mult
'IP' 'ED'	NO	10	10	10	30	30	183	Mult

Table 14: Example of **Query File** (Part 3)

PrincipalBfAf	DiagCareSettingBfAf	ProcCareSettingBfAf	BlackOutAf	NDCLengthBfAf	DiagLengthBfAf
NO	'IP' 'ED'	'IP' 'ED'	0	9	3
NO	'IP' 'ED'	'IP' 'ED'	0	9	3



Table 15: Example of <u>NDC Code Map File</u>

NDC	GenericName	DrugClass
00002010102	AMMONIUM CHLORIDE	AMMONIUM CHLORIDE
00002012502	ASPIRIN	ASPIRIN
00002012504	ASPIRIN	ASPIRIN

Table 16: Example of Procedure Code Map File

РХ	PX_CodeType	GeneralName
E0459	HC	CHESTWRAP
C9265	HC	INJECTIONROMIDEPSIN1MG
S4011	HC	INVITROFERTILIZATION

Table 17: Example of Diagnosis Code Map File

DX	DX_CodeType	GeneralName
001	09	CHOLERA
004	09	SHIGELLOSIS
005	09	OTHERFOODPOISONING

Table 18: Example of Output Table Selection File

DOCTADNAME	DOCTADDECCD	TADMANAE	TAB-
DOCTABNAME	DOCTABDESCR	TABNAME	REQUIRED
	Global Denominators	dentable0	Y
	Global Numerators	numtable0	Y
ITable1	Incident index date summary table stratified by Group	itable1	Y
ITable2	Incident index date summary table stratified by Group and Year	itable2	Y
	Incident index date summary table stratified by Group, Year and		
ITable3	Month	itable3	Y
	Incident index date summary table stratified by Group, Sex and Age		
ITable4	Group	itable4	Y
PTable1	Prevalent index date summary table stratified by Group	ptable1	Y
PTable2	Prevalent index date summary table stratified by Group and Year	ptable2	Y
	Prevalent index date summary table stratified by Group, Year and		
PTable3	Month	ptable3	Y
	Prevalent index date summary table stratified by Group, Sex and Age		
PTable4	Group	ptable4	Y
	Top pre/post index date claims according to number of DX code		
DX03_ByCodeCount	occurrences if DX mapping file is not provided	dx03_bycodecount	Y
	Top pre/post index date claims according to the number of members		
DX03_ByPatCount	having the DX code occurrence if DX mapping file is not provided	dx03_bypatcount	Y
	Pre/post index date unique DX codes if DX mapping file is not		
DX03_UCodeCount	provided	dx03_ucodecount	Y
	Top pre/post index date claims according to number of PX09 code		
PX09_ByCodeCount	occurrences if PX mapping file is not provided	px09_bycodecount	Y
	Top pre/post index date claims according to the number of members		
PX09 ByPatCount	having the PX09 code occurrence if PX mapping file is not provided	px09 bypatcount	Y



DOCTABNAME	DOCTABDESCR	TABNAME	TAB- REQUIRED
	Pre/post index date unique PX09 codes if PX mapping file is not		
PX09_UCodeCount	provided	px09_ucodecount	Y
	Top pre/post index date claims according to number of PXC4 code		
PXC4_ByCodeCount	occurrences if PX mapping file is not provided	pxc4_bycodecount	Υ
	Top pre/post index date claims according to the number of members		
PXC4_ByPatCount	having the PXC4 code occurrence if PX mapping file is not provided	pxc4_bypatcount	Y
PXC4_UCodeCount	Pre/post index date unique PXC4 codes if PX mapping file is not provided	pxc4_ucodecount	Y
	Top pre/post index date claims according to number of PXHC code		
PXHC_ByCodeCount	occurrences if PX mapping file is not provided	pxhc_bycodecount	Y
	Top pre/post index date claims according to the number of members		
PXHC_ByPatCount	having the PXHC code occurrence if PX mapping file is not provided	pxhc_bypatcount	Y
	Pre/post index date unique PXHC codes if PX mapping file is not		
PXHC_UCodeCount	provided	pxhc_ucodecount	Y
	Top pre/post index date claims according to number of NDC code		
RX09_ByCodeCount	occurrences if NDC mapping file is not provided	rx09_bycodecount	Y
	Top pre/post index date claims according to the number of members		
RX09_ByPatCount	having the NDC code occurrence if NDC mapping file is not provided	rx09_bypatcount	Y
	Pre/post index date unique NDC codes if NDC mapping file is not		
RX09_UCodeCount	provided	rx09_ucodecount	Y
	Top pre/post index date claims according to number of mapping		
MAP_RXGEN_ByCodeCount	generic name occurrences if NDC mapping file is provided	map_rxgen_bycodecount	Υ
	Top pre/post index date claims according to the number of members		N/
MAP_RXGEN_ByPatCount	having the generic name occurrence if NDC mapping file is provided	map_rxgen_bypatcount	Ŷ
	Pre/post index date unique generic name if NDC mapping file is		V
MAP_RXGEN_UC0deCount	provided	map_rxgen_ucodecount	Ŷ
MAD DYCLE DyCodeCount	lop pre/post index date claims according to number of mapping drug	man mula husadasaunt	V
MAP_RXCLS_ByCodeCount	class occurrences if NDC mapping file is provided	map_rxcis_bycodecount	Ŷ
MAD DYCLE DyDatCount	howing the drug class accurrence if NDC menning file is provided	man mula hunataaunt	V
MAP_RACES_ByPatCount	Draving the drug class occurrence if NDC mapping file is provided	map_rxcis_bypatcount	Y
MAP_RXCLS_OCOdeCount	Ten pro (next index date unique drug class if NDC mapping file is provided	map_rxcis_ucodecount	Ŷ
MAR DX ByCodeCount	rop pre/post index date claims according to number of mapping	man dy bysodosount	v
	Top pro (post index data claims according to the number of members		T
	having the general diagnosis occurrence if DX manning file is		
MAP DX ByPatCount	provided	man dy hypatrount	v
	Province		
MAP DX UCodeCount	nrovided	man dx ucodecount	v
	Top pre/post index date claims according to number of manning		•
MAP PX ByCodeCount	general procedure occurrences if PX mapping file is provided	map px bycodecount	Y
	Top pre/post index date claims according to the number of members	,,,,,,,,	
	having the general procedure occurrence if PX mapping file is		
MAP PX ByPatCount	provided	map px bypatcount	Y
	Pre/post index date unique general procedure if PX mapping file is		
MAP PX UCodeCount	provided	map px ucodecount	Y

In this example, suppose that we have a QUERYFILE named queryfile.sas7bdat and a NDCCODEMAP mapping file named ndc_lookup.sas7bdat. Furthermore, we have:

- To be selected members need to have at least 365 days of medical and drug coverage before index date
- Any enrollment gap of less than 45 days is considered administrative and must be ignored
- The query period spans the years 2000 to 2011



- The following age groups: 18-44 45-64 65+ will be used to aggregate results
- Only certain output tables should be preserved

For this request, the program could be executed using the following SAS Macro call: