MINI-SENTINEL MODULAR PROGRAMS

MODULAR PROGRAM 6: FREQUENCY AND DURATION OF TREATMENT FOLLOWING AN EVENT OF INTEREST

Documentation version 7.0

Prepared by the Mini-Sentinel Operations Center
For use with Modular Program 6 version 7.0
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Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) 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 Sentinel Initiative, 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	By
7.0	12/17/2013	• Updated output tables to include amount supplied metrics • Added specifications for and an example of optional "Dispensing Processing File" • Added macro parameter "RunID"	Mini-Sentinel Operations Center
6.0	8/28/2013	• Added Macro parameter "COVERAGE" • Added Event File parameter "ENRDAYS" • Added parameter "DESCR" to Event, Incident Event, Post-Event Treatment, Incident Post-Event Treatment and Inclusion/Exclusion Conditions files	Mini-Sentinel Operations Center
5.0	5/16/2013	• Revised the way the MP6 matches codes of interest to allow either exact code match and/or wildcard match. • Added optional Output Table Selection module to instruct the MP6 to preserve only certain output tables in the final output library. • Revised various input files to allow diagnosis codes to be queried, allowing the requester to now use any type of codes in any input files.	Mini-Sentinel Operations Center
4.0	3/14/2013	• Revised Event, Incident Event, Post-Event Treatment, and Incident Post-Event treatment files to allow Laboratory table queries. • Added specifications for two input files "Lab Code File" and "Lab Care Setting File" required if Laboratory table is queried. • Added CARESETTING and PRINCIPAL parameters to Post-Event Treatment and Incident Post-Event Treatment files.	Mini-Sentinel Operations Center
3.0	1/25/2013	• Revised former "Pre-existing Condition File" to be the new "Inclusion/Exclusion Conditions File" and updated functionality, file, and output descriptions. • Made clarifications to text based on user feedback.	Mini-Sentinel Operations Center
2.1	11/15/2012	• Up-versioned due to increment from mp6_2.0 to mp6_2.1	Mini-Sentinel Operations Center
2.0	11/7/2012	• 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, events, date ranges, age ranges, and other implementation details. This document describes the key program specifications and main assumptions underlying each of the parameters for Modular Program 6 (MP6) version 7.0. 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 term “scenario” is used to refer to a set of parameters and criteria used to define an execution of the MP. The “requester” refers to an individual (or group of individuals) who initiates the MP request and defines the scenarios. The term “request programmer” refers to an individual who creates request Input Files and distributes the MP to the Data Partners.

The term “claim” is used to represent either an outpatient pharmacy dispensing or medical encounter/record containing codes of interest.

The term “lab code” is used to refer to an MSOC assigned 8-digit code representing a unique combination of lab test name, test subcategory, and specimen source. Lab codes are used to query the MSCDM Laboratory table using the same mechanism that National Drug Codes (NDCs), procedure, and diagnosis codes use to query the Dispensing, Procedure, and Diagnosis tables, respectively.

The terms "event" and “event of interest” are used to represent the occurrence of a diagnosis, procedure, outpatient pharmacy dispensing, and/or lab test as defined by the MP requester. An event can therefore be defined using any set of NDCs, diagnosis, procedure and/or lab codes. For example, the occurrence of a vaccination can be defined based on the occurrence of specific procedure codes in the procedure file.

The “index date” is the service date on the claim used to define the event of interest for outpatient pharmacy dispensings, diagnosis and procedure codes; index date is defined based on available data (using the first populated date in this hierarchy: lab date, result date, and order date) if a lab test is used to define an event of interest. Note that events, not exposures, are used to define index dates in MP6.

A “lookup period” is a user defined number of days after the index date, where MP6 searches for evidence of treatment. The “lookup period start date” and the index date are the same date.

“Post-event treatment” is defined as the occurrence of an outpatient pharmacy dispensing, procedure, diagnosis, or lab test. A post-event “treatment episode” or “episode” is a period of continuous treatment defined using outpatient pharmacy dispensings, procedures, diagnoses, and lab tests. For dispensings, a treatment episode is a dispensing sequence that has no interruption in days supply greater than an “allowable gap.” The allowable gap is the number of days used to bridge dispensings to create a continuous treatment episode.

[1] See http://www.mini-sentinel.org/data_activities/ for more information about the MSCDM.

The term "condition" is used to represent a medical code (or a group of codes) that identify a medical condition of interest. In MP6, the cohort can be restricted to members with and/or without condition(s).

The term "member" is used to represent an individual with relevant enrollment and other criteria (as specified by the MP parameters).

The execution of MP6 allows information for multiple scenarios to be generated at the same time. Results from all scenarios are included in the MP output tables and can be differentiated using "group names" defined by the requester. This document describes the process for only one scenario to be tested.

III. PROGRAM SUMMARY

MP6 is used to describe treatment (medical care) in a pre-specified period following an event of interest. The program identifies events of interest that meet requester-defined criteria, creates lookup periods as fixed periods of time following the index date, and scans the lookup period to determine if a treatment episode of interest is observed. Treatment episodes are created to determine the duration of post-event treatment and the "post-event treatment intensity ratio", *i.e.*, the percentage of days a member is treated during the lookup period. For example, the program can identify all members who use beta blockers (treatment of interest) 365 days after a diagnosis of acute myocardial infarction (index date used to define 365 day lookup period). MP6 will then calculate the percentage of lookup period days members are treated with a beta blocker.

MP6 also has the ability to define an event and/or post-event treatment using laboratory data. A user can therefore examine the number of resulted lab tests following an event of interest (*e.g.*, the number of resulted HgbA1C labs following a diagnosis of diabetes) or the occurrence of a treatment of interest following a resulted lab test (*e.g.,* the occurrence of insulin treatment following a resulted HGBA1C lab test). Note that all queries of laboratory data will examine the occurrence of "resulted" lab tests. The MSCDM Laboratory table only contains information on resulted lab tests; information on lab tests that occurred but did not have valid results is excluded from the table and therefore cannot be queried.

MP6 has three optional modules available. One is an inclusion/exclusion feature to further restrict the analysis to members with and/or without "conditions" before or after an index date defined using any combination of diagnosis, procedure and/or NDCs. Another allows MP6 to output a subset of result tables generated, reducing workload to compile and review results that are not relevant to a specific request. The final optional module allows the user to define how days supply and amount supplied on each dispensing should be processed by the MP.

MP6 generates metrics for both a prevalent cohort (characterizing all events and subsequent treatment during the query period) and an incident cohort (characterizing incident events and subsequent incident treatment during the query period). One run of MP6 generates a total of fifty-three result tables, including twenty-five each for the prevalent and incident cohorts (for each cohort, five unique tables and twenty tables containing stratified results of the four unique tables [stratified by year, year/month, age group, and sex are generated]). An additional table details the number of dispensings excluded from consideration by the MP based on user-defined parameters in the Dispensing Processing File. Two additional tables containing full summary statistics are also generated. While the MP6 output reports several metrics, the main metrics are the proportion of patients treated following an event of interest,

mean time to treatment following an event of interest, and post-event treatment intensity. For more details on result tables, see Section IX.

MP6 requires the specification of several parameters to define a scenario. These include program parameters that specify a request identifier, execution (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 event(s) of interest, lookup period(s), and treatment episodes must also be specified.

The first input file is the Event File, which defines events of interest (index date(s)) and lookup periods. The second file is the Incident Event File; it is optional and is used to refine how incident events are defined. The third file is the Post-Event Treatment File, which defines post-event treatment episodes of interest. The fourth file is the Incident Post-Event Treatment File, which is optional and is used to refine how incident treatment episodes are defined. The fifth file is the optional Inclusion/Exclusion Conditions File, which defines the outpatient pharmacy medications, medical procedures and/or diagnoses used to restrict the cohort to members with and/or without conditions of interest. The sixth file is the optional Lab Care Setting File, which maps procedure and diagnosis code care settings to the user defined equivalent lab test care settings. The seventh file is the Lab Code File, which assigns an 8-digit code for each combination of lab test name, subcategory, and specimen source, to facilitate querying the MSCDM Laboratory table. The Lab Code File is defined by the MSOC and does not require requester inputs. The eighth file is the Output Table Selection File, which defines the subset of MP6 output files to generate. The ninth file is the optional Dispensing Processing File which defines allowable ranges for days supplied and amount supplied values, and defines how multiple dispensings on the same day are handled. All parameters and input file specifications are described in Section IV.

IV. PROGRAM PARAMETER AND INPUT FILE SPECIFICATIONS

A. PROGRAM PARAMETER SPECIFICATIONS

There are sixteen main program parameters that may be specified. These include a request identifier, a run identifier, start and end dates for the query period, age stratifications, coverage type requirements, an allowed enrollment gap used to create continuous enrollment periods, and nine input files (the Event File, Incident Event File, Inclusion/Exclusion Conditions File, Post-Event Treatment File, Incident Post-Event Treatment File, Lab Care Setting File, Lab Code File, Output Table Selection File, and Dispensing Processing File).

Table 1 contains detailed specifications for each of these required parameters.

Table 1: Main Program Parameter Specification

Parameter	Field Name	Description
Request Identifier	REQUESTID	**Details**: a request identifier. The identifier is appended to all output file names. **Note 1:** must be 5 characters in length. The REQUESTID should start with “mpr” and include two additional digits with the assigned request number.

Parameter	Field Name	Description
		Defined by: Request programmer **Input type:** Required **Format:** Alphanumeric **Example**: REQUESTID=mpr01
Run Identifier	RUNID	**Details**: a run identifier to denote each execution of the program. The identifier is 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
User-Defined Coverage Type Requirement	COVERAGE	**Details:** an optional parameter to allow medical and drug coverage type requirements to be user-defined and not CODETYPE dependent. 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 required is enforced for both the required Washout Period and the Minimum Enrollment Pre-Index Days features (see WASHPER and ENRDAYS parameters in the Event File 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
Enrollment Gap	ENROLGAP	**Details:** sets the number of days that will be bridged between two consecutive enrollment periods to create a "continuously enrolled" period. For example, if ENROLGAP=30,

Parameter	Field Name	Description
		COVERAGE=MD, and a member is eligible for medical and drug coverage in periods 1/1/2007-3/27/2007 and 4/1/2007-12/21/2007 (*i.e.,* a 4-day gap between two consecutive enrollment episodes), the member will be considered continuously enrolled from 1/1/2007 to 12/21/2007. Any gaps in enrollment greater than 30 days will result in a new enrollment period, and all the days in the gap will be considered un-enrolled. **Note 1**: a gap of 45-days is recommended for most uses. **Note 2:** multiple continuous enrollment periods per member may be assessed. **Defined by:** Requester **Input type:** Required **Format**: Numeric **Example**: ENROLGAP=45 (gaps less than or equal to 45 days will be "bridged" to form one "continuously enrolled" sequence)
Query Start Date	QUERYFROM	**Details:** date for the start of the query identification period. If QUERYFROM =03/01/2008, only events occurring on or after this date will be considered. **Defined by:** Requester **Input type:** Required **Format:** mm/dd/yyyy **Example**: QUERYFROM=03/01/2008
Query End Date	QUERYTO	**Details:** date for the end of the query identification period. If QUERYTO=03/31/2009, only events occurring before this date will be considered. **Note 1:** QUERYTO only binds the event date (*i.e.,* the lookup period start date). Lookup periods may extend beyond QUERYTO if they start between QUERYFROM and QUERYTO. **Defined by:** Requester **Input type:** Required **Format:** mm/dd/yyyy **Example:** QUERYTO=03/31/2009
Event File	QUERYFILE	**Details:** name of the .sas7bdat or .cport dataset that includes the codes used to identify the event(s) (index date(s)) of interest and lookup period duration. 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: Required **Format: .**sas7bdat or .cport file format **Example:** QUERYFILE=query.sas7bdat or query.cport
Incident Event File	INCQUERYFILE	**Details:** name of the .sas7bdat or .cport dataset refining the incident event definition(s). It contains additional codes and various parameters to further refine how incidence of each 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 Event File, see Section IV.B. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** INCQUERYFILE=incquery.sas7bdat or incquery.cport
Post-Event Treatment File	POSTDIAGFILE	**Details:** name of the .sas7bdat or .cport dataset identifying the codes used to define post-event treatment episodes. The file name, including its appropriate extension, must be entered. For specific details on the content of this file, please see Section IV.B. **Named by:** Request programmer **Input type:** Required **Format: .**sas7bdat or .cport file format **Example:** POSTDIAGFILE=postdiag.sas7bdat or postdiag.cport
Incident Post-Event Treatment File	INCPOSTDIAGFILE	**Details:** name of the .sas7bdat or .cport dataset refining the incident treatment episode(s) definition. It contains additional codes and various parameters to further refine how incidence of each treatment episode must be defined. The file name, including its extension, must be entered. For specific details on the content of this file, please see Section IV.B. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** INCPOSTDIAGFILE=incpostdiag.sas7bdat or incpostdiag.cport
Inclusion/Exclusion Conditions File	CONDFILE	**Details:** name of the SAS dataset defining the inclusion or exclusion of condition(s) of interest. It lists the codes of interest and various parameters to specify how each code must be queried. 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:** CONDFILE=cond.sas7bdat or cond.cport
Lab Care Setting File	PTLOCCODEMAP	**Details:** name of the SAS dataset defining the mapping between lab care settings and procedure/diagnosis care settings. 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 **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** PTLOCCODEMAP =ptloc.sas7bdat or ptloc.cport
Lab Code File	LABSCODEMAP	**Details:** name of the SAS dataset defining the 8-digit lab code used to query the Laboratory table based on lab test name, test subcategory, and specimen source. 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 **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** LABSCODEMAP =labscode.sas7bdat or labscode.cport
Output Table Selection File	OUTTABLESFILE	**Details:** name of the SAS dataset defining the output table(s) to be preserved in 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 **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** OUTTABLESFILE = output.sas7bdat or output.cport
Dispensing Processing File	STOCKPILINGFILE	**Details:** name of the SAS dataset defining how dispensings, days supplied, and amount supplied are handled by the MP. The file name, including its extension, must be entered. For specific details on the content of this file, see Section V.C. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** STOCKPILINGFILE = stockpil.sas7bdat or stockpil.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.

Parameter	Field Name	Description
		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 must be specified in the Event, Incident Event, Post-Event Treatment, Incident Post-Event Treatment, Inclusion/Exclusion Conditions, Lab Care Setting, Lab Code, and Output Table Selection files.

1. Event File

The Event File is required. It contains the comprehensive set of codes used to define the event(s) of interest. Lab codes, NDCs, International Classification of Diseases (ICD) diagnosis and procedure codes, and/or Healthcare Common Procedure Coding System (HCPCS) codes can be used to define events, in combination with a care setting. Event(s) can be defined using any mix of allowed code types.

The structure of the file must reflect how codes should be queried to define a unique event. The GROUP field is used to group all codes pertaining to a given event of interest. Table 2 describes the specifications for the Event File.

Table 2: Event File Specification

Parameter	Field Name	Description
Name of Event Group	GROUP	**Details:** standardized name used to refer to a GROUP for event(s) of interest to be queried. **Note 1**: multiple event groups can be defined within the same Event File. In this case all events are queried independently and results are reported separately and labeled using each 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:** CVD
Name of Event SubGroup	SUBGROUP	**Details:** standardized name used to refer to a specific event of interest within a given GROUP. **Note 1:** the SUBGROUP field is used by the stockpiling algorithm as group categories to adjust claim service dates. See Section V.B for more details. **Note 2:** useful when a GROUP contains multiple events of interest. For example, if GROUP= "CVD" SUBGROUP could take values of "Stroke" and "PVD". **Note 3:** no output will be presented by SUBGROUP. All output is presented at the GROUP level. **Named by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $30; special characters (*e.g.*, commas, periods, hyphens, etc) allowed and underscores must be used to mark spaces. **Example:** Stroke, PVD
Event Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this file. Valid values are: • **DX09:** ICD-9-CM diagnoses • **DX10:** ICD-10-CM diagnoses • **DX11:** ICD-11-CM diagnoses • **RX09:** 9-digit NDC • **RX11**: 11-digit NDC • **PX09:** ICD-9-CM procedure

Parameter	Field Name	Description
		• **PX10:** ICD-10-CM procedure • **PX11:** ICD-11-CM procedure • **PXC4:** CPT-4 (*i.e.*, HCPCS Level I) • **PXHC:** HCPCS (*i.e.*, HCPCS Level II) • **PXH3:** HCPCS Level III • **PXC2:** CPT Category II • **PXC3:** CPT Category III • **LABS:** 8-digit lab code **Note 1:** the eight-digit lab code (LABS) was developed by MSOC for simpler querying of the Laboratory table; these are not LOINCs. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4. **Example:** PX09
Event Codes of Interest	CODE	**Details**: NDC, ICD, and HCPCS code values for the event(s) of interest. **Note 1:** codes are matched using exact values (*i.e.*, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (e.g., 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:** remove decimal points in the code value. **Note 3**: CODETYPE must be consistent with the expected format of the CODE value (*e.g.*, MP6 will not find any valid matches in the data for CODETYPE=PX11 and a 4-digit diagnosis code value). **Note 4**: duplicate CODETYPE-CODE combinations in a given GROUP are removed by the MP6 algorithm. **Defined by:** Requester, with support from the MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11. **Example:** 3570
Event Code Description	DESCR	**Details:** description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files. **Note 1:** this parameter is optional (i.e., the MP algorithm will not fail if this parameter is excluded from the Event File)

Parameter	Field Name	Description
		Defined by: Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Event Principal Diagnosis Indicator	PRINCIPAL	**Details:** for a diagnosis CODETYPE (*e.g.,* DX09, DX10, DX11), 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. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $3. **Example:** YES
Event Care Setting	CARESETTING	**Details:** the care settings considered for the individual diagnosis, lab or procedure codes. 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 1:** CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal 'IP' for one diagnosis code and 'IP' 'ED' for another diagnosis code *in the same GROUP*. **Note 2:** care setting values in the MSCDM Laboratory table have different valid values than the Diagnosis and Procedure tables. Requesters may develop their own mapping of care settings for each request using the optional Lab Care Setting File; by default, values will be mapped as: I: Inpatient = **IP** O: Outpatient = **AV** E: Emergency Department = **ED** H: Home = **OA** U: Unknown = **OA** **Defined by:** Requester **Input type:** Optional

Parameter	Field Name	Description
		Format: Alphanumeric; SAS character $20. **Example:** 'IP' 'ED'
Event Incidence Type	WASHTYP	**Details:** selects how incidence will be defined. As detailed in Section V.E , the event incidence type can take the following values: • **MIN**: minimum incidence -- identifies and reports metrics only for the *first* valid incident event during the query period, and uses ALL prior observed claims to determine incidence. That is, incidence is defined as the first event during the query period with no evidence of a prior event using all available data. • **SING**: single incidence -- identifies and reports metrics only for the *first* valid incident event during the query period, and uses claims observed during the specified WASHPER days to determine incidence. That is, incidence is defined as the first event during the query period with no evidence of a prior event during WASHPER days. • **MULT**: multiple incidence -- identifies and reports metrics for *all* valid incident events during the query period, and uses claims observed during the specified WASHPER days to determine incidence. That is, incidence is defined as any event during the query period with no evidence of an event during the prior WASHPER days. **Note 1:** WASHTYP parameter is used in conjunction with the Event Washout Period (WASHPER; see below) to define a valid incident event. **Note 2:** events meeting incidence criteria are used to create lookup periods; the index date is the same as the lookup period start date. **Note 3**: the set of all events reported using the single incidence case is a subset of all events from the multiple incidence case. **Note 4:** the MP6 algorithm may use days before QUERYFROM to ensure incidence criteria are met. **Note 5**: MIN setting should be used with caution as interpretation is complex. An event that meets the MIN criteria must occur during the query period and cannot be preceded by a disqualifying event at *any time* during enrollment; that is, the lookback period to define incidence is not limited to the washout period. See Section V.E for details. **Defined by:** Requester, with support from the MSOC as needed

Parameter	Field Name	Description
		Input type: Required **Format:** Alphanumeric; SAS character $4; case sensitive (upper case only). **Example:** MULT
Event Washout Period	WASHPER	**Details:** length of washout period in days. The event washout period is a period before the index date/ lookup period start date during which a member cannot have evidence of event(s) of interest or any other event(s) specified in the Incident Event File. **Note 1**: length of event washout period days must be the same within a given event GROUP. **Note 2**: used in conjunction with any Event Incidence Types. **Note 3:** the MP algorithm may use days before QUERYFROM to determine if continuous enrollment and incidence criteria are met. **Note 4:** when WASHTYP=MIN, WASHPER is only used to assess continuous enrollment eligibility. **Note 5**: in conjunction with the ENROLGAP, COVERAGE, and minimum pre-index enrollment days (ENRDAYS) parameters, the washout period parameter is used to ensure that appropriate enrollment requirements are met. Since at least WASHPER days of enrollment must be found prior to index date this minimum enrollment days requirement can only be binding if ENRDAYS > WASHPER (See Section V.A). If enrollment requirements prior to index date are not met, lookup period incidence cannot be determined and thus the lookup period is excluded from output metrics. **Defined by:** Requester **Input type:** Required (0 must be entered if no washout is required) **Format:** Numeric **Example:** 183
Minimum Pre-Index Enrollment Days	ENRDAYS	**Details:** irrespective of what query incidence type (WASHTYP) is specified, optional parameter to further restrict the number of days of continuous enrollment prior to incident event index date to reach a certain minimum. **Note 1**: if not specified by the requester a default value of 0 day is used by the MP algorithm. **Note 2**: if specified must be the same within a given query

Parameter	Field Name	Description
		GROUP. **Note 3**: in conjunction with the ENROLGAP, COVERAGE, and WASHPER parameters, the minimum pre-index enrollment days parameter is used to ensure that appropriate enrollment requirements are met. Since at least WASHPER days of enrollment must be found prior to index date this minimum enrollment days requirement can only be binding if ENRDAYS > WASHPER (See Section V.A). If enrollment requirements prior to index date are not met, event incidence cannot be determined and thus the event is excluded from output metrics. **Named by:** Requester **Input type:** Optional (default value is 0) **Format:** Numeric **Example:** 365
Lookup Period Duration	LOOKUPPER	**Details:** length of lookup period in days. This is the number of days following the index date that the program scans for valid treatment episodes. The lookup period includes the index date (*i.e.*, the index date is day 1). **Note 1:** length must be greater than 0. **Note 2**: to allow a drug/procedure to occur any time after a diagnosis, enter a value of 99999. **Defined by:** Requester **Input type:** Required (0 must be entered if no washout is required) **Format:** Numeric **Example:** 30
Minimum Lookup Period Duration	MINFOLLOWPER	**Details:** minimum number of enrollment days required after an index date. For example, if MINFOLLOWPER=10, a member must have 10 or more days of continuous enrollment in drug and medical benefit coverage following the index date in order for the lookup period to be included in output metrics. **Defined by:** Requester **Input type:** Required (0 must be entered if no minimum follow-up period is required) **Format:** Numeric **Example:** 10

2. Incident Event File

The Incident Event File is optional. If defined, the file contains the comprehensive set of codes used to refine the incidence definition of the event(s) of interest. Just like the Event File, event(s) of interest can

be defined using any mix of the following allowed code types: NDCs, lab codes, ICD diagnosis and procedure codes and/ or HCPCS codes.

The GROUP structure of the Incident Event File must match that of the Event File. That is, for each GROUP defined in the Incident Event File a matching GROUP must be found in the Event File to refine the incidence definition of the event(s) of interest.

By default, for a given GROUP MP6 uses the list of codes included in the Event File to determine event incident status (as of the index date). The Incident Event File is used to refine incidence based on a set of codes and/or parameters that are different than those used to define the events of interest in the Event File. For example, a requester may be interested in examining the occurrence of Diagnosis 1, but wants all incident Diagnosis 1 to be free of Diagnosis 1, 2 and 3 in the 183 days before the Diagnosis 1 index date. In this case, the list of codes for Diagnosis 1 would be included in the Event File and the list of codes for Diagnosis 2 and Diagnosis 3 would be included in the Incident Event File. Table 3 contains detailed specifications for the Incident Event File.

Table 3: Incident Event File Specification

Parameter	Field Name	Description
Name of Event Group	GROUP	**Details:** standardized name used to refer to a GROUP for event(s) of interest to be queried. **Request Programmer Note 1**: in many cases value must match GROUP values from the Event File. In the case where all codes in the Incident Event File are used to assess incidence for *all* GROUPs in the Event File, this field may be left blank. **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:** CVD
Name of Event SubGroup	SUBGROUP	**Details:** standardized name used to refer to a specific event of interest within a given GROUP. **Note 1:** the SUBGROUP field is used by the stockpiling algorithm as group categories to adjust claim service dates. See Section V.B for details. **Note 2:** useful when a GROUP contains multiple events of interest. For example, if GROUP= “CVD” SUBGROUP could take values of “Stroke” and “PVD”. **Note 3:** no output will be presented by SUBGROUP. All output is presented at the GROUP level. **Named by:** Request programmer **Input type:** Required

Parameter	Field Name	Description
		Format: Alphanumeric; SAS character $30; special characters (*e.g.*, commas, periods, hyphens, etc) allowed and underscores must be used to mark spaces. **Example:** Stroke, PVD
Incident Only Event Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this file. Valid values are: • **RX09:** 9-digit NDC • **RX11:** 11-digit NDC • **PX09:** ICD-9-CM procedure • **PX10:** ICD-10-CM procedure • **PX11:** ICD-11-CM procedure • **PXC4:** CPT-4 (*i.e.*, HCPCS Level I) • **PXHC:** HCPCS (*i.e.*, HCPCS Level II) • **PXH3:** HCPCS Level III • **PXC2:** CPT Category II • **PXC3:** CPT Category III • **DX09:** ICD-9-CM diagnoses • **DX10:** ICD-10-CM diagnoses • **DX11:** ICD-11-CM diagnoses • **LABS:** 8-digit lab code **Note 1:** the eight-digit lab code (LABS) was developed by MSOC for simpler querying of the Laboratory table; these are not LOINCs. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4. **Example:** DX09
Incident Only Event Codes	CODE	**Details:** code values to be used to refine the event incidence definition. For example, if a requester is examining occurrence of DIAGNOSIS 1 but wants incidence of DIAGNOSIS 1 to be defined with respect to DIAGNOSIS 1 *and* DIAGNOSIS 2, the Incident Only Event Code fields would include DIAGNOSIS 2 codes. **Note 1:** codes are matched using exact values (*i.e.*, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (e.g., 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:** remove decimal points in the code value.

Parameter	Field Name	Description
		Note 3: CODETYPE must be consistent with the expected format of the CODE value (*e.g.*, MP6 will not find any valid matches in the data for CODETYPE=PX11 and a 4-digit diagnosis code value). **Note 4**: duplicate CODETYPE-CODE combinations in a given query GROUP are removed by the MP6 algorithm. **Defined by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11 **Example:** 3570
Incident Event Code Description	DESCR	**Details:** description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files. **Note 1:** this parameter is optional (i.e., the MP algorithm will not fail if this parameter is excluded from the Incident Event File) **Defined by:** Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Incident Event Principal Diagnosis Indicator	PRINCIPAL	**Details:** for a diagnosis CODETYPE (*e.g.,* DX09, DX10, DX11), 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. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $3. **Example:** YES
Incident Event Care Setting	CARESETTING	**Details:** the care settings considered for the diagnosis, procedure, or lab codes. 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 1:** CARESETTING is allowed to vary between CODEs within

Parameter	Field Name	Description
		the same GROUP. For example, CARESETTING is allowed to equal 'IP' for one diagnosis code and 'IP' 'ED' for another diagnosis code *in the same GROUP*. **Note 2:** care setting values in the MSCDM Laboratory table have different valid values than the Diagnosis and Procedure tables. Requesters may develop their own mapping of care settings for each request using the optional Lab Care Setting File; by default, values will be mapped as: I: Inpatient = **IP** O: Outpatient = **AV** E: Emergency Department = **ED** H: Home = **OA** U: Unknown = **OA** **Defined by:** Requester **Input type:** Optional **Format:** Alphanumeric; SAS character $20. **Example:** 'IP' 'ED'

3. Post-Event Treatment File

The Post-Event Treatment File is required. It contains the comprehensive set of codes used to define post-event treatment. Lab codes, NDCs, ICD diagnosis and procedure codes and/or HCPCS codes can be used to define treatment episodes of interest. Post-event treatment(s) can be defined using any mix of allowed code types.

The structure of the Post-Event Treatment File must reflect how codes should be queried to define a unique treatment episode. The GROUP structure of the Post-Event Treatment File must match that of the Event File; *i.e.*, for each GROUP defined in the Event File a matching GROUP must be found in the Post-Event Treatment File. Table 4 describes specifications for this file.

Table 4: Post-Event Treatment File Specification

Parameter	Field Name	Description
Name of Event Group	GROUP	**Details:** standardized name used to refer to an event GROUP for post-event treatment(s) of interest to be queried. **Note 1**: must match GROUP values from the Event File. **Note 2**: if multiple codes are needed to define a treatment episode, they must be grouped using the same GROUP value. **Named by:** Request programmer **Input type:** Required

Parameter	Field Name	Description
		Format: Alphanumeric; SAS character $30; no special characters (*e.g.*, commas, periods, hyphens, etc) allowed, and underscores must be used to mark spaces. **Example:** CVD
Name of Post-Event Treatment Group	POSTDIAGGROUP	**Details:** standardized name used to refer to individual post-event treatments. This parameter instructs the program on what Event/Post-Event relationships to output. **Note 1:** useful when interested in multiple post-event treatments. For example, if GROUP= "CVD", POSTDIAGGROUP could take values of "ACE_Inhibitors" or "Beta_Blockers" to differentiate types of treatment. **Note 2:** if specified, will determine how output is grouped (*e.g.*, if GROUP= "CVD", and POSTDIAGGROUP= "ACE_Inhibitors" for some codes and "Beta_Blockers" for other codes, output will be presented for CVD → ACE Inhibitors and CVD → Beta Blockers separately). **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:** ACE_Inhibitors
Name of Post-Event Treatment Subgroup	SUBGROUP	**Details:** standardized name used to refer to specific drugs, procedures, diagnoses, or labs. **Note 1:** useful when individual post-event treatments are comprised of multiple drugs/procedures. For example, if GROUP= "CVD" and POSTDIAGGROUP= "ACE_Inhibitors", SUBGROUP may take the values "enalapril" or "lisinopril" to differentiate drugs. **Note 2:** SUBGROUP field is used by the stockpiling algorithm as group categories to adjust claim service dates. See Section V.C for more details. **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:** enalapril
Post-Event Treatment Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this file.

Parameter	Field Name	Description
		Valid values are: • **RX11**: 11-digit NDC • **RX09**: 9-digit NDC • **PX09**: ICD-9-CM procedure • **PX10**: ICD-10-CM procedure • **PX11**: ICD-11-CM procedure • **PXC4**: CPT-4 procedure (*i.e.*, HCPCS Level I) • **PXHC**: HCPCS procedure (*i.e.*, HCPCS Level II) • **PXH3**: HCPCS Level III procedure • **PXC2**: CPT Category II procedure • **PXC3**: CPT Category III procedure • **DX09:** ICD-9-CM diagnoses • **DX10:** ICD-10-CM diagnoses • **DX11:** ICD-11-CM diagnoses • **LABS:** 8-digit lab code **Note 1:** the eight-digit lab code (LABS) was developed by MSOC for simpler querying of the Laboratory table; these are not LOINCs. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4 **Example:** PX09
Post-Event Treatment Codes	CODE	**Details:** code values to be used to define post-event treatment. **Note 1:** codes are matched using exact values (*i.e.*, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (e.g., 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 must be consistent with the expected format of the CODE value (*e.g.*, MP6 will not find any valid matches in the data for CODETYPE=RX11 and a 9-digit NDC value). **Note 5**: duplicate CODETYPE-CODE combinations in a given GROUP are removed by the MP6 algorithm.

Parameter	Field Name	Description
		Defined by: Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11 **Example:** 12345678922
Post-Event Treatment Code Description	DESCR	**Details:** description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files. **Note 1:** this parameter is optional (i.e., the MP algorithm will not fail if this parameter is excluded from the Post-Event Treatment File) **Defined by:** Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Post-Event Treatment Code Count De-Duplicate Indicator	CODECOUNT	**Details:** instructs the MP6 algorithm whether to de-duplicate multiple occurrences of the same NDC, procedure, diagnosis, or lab code on the same day. If CODECOUNT=1, the MP6 algorithm will only count one code per member per day; If CODECOUNT=0, the MP6 algorithm will include all occurrences of each code in output metrics. **Note 1:** useful when querying post-event labs, as the user will be able to observe the occurrence of multiple tests for the same lab on the same day. **Defined by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Numeric **Example:** 1
Post-Event Treatment Principal Diagnosis Indicator	PRINCIPAL	**Details:** for a diagnosis CODETYPE (*e.g.,* DX09, DX10, DX11), 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. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $3. **Example:** YES
Post-Event Treatment Care Setting	CARESETTING	**Details:** the care settings considered for the individual lab, procedure or diagnosis codes. If all care settings are wanted, leave the field blank. The following are valid entries; all entries

Parameter	Field Name	Description
		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 1:** CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal 'IP' 'ED' for another procedure code *in the same GROUP*. **Note 2:** care setting values in the MSCDM Laboratory table have different valid values than the Procedure tables. Requesters may develop their own mapping of care settings for each request using the optional Lab Care Setting File; by default, values will be mapped as: I: Inpatient = **IP** O: Outpatient = **AV** E: Emergency Department = **ED** H: Home = **OA** U: Unknown = **OA** **Defined by:** Requester **Input type:** Optional **Format:** Alphanumeric; SAS character $20. **Example:** 'IP' 'ED'
Post-Event Treatment Incidence Type	WASHTYP	**Details:** selects how post-event treatment incidence will be defined. As detailed in Section V.E, the post-event treatment incidence type can take the following values: • **MIN**: minimum incidence -- identifies and reports metrics only for the *first* valid incident post-event treatment episode during the query period, and uses ALL prior observed claims to determine incidence. That is, incidence is defined as the first post-event treatment episode during the query period with no evidence of prior treatment using *all* available data. • **MULT**: multiple incidence -- identifies and reports metrics for *all* valid incident treatment episodes during the query period and uses treatment episodes observed during the specified WASHPER days to determine incidence. That is, incidence is defined as any post-event treatment during the query period with

Parameter	Field Name	Description
		no evidence of treatment during the prior WASHPER days. **Note 1:** WASHTYP parameter is used in conjunction with the Post-Event Washout Period (WASHPER; see below) to define a valid incident post-event treatment episode. **Note 2:** the MP6 algorithm may use days before QUERYFROM to ensure incidence criteria are met. **Note 3**: MIN setting should be used with caution as interpretation is complex. A treatment episode that meets the MIN criteria must occur during the query period and cannot be preceded by a disqualifying treatment episode at any time during enrollment; that is, the look-back period to define incidence is not limited to the washout period. See Section V.E for details. **Defined by:** Requester, with support from the MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $4; case sensitive (upper case only). **Example:** MULT
Post-Event Treatment Washout Period	WASHPER	**Details:** length of post-event treatment washout period in days. The washout period is a period before the index date (*i.e.*, date of event/lookup period start) during which a member cannot have evidence of treatment(s) of interest or any other treatment(s) specified in the Incident Post-Event Treatment File. The washout period is also used to ensure that enrollment requirements are met. If a member has fewer than WASHPER days of enrollment before the index date, the event is excluded from the incident evaluation. **Note 1:** the post-event treatment washout period looks back from the index date (*i.e.*, the event date/lookup period start date), not the treatment episode start date. **Note 2:** the MP6 algorithm may use days before QUERYFROM to determine if continuous enrollment and incidence criteria are met. **Note 3:** when WASHTYP=MIN, WASHPER is only used to assess continuous enrollment eligibility. **Note 4**: length of post-event treatment washout period days

Parameter	Field Name	Description
		must be the same within a given GROUP. **Note 5**: required and used in conjunction with any post-event incidence types (WASHTYP; see above). **Defined by:** Requester **Input type:** Required (0 must be entered if no washout is required) **Format:** Numeric **Example:** 183
Post-Event Treatment Episode Gap	EPISODEGAP	**Details**: the treatment episode allowable gap in days. For a given claim, a gap of more than EPISODEGAP days between the claim date and the end of days of supply of the previous claim triggers a new treatment episode. **Defined by:** Requester **Input type:** Required (0 must be entered if no gap is required) **Format:** Numeric **Example:** 5
Post-Event Lab Frequency Categories	CATS	**Details**: frequency of post-event lab test output categories. Relevant only for requests examining post-event labs. Categories must be separated by a space; categories including more than one value must be listed as a range separated by a dash. The "+" symbol indicates if a category should capture frequencies greater than or equal to the listed value. For example, if a requester wants the frequency of lab test categories to be 0, 1, 2 to 3, and greater than or equal to 4, the input file should list: 0 1 2-3 4+. **Note 1:** if the post-event treatment of interest is not a lab, leave this parameter blank. **Defined by:** Requester **Input type:** Optional **Format:** SAS $10 **Example:** 0 1 2-3 4+

4. Incident Post-Event Treatment File

The Incident Post-Event Treatment File is optional. If defined, the file contains the comprehensive set of codes used to refine the incidence definition of the post-event treatment of interest. Just like the Post-Event Treatment File, treatment(s) of interest can be defined using any mix of the following allowed code types: lab codes, NDCs, ICD diagnosis and procedure codes and/or HCPCS codes.

The GROUP structure of the Incident Post-Event Treatment File must match that of the Post-Event Treatment File. That is, for each GROUP defined in the Incident Post-Event Treatment File a matching GROUP must be found in the Post-Event Treatment File.

By default, for a given GROUP MP6 uses the list of codes included in the Post-Event Treatment File to determine the incident status of identified treatment episodes (as of the index date). The Incident Post-Event Treatment File is used to refine incidence based on a set of codes different than those used to define the post-event treatment(s) of interest in the Post-Event Treatment File. For example, a requester may be interested in examining treatment with Drug A, but wants all incident users of Drug A to be free of Drug A, B and C in the 183 days before the Drug A index date. In this case, the list of codes for Drug A would be included in the Post-Event Treatment File, and the list of codes for Drugs B and C would be included in the Incident Post-Event Treatment File.

Table 5 describes specifications for this file.

Table 5: Incident Post-Event Treatment File Specification

Parameter	Field Name	Description
Name of Event Group	GROUP	**Details:** standardized name used to refer to a GROUP for event(s) of interest to be queried. **Note 1**: must match GROUP values from the Post-Event Treatment File. **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:** Insulin1
Name of Post-Event Treatment Group	POSTDIAGGROUP	**Details:** standardized name used to refer to individual post-event treatments. This parameter instructs the program on what Event/Post-Event Treatment relationships to output. **Note 1**: must match POSTDIAGGROUP values from the Post-Event Treatment File. **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:** ACE_Inhibitors
Name of Post-Event Treatment Subgroup	SUBGROUP	**Details:** standardized name used to refer to specific drugs, procedures, diagnoses or labs associated with post-event treatments. **Note 1:** useful when individual post-event treatments are comprised of multiple drugs/procedures. For example, if

Parameter	Field Name	Description
		GROUP= “CVD” and POSTDIAGGROUP= “ACE_Inhibitors”, SUBGROUP may take the values “enalapril” or “lisinopril” to differentiate drugs. **Note 2:** SUBGROUP field is used by the stockpiling algorithm as group categories to adjust claim service dates. See Section V.C for more details. **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:** enalapril
Incident Only Post-Event Treatment Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this file. Valid values are: • **RX11**: 11-digit NDC • **RX09**: 9-digit NDC • **PX09**: ICD-9-CM procedure • **PX10**: ICD-10-CM procedure • **PX11**: ICD-11-CM procedure • **PXC4**: CPT-4 procedure (*i.e.*, HCPCS Level I) • **PXHC**: HCPCS procedure (*i.e.*, HCPCS Level II) • **PXH3**: HCPCS Level III procedure • **PXC2**: CPT Category II procedure • **PXC3**: CPT Category III procedure • **DX09:** ICD-9-CM diagnoses • **DX10:** ICD-10-CM diagnoses • **DX11:** ICD-11-CM diagnoses • **LABS:** 8-digit lab code **Note 1:** the eight-digit lab code (LABS) was developed by MSOC for simpler querying of the Laboratory table; these are not LOINCs. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4 **Example:** PX09
Incident Only Post-Event Treatment Codes	CODE	**Details:** NDCs, lab codes, diagnosis and/or procedure codes used to refine the incident definition for the post-event treatment of interest. For example, if a requester is examining DRUG A and requests that incidence of DRUG A to be defined with respect to

Parameter	Field Name	Description
		DRUG A *and* DRUG B, the Incident Only Post-Event Treatment Code fields would include DRUG B codes. **Note 1:** codes are matched using exact values (*i.e.*, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (e.g., 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 must be consistent with the expected format of the CODE value (*e.g.*, MP6 will not find any valid matches in the data for CODETYPE=RX11 and a 9-digit NDC value). **Note 5**: duplicate CODETYPE-CODE combinations within the same GROUP are removed by the MP6 algorithm. **Defined by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11 **Example:** 12345678922
Incident Post-Event Treatment Code Description	DESCR	**Details:** description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files. **Note 1:** this parameter is optional (i.e., the MP algorithm will not fail if this parameter is excluded from the Incident Post-Event Treatment File) **Defined by:** Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Incident Post-Event Treatment Principal Diagnosis Indicator	PRINCIPAL	**Details:** for a diagnosis CODETYPE (*e.g.,* DX09, DX10, DX11), 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. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $3.

Parameter	Field Name	Description
		Example: YES
Incident Post-Event Treatment Care Setting	CARESETTING	**Details:** the care settings considered for the individual incident lab or procedure codes. 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 1:** CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal 'IP' for one procedure code and 'IP' 'ED' for another procedure code *in the same GROUP*. **Note 2:** care setting values in the MSCDM Laboratory table have different valid values than the Procedure table. Requesters may develop their own mapping of care settings for each request using the optional Lab Care Setting File; by default, values will be mapped as: I: Inpatient = **IP** O: Outpatient = **AV** E: Emergency Department = **ED** H: Home = **OA** U: Unknown = **OA** **Defined by:** Requester **Input type:** Optional **Format:** Alphanumeric; SAS character $20. **Example:** 'IP' 'ED'

5. Inclusion/Exclusion Conditions File

The Inclusion/Exclusion Conditions File is optional. It is used to 1) include in the cohort only those members having evidence of certain conditions; 2) exclude from the cohort those members having evidence of certain conditions; or 3) combine inclusion and exclusion criteria to define the cohort. If defined, this file contains the comprehensive set of codes used to define the inclusion and exclusion condition(s) of interest.

The MP6 Inclusion/Exclusion Conditions File allows inclusion of the following code types: NDCs, ICD diagnosis and procedure codes and/or HCPCS codes to define condition(s) of interest. Any condition(s) can be defined using a mix of these allowed code types. A different lookback period can be defined for each condition code specified. Values of the GROUP fields must match between the Event File and the Inclusion/Exclusion Conditions File.

Table 6 contains detailed specifications for this file.

Table 6: Inclusion/Exclusion Conditions File Specification

Parameter	Variable Name	Description
Name of Event Group	GROUP	**Details:** standardized name used to refer to a GROUP for event(s) of interest to be queried. **Note 1**: must match GROUP values from the Event File. **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:** CVD
Name of Condition SubGroup	SUBGROUP	**Details:** contains names of subgroups of condition codes in this file. This variable is not used by the MP algorithm but it is useful for tracking purposes. **Request Programmer Note 1:** while not used by the MP6 algorithm, this variable must be included in the CONDFILE. **Named by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $30; special characters (e.g., commas, periods, hyphens, etc) allowed and underscores must be used to mark spaces. **Example:** Hypertension
Condition Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this file. Valid values are: • **RX11:** 11-digit NDC • **RX09:** 9-digit NDC • **PX09**: ICD-9-CM procedure • **PX10**: ICD-10-CM procedure • **PX11**: ICD-11-CM procedure • **PXC4**: CPT-4 procedure (*i.e.*, HCPCS Level I) • **PXHC**: HCPCS procedure (*i.e.*, HCPCS Level II) • **PXH3**: HCPCS Level III procedure • **PXC2**: CPT Category II procedure • **PXC3**: CPT Category III procedure • **DX09**: ICD-9-CM diagnosis • **DX10**: ICD-10-CM diagnosis • **DX11**: ICD-11-CM diagnosis

Parameter	Variable Name	Description
		Defined by: Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4 **Example:** PXHC
Condition Codes	CODE	**Details:** drug, diagnosis or procedure code values to define condition(s) of interest. **Note 1:** codes are matched using exact values (*i.e.*, 3-digit code lookup requires an exact 3-digit code match). Wildcard match (*) functionality is also available (e.g., 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:** remove decimal points in the code value. **Note 3**: CODETYPE must be consistent with the expected format of the CODE value (*e.g.*, MP6 will not find any valid matches in the data for CODETYPE=PXC4 and a 3-digit CODE value). **Note 4**: duplicate CODETYPE - CODE combinations within GROUPs are removed by the MP6 algorithm. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $11 **Example:** J3490
Condition Code Description	DESCR	**Details:** description of the NDC, diagnosis, or procedure code listed in the CODE field. Used primarily by request programmers to include meaningful code definitions in input files. **Note 1:** this parameter is optional (i.e., the MP algorithm will not fail if this parameter is excluded from the Inclusion/Exclusion Conditions File) **Defined by:** Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Inclusion/Exclusion Indicator	INCLUSION	**Details:** indicates whether each condition CODE specified is for an inclusion (=1) or exclusion (=0) criterion. **Named by:** Requester **Input type:** Required **Format:** Numeric **Example:** 1

Parameter	Variable Name	Description
Lookback Period Start	CONDFROM	**Details:** defines the start of the lookback period for each condition code specified, expressed in terms of "days from Index Date". This parameter is used in conjunction with CONDTO to define the lookback period length. For example, if Index Date=01/08/2009 and CONDFROM for a given condition code is set to -7, the MP algorithm will start looking for that condition code on 01/01/2009. **Note 1**: individual condition codes within a same GROUP are allowed to have different lookback periods and therefore have different CONDFROM and CONDTO values. **Note 2**: the index date is "day zero". Therefore, if zero is included in the CONDFROM-CONDTO interval for a given condition code, the index date is included in the lookback period. **Note 3**: if CONDFROM > 0 then the lookback period will start after the index date. **Named by:** Requester **Input type:** Required **Format:** Numeric **Example:** -180
Lookback Period End	CONDTO	**Details:** defines the end of the lookback period for each condition code specified, expressed in terms of "days from Index Date". This parameter is used in conjunction with CONDFROM to define the lookback period length. For example, if Index Date=01/08/2009 and CONDTO for a given condition code is set to -1, the MP algorithm will look for that condition code between the CONDFROM date through 01/07/2009. **Note 1**: individual condition codes within the same Query GROUP are allowed to have different lookback periods and therefore have different CONDFROM and CONDTO values. **Note 2**: the index date is "day zero". Therefore if zero is included in the CONDFROM-CONDTO interval for a given code the index date is included in the lookback period. **Named by:** Requester **Input type:** Required **Format:** Numeric **Example:** -1
Condition Care Setting	CARESETTING	**Details:** contains the care settings considered for the individual condition diagnosis or procedure codes. 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:

Parameter	Variable Name	Description
		• **IP:** inpatient hospital stays • **IS:** non-acute institutional stays • **ED:** emergency department visits • **AV:** ambulatory visits • **OA:** other ambulatory visits **Note 1:** CARESETTING is allowed to vary between CODEs within the same GROUP. For example, CARESETTING is allowed to equal 'IP' for one diagnosis code and 'IP' 'ED' for another diagnosis code *in the same GROUP*. **Defined by:** Requester **Input type:** Optional **Format:** Alphanumeric; SAS character $20. **Example:** 'IP' 'ED'
Condition Principal Diagnosis Indicator	PRINCIPAL	**Details:** for a diagnosis CODETYPE (*e.g.*, DX09, DX10, DX11), 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. For codes other than diagnosis codes, PRINCIPAL must be set equal to NO. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $3. **Example:** YES

6. Lab Care Setting File

The Lab Care Setting File is required if the MSCDM Laboratory table is queried by the Event, Incident Event, Post-event Treatment, or Incident Post-event Treatment files (*i.e.*, CODETYPE=LABS in any of these files). The file is used to map care setting values from the variable PT_LOC in the MSCDM Laboratory table to the variable ENCTYPE in the MSCDM Procedure and Diagnosis tables. This allows for a single care setting parameter (CARESETTING) in each input file that processes both lab and utilization data.

Using the default values, if a requester specifies that event(s) of interest in the Event File must occur in the inpatient setting (CARESETTING='IP'), the MP6 algorithm will search for events defined via diagnosis and procedure codes where ENCTYPE= 'IP' in the MSCDM Diagnosis and Procedure tables and search for events defined via lab codes where PT_LOC= 'I' in the MSCDM Laboratory table.

There are two parameters that must be specified in the file; both must be specified by the requester. Table 7 contains detailed specifications for this file.

Table 7: Lab Care Setting File Specification

Parameter	Variable Name	Description

Parameter	Variable Name	Description
Laboratory Table Care Setting	PT_LOC	**Details:** value of the care setting parameter in the MSCDM Laboratory table. Valid values include: • **I:** Inpatient • **O:** Outpatient • **E:** Emergency Department • **H:** Home • **U:** Unknown or Missing **Defined by:** Requester **Input type:** Required **Format:** SAS character $1. **Example:** I
Procedure/Diagnosis Table Care Setting	ENCTYPE	**Details:** value of the care setting parameter in the MSCDM Diagnosis and Procedure tables. Valid values include: • **IP:** inpatient hospital stays • **IS:** non-acute institutional stays • **ED:** emergency department visits • **AV:** ambulatory visits • **OA:** other ambulatory visits **Defined by:** Requester **Input type:** Required **Format:** SAS character $2. **Example:** IP

7. Lab Code File

The Lab Code File is a master lookup file of valid lab codes developed and maintained by MSOC and the Clinical Data Workgroup. As the workgroup continues to improve and enhance the Laboratory table specifications and allowable values, this master lookup file can be modified to ensure that MP6 always queries the MSCDM Laboratory table based on the current specifications.

The Lab Code File is required if the MSCDM Laboratory table is queried by the Event, Incident Event, Post-event Treatment, or Incident Post-event Treatment files (*i.e.*, CODETYPE=LABS in any of these files). This file includes a comprehensive list of all "lab codes" denoting allowable combinations of lab test name, lab test subcategory and specimen source. Lab codes are 8-digit identifiers developed by MSOC and the Clinical Data Workgroup to represent a unique laboratory test. The first digit is an "L" indicative of a lab code, digits 2-4 indicate a unique lab test name, digits 5-6 indicate a unique lab test subcategory, and digits 7-8 indicate a unique specimen source. The use of a lab code, rather than a combination of multiple variables, allows for a single code parameter (CODE) in each input file that processes both lab

and utilization data.

Requesters do not need to provide input parameters for this file. The file will be continually maintained by MSOC and the Clinical Data Workgroup to ensure that the file conforms to the most current version of the MSCDM Laboratory table specifications. Table 8 contains detailed specifications for this file.

Table 8: Lab Code File Specification

Parameter	Variable Name	Description
Lab Test Name	MS_TEST_NAME	**Details:** value of the lab test name parameter in the MSCDM Laboratory table. Valid values include: • **ALP:** alkaline phosphatase • **ALT:** alanine aminotransferase • **ANC:** absolute neutrophil count • **BILI_TOT:** total bilirubin • **CK:** creatine kinase • **CK_MB:** creatine kinase MB • **CK_MBI:** creatine kinase MB/creatine kinase total • **CREATININE:** creatinine • **D_DIMER_QL:** d_dimer (qualitative) • **D_DIMER_QN:** d_dimer (quantitative) • **GLUCOSE:** glucose • **HGB:** hemoglobin • **HGBA1C:** glycosylated hemoglobin • **INF_A:** influenza virus A • **INF_AB:** influenza virus A + B • **INF_B:** influenza virus B • **INF_NS:** influenza virus not specified • **INR:** international normalized ratio • **LIPASE:** lipase • **PG_QL:** Pregnancy test (qualitative) • **PG_QN:** Pregnancy test (quantitative) • **PLATELETS:** platelet count in blood • **TROP_I:** Troponin I Cardiac • **TROP_T_QL:** Troponin T Cardiac (qualitative) • **TROP_T_QN:** Troponin T Cardiac (quantitative) **Defined by:** MSOC **Input type:** Required **Format:** SAS character $10. **Example:** ALP
Lab Test Subcategory	MS_TEST_SUB_CATEGORY	**Details:** value of the lab test subcategory parameter in the MSCDM Laboratory table.

Parameter	Variable Name	Description
		Valid values include: • **BHCG:** Beta Human Choriogonadotropin • **DDU:** d-dimer units • **EIA:** immunoassay • **FEU:** fibrinogen equivalent units • **FST:** fasting • **HCG:** Human Choriogonadotropin • **IF:** immunofluorescence • **NS:** not specified • **PCR:** probe and target amplication • **RAN:** random • **VTC:** organism-specific culture **Defined by:** MSOC **Input type:** Required **Format:** SAS character $6. **Example:** NS
Lab Specimen Source	SPECIMEN_SOURCE	**Details:** value of the lab specimen source parameter in the MSCDM Laboratory table. Valid values include: • **BAL:** bronchoalveolar lavage • **BALBX:** bronchoalveolar biopsy • **BLOOD:** blood • **CSF:** cerebral spinal fluid • **NPH:** nasopharynx swab • **NPWASH:** nasopharyngeal wash • **NS:** not specified • **NSWAB:** nasal swab or nose specimen • **NWASH:** nasal wash • **OTHER:** other • **PLASMA:** plasma • **PPP:** platelet poor plasma • **SERUM:** serum • **SPUTUM:** sputum • **SR_PLS**: serum/plasma • **THRT:** throat swab, oropharyngeal swab • **UNK:** unknown or missing • **URINE:** urine **Defined by:** MSOC **Input type:** Optional **Format:** SAS character $6.

Parameter	Variable Name	Description
		Example: BAL
Lab Code Type	CODETYPE	**Details:** code type indicative of labs in the Event, Incident Event, Post-event Treatment, and Incident Post-event Treatment files. Valid value: • LABS **Defined by:** MSOC **Input type:** Required **Format:** SAS character $4. **Example:** LABS
Lab Code	CODE	**Details:** code indicative of the MS_Test_Name, MS_Test_Sub_Category, and Specimen_Source combination. **Defined by:** MSOC **Input type:** Required **Format:** SAS character $11. **Example:** LABS

8. Output Table Selection File

The Output Table Selection File 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 required 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 MP6.
Table 9 contains detailed specifications for the Output Table Selection File, and a template is provided in Section X.

Table 9: Output Table Selection File Specification

Parameter	Variable Name	Description
Name of Table in MP Documentation	DOCTABNAME	**Details:** contains the name of the table as specified in the MP documentation. **Note 1:** this is not the actual name used inside the program but to the name as listed in the documentation. **Named by:** Request programmer **Input type:** Optional, for reference only, dropped at the start of the

Parameter	Variable Name	Description
		MP execution. **Format:** Alphanumeric; SAS character $30. **Example:** Table1
Description of Table in MP Documentation	DOCTABDESCR	**Details**: contains the description of the table as specified in the table titles of the modular program 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, Total Dispensings and Days of Supply
Name of Table Generated by MP	TABNAME	**Details**: contains the name of the table generated by the modular 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 Indicator	TABREQUIRED	**Details:** indicates whether TABNAME must be preserved. Valid values are: • **Y:** preserve table in output • **N:** remove table from output **Named by:** Request programmer **Input type**: Required **Format**: Alphanumeric; SAS character $1. **Example**: Y

9. Dispensing Processing File

The Dispensing Processing File is optional. It is used to instruct the MP algorithm on how valid dispensings are selected and used by the stockpiling algorithm to create post-event treatment episodes. Requesters can require restrictions on days supplied and amount supplied values for dispensings that are considered by the modular program, and determine how the program adjusts dispensing dates based on the amount of overlap between adjacent dispensings.

There are five required parameters that must be specified.

Table 10: Dispensing Processing File Specification

Parameter	Variable Name	Description
Name of Event Group	GROUP	**Details:** standardized name used to refer to an event GROUP for events of interest to be queried.

Parameter	Variable Name	Description
		Note 1: must match GROUP values from the Event File. **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:** CVD
Same Day Dispensing Processing Indicator	SAMEDAY	**Details**: defines how same day dispensings are processed. The first position indicates how days supplied (RxSup in the MSCDM) is handled; the second position indicates how amount supplied (RxAmt in the MSCDM) is handled. Valid values (for each position are): **a:** adds all (amount supplied or days supplied) values for dispensings in the same GROUP/SUBGROUP on the same day **n:** uses minimum (amount supplied or days supplied) value for dispensings in the same GROUP/SUBGROUP on the same day **x:** uses maximum (amount supplied or days supplied) value for dispensings in the same GROUP/SUBGROUP on the same day **m:** uses mean (amount supplied or days supplied) value for dispensings in the same GROUP/SUBGROUP on the same day **Note 1**: a total of 16 combinations are possible (e.g., aa, an, etc.). **Note 2**: default value is “aa”. **Defined by:** Requester **Input type:** Required **Format:** SAS character $2 **Example:** SAMEDAY = aa
Range of Allowable Days Supplied Values	SUPRANGE	**Details:** specifies the allowable range of days supplied values (variable RxSup in the MSCDM) that are allowed for a dispensing to be used to create valid treatment episodes. Valid values are: **x<-HIGH:** value must be > x **y-HIGH**: value must be >= y **LOW-<x**: value must be < x **x-y**: value must be between x and y inclusively **x<-y**: value must be greater than x and less or equal than y **x-<y**: value must be greater or equal than x and less than y **x<-<y**: value must be between x and y but not equal **Note 1**: allowable values can also be discrete, e.g., “10”, “20”.

Parameter	Variable Name	Description
		Note 2: failing to be in the specified range excludes a dispensing from consideration. **Note 3:** default is "0<-HIGH", indicating that the program will not consider days supplied values of 0 or less. **Defined by**: Requester **Input type**: Required **Format**: SAS character $40 **Examples**: SUPRANGE=5-<80; SUPRANGE = 0<-HIGH
Range of Allowable Amount Supplied Values	AMTRANGE	**Details:** specifies the allowable range of amount supplied values (variable RxAmt in the MSCDM) that are allowed for a dispensing to be used to create valid treatment episodes. Valid values are: **x<-HIGH:** value must be > x **y-HIGH**: value must be >= y **LOW-<x**: value must be < x **x-y**: value must be between x and y inclusively **x<-y**: value must be greater than x and less or equal than y **x-<y**: value must be greater or equal than x and less than y **x<-<y**: value must be between x and y but not equal **Note 1**: allowable values can also be discrete, e.g., "10", "20". **Note 2**: failing to be in the specified range excludes a dispensing from consideration. **Note 3:** default is "0<-HIGH", indicating that the program will not consider amount supplied values of 0 or less. **Defined by**: Requester **Input type**: Required **Format**: SAS character $40 **Examples**: SUPRANGE=5-<80; SUPRANGE = 0<-HIGH
Overlap Percentage Processing	PERCENTDAYS	**Details:** the maximum percentage overlap of previous dispensing's days supply allowed for pushing dispensing dates forward. When this percentage is exceeded, the previous dispensing's days supply is truncated at the day prior to the next dispensing date. If this parameter is left blank, no truncation will occur and any overlap of supply between dispensing will be corrected by pushing overlapping days supplied forward. **Note 1**: default is 0.

Parameter	Variable Name	Description
		Defined by: Requester Input type: Optional Format: Numeric Example: PERCENTDAYS = 0.25

V. KEY DEFINITIONS

A. ENROLLMENT REQUIREMENTS

For either prevalent or incident scenarios, all claims used by the MP algorithm to select members of interest and identify event(s) 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.

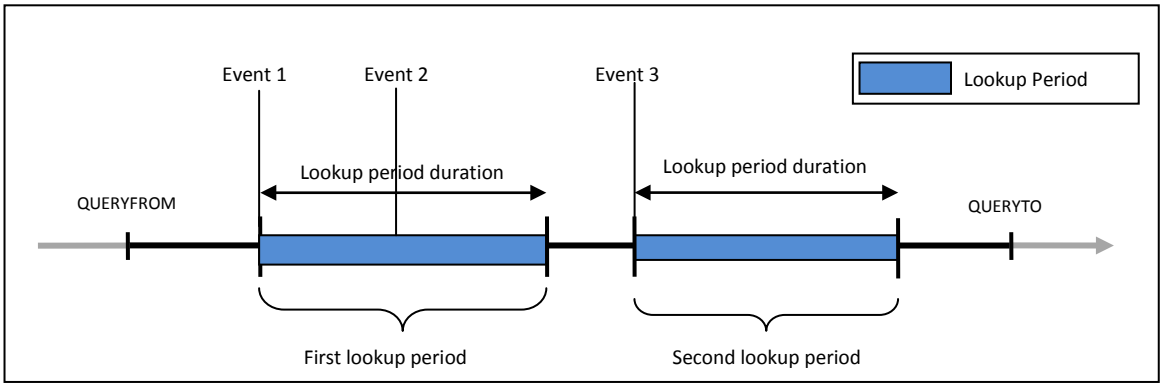
Continuous enrollment periods are then constructed by bridging all enrollment records of the correct coverage type. That is, using the main ENROLGAP parameter, two (or more) consecutive enrollment periods separated by (no more) than ENROLGAP days are bridged together to form a longer, continuous enrollment 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 creation of event lookup periods and other inclusion/exclusion criteria.

Since each event lookup period can only be considered incident with at least WASHPER days free of any of the event(s) of interest (or any other event(s) specified in the Incident Event File), the MP algorithm by default ensures that at least WASHPER days of continuous enrollment with the relevant coverage type are found before the index date **no matter how many minimum pre-index enrollment days are requested** (as specified by the ENRDAYS parameter of the Event File). Therefore the minimum pre-index enrollment days requirement can only be binding if it requires more days than those already requested by the required WASHPER parameter (i.e., if ENRDAYS > WASHPER). For example, if the required WASHPER is set to 183 days, a minimum number of pre-index enrollment days of ENRDAYS=183 (or less) does not impact what records are used to select the desired cohort of members.

B. EVENT LOOKUP PERIODS

The event lookup period is defined as a fixed window of time following an event where the program searches for evidence of treatment. Figure 1 illustrates the event lookup period concept.

Figure 1: Illustration of Event Lookup Period



In Figure 1, a member has three claims for an event of interest during the query period (period delimited by the QUERYFROM to QUERYTO dates). The lookup period has been set at 365 days by the requester. Event 1 and Event 3 will both initiate a lookup period; however, since Event 2 occurs during the lookup period initiated by Event 1, it does not trigger a new lookup period.

If a member is not enrolled for the entire duration of the lookup period, the lookup period will be truncated to reflect the end of enrollment. If the member is enrolled and the lookup period goes beyond the QUERYTO date, the lookup period will not be truncated. For example, consider a request for the query period 1/1/2005-12/31/2007. If a lookup period duration is set to 30 days, and a lookup period begins on 12/22/2007, the full duration of the lookup period (*i.e.*, 12/22/2007 – 1/20/2008) will be scanned for post-event treatment codes of interest and included in output metrics.
It is possible in MP6 to set a minimum lookup period duration. Using the Minimum Lookup Period Duration (MINFOLLOWPER) parameter in the Event File, a requester can set the minimum number of days required for a lookup period. For example, if MINFOLLOWPER was set to 5 days, and a member had 3 days of continuous enrollment during the lookup period, this period would not be included in the output metrics generated by MP6.

C. POST-EVENT TREATMENT EPISODES

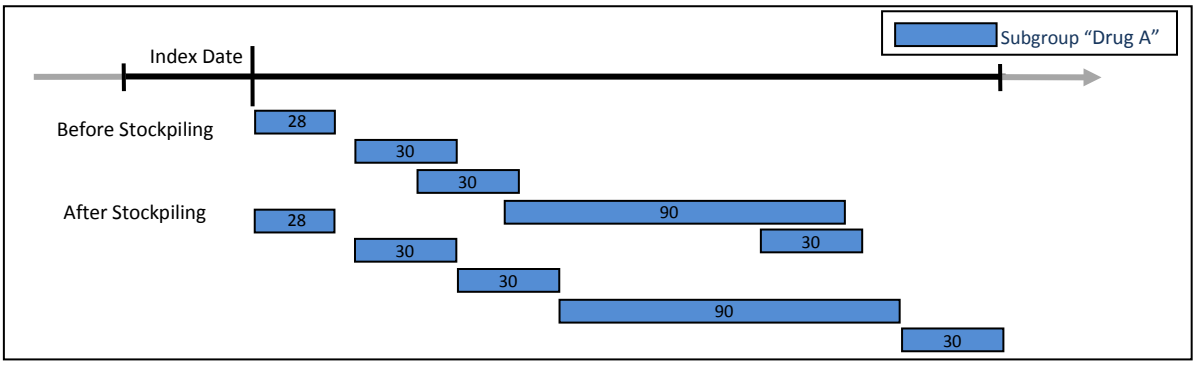
Post-event treatment episodes are created to determine post-event treatment duration and intensity in MP6. A post-event treatment episode can be defined using procedure codes, diagnosis codes, lab codes and/or NDCs. Regardless of the codes used, an episode is defined as an uninterrupted sequence of treatment with claims of the same post-event treatment group; a treatment episode ends when this sequence is interrupted by a gap in days supply that is greater than the allowable gap (Section V.C). For claims of drug code types (*i.e.*, RX09 and RX11) the days supply are from MSCDM Dispensing table. For procedure or lab code types the MP6 algorithm assigns a default value of one day of supply.

1. Stockpiling Algorithm

Because members may refill their drug prescriptions before the end of days supply of the current prescription, a stockpiling algorithm is used to correctly account for claims with overlapping supply of the same GROUP/SUBGROUP combination. Since this early-refill pattern can artificially reduce the length of the treatment episode, the dispensing date of the subsequent overlapping dispensing is adjusted. For example, all codes contained in SUBGROUP “DRUG A” in GROUP “Event 1”will be input

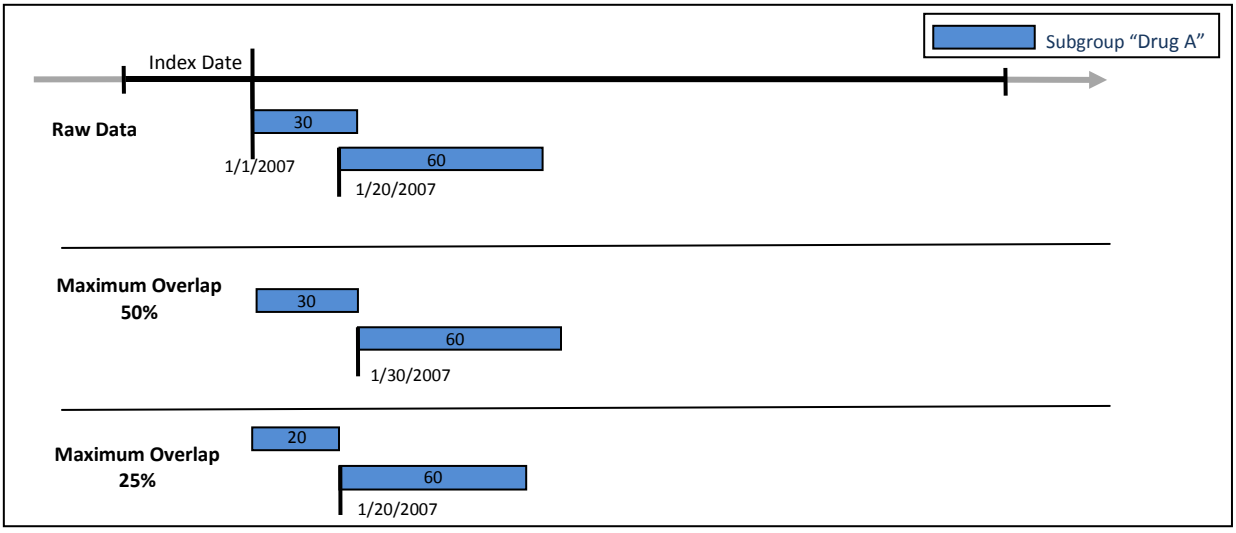
together in the stockpiling algorithm to adjust claim service dates. Claims in subgroup "DRUG B" in event group "Event 1" will be adjusted separately from the DRUG A claims. Once service dates have been adjusted at the SUBGROUP level, treatment episodes are created at the GROUP level using all "Event 1" claims with adjusted dates. Figure 2 illustrates the stockpiling algorithm and how the service dates of various claims of the same GROUP/SUBGROUP combination are adjusted. Note that this stockpiling process occurs before the identification of continuous treatment episodes.

Figure 2: Stockpiling Algorithm of MP6



Requesters can specify which dispensings are considered by the MP and how dispensings are stockpiled. The Dispensing Processing File allows requesters to specify a range of allowable days supplied (RxSup in the MSCDM) and amount supplied (RxAmt in the MSCDM) that are considered by the stockpiling algorithm. For example, a requester could instruct the MP to only include dispensings with a days supplied < 90. Only dispensings with a days supplied <90 will then be considered by the program and used by the stockpiling algorithm. Additionally, a requester can specify conditions under which dispensing dates are adjusted using the PERCENTDAYS parameter. The PERCENTDAYS parameter sets a maximum percentage of overlap between two dispensings to adjust dispensing dates. For example, consider the dispensing pattern in Figure 3, where the first and second dispensings overlap by 10 days.

Figure 3: Use of Maximum Percentage Overlap in Stockpiling Algorithm

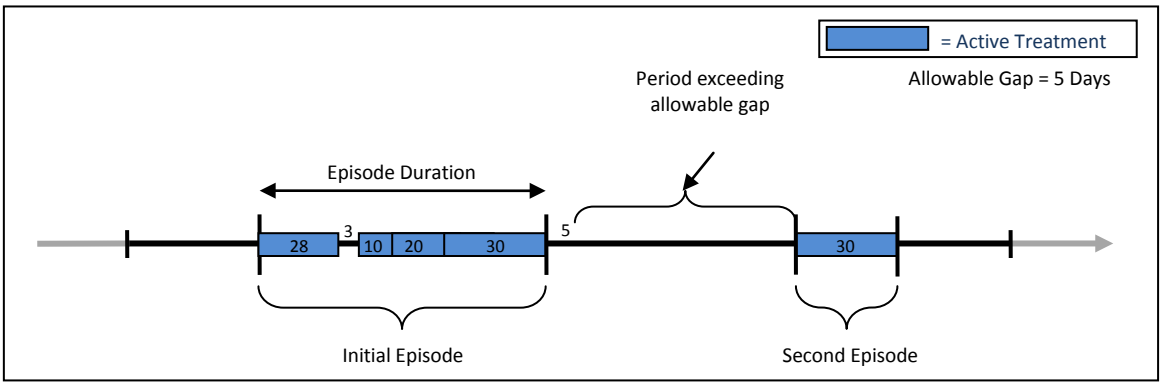


If a requester specifies a maximum overlap of 50%, the stockpiling algorithm will only augment dispensing dates if the number of days of overlap between the two dispensing is less than (30 days * .5) = 15 days. Since the dispensings overlap by 10 days (<15 days) the start date of the second dispensing is adjusted to 1/30/2007 (30 days after the first dispensing date). However, if a requester specifies a maximum overlap of 25%, the stockpiling algorithm will only augment dispensing dates if the number of days of overlap between the two dispensing is less than (30 days * .25) = 7 days (value is rounded down). Since the dispensings overlap by 10 days (> 7 days) the start date of the second dispensing is not adjusted and the first dispensing's days supply is truncated at 20 days.

2. Allowable Gap and Length of Treatment Episodes

The allowable gap (defined by the EPISODEGAP parameter in the Post-Event Treatment File) is the maximum number of interrupted days supply that can be found between two claims of the same GROUP to be considered part of the same treatment episode. If there is a gap of treatment between two claims of the same post-event treatment group smaller than or equal to the allowable gap, the MP6 algorithm "bridges" these two claims to build a continuous treatment episode. If, however, the allowable gap is exceeded between the same two claims, the treatment episode ends at the first claim's end of supply and a new treatment episode starts at the beginning of the second claim. Figure 4 summarizes the treatment episode and allowable gap concepts.

Figure 4: Illustration of Treatment Episode and Allowable Gap of MP6



In Figure 4, an allowable gap of treatment of five days is used. The "active treatment" (in blue) corresponds to the days supply for claims of a given post-event treatment GROUP. Four claims make up the first treatment episode since there is only a 3-day interruption in treatment between the first and second dispensing; that gap is "bridged" by the MP6 algorithm to create a single episode.

Episode Start and End Dates

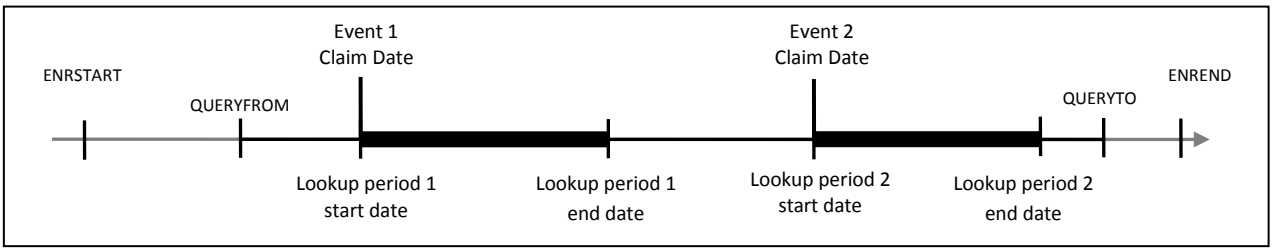
The treatment episode start date is the service date on the first claim of the episode. The treatment episode end date corresponds to the earliest of:

1. The date of the last day of supply preceding a treatment gap that is greater or equal to the "allowable gap" (as in Figure 4);
2. An interruption in the member's enrollment; or
3. The MSDD end date.

D. PREVALENCE-BASED COHORT

The prevalence-based cohort is composed of all members who have at least one event of interest (as defined in the Event File) during the query period, delimited by the QUERYFROM to QUERYTO dates as illustrated in Figure 5. The claim date for each event of interest considered must fall during continuous enrollment of relevant coverage type. Event claim dates are used to create prevalent lookup periods. Figure 5 illustrates a member with two prevalent lookup periods.

Figure 5: Prevalent Lookup Periods



E. INCIDENCE-BASED COHORT

For the incidence-based cohort, only incident events are considered valid. Valid events are those for which, as of the index date, meet the incident event and post-event treatment criteria.

1. Incident with Respect to Lookup Period Defining Event

Incident events can be defined in three different ways by the requester, using the minimum, single, or multiple incidence type options.

a) Minimum Incidence (MIN) for Event

Under the minimum incidence option, members can have only one incident event/lookup period during the query period and the claim used to define the index date must be the first one observed for that member in all enrollment periods with the appropriate coverage type. Minimum incidence is thus defined as evidence of one claim for the event of interest during the query period that satisfies the two conditions below. 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 (if specified by the Minimum Pre-Index Enrollment Days parameter in the Event File) and WASHPER days (specified by the Washout Period parameter) before the event index date.
2. Member has no evidence of another claim with an event code or Incident Event File code during any enrollment period before the index date. That is, the MP algorithm queries the set of data available before the index claim date (regardless of the specified query period) to ensure that no claim with an event code or Incident Event File code is observed during enrollment periods of relevant type.

b) Single Incidence (SING) for Event

Under the single incidence option, members can have only one incident event/lookup period during the query period, and the claim used to define the lookup period must meet the following incidence conditions:

1. Member is continuously enrolled at least ENRDAYS (if specified by the Minimum Pre-Index Enrollment Days parameter in the Event File) and WASHPER days (specified by the Washout Period parameter) before the index date.
2. Member has no evidence of an event during the WASHPER days (specified by the Washout Period parameter in the Event File) before the index date.
3. Claim is the first claim meeting conditions 1 and 2 during the query period. Under this condition, a member can only have one event/lookup period during the query period.

c) Multiple Incidence (MULT) for Event

Under the multiple incidence option the MP algorithm identifies and reports metrics for all events/lookup periods meeting the following two conditions:

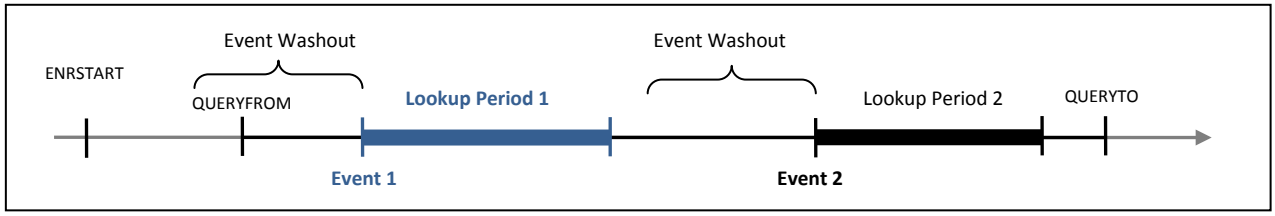
1. Member is continuously enrolled at least ENRDAYS (if specified by the Minimum Pre-Index Enrollment Days parameter in the Event File) and WASHPER days (specified by the Washout Period parameter) before the index date.
2. Member has no evidence of an event during the WASHPER days (specified by the Washout Period parameter in the Event File) before the index date.

d) Examples

The following examples illustrate the implications of event incidence type options. While the MP6 algorithm can evaluate multiple enrollment periods per member, for simplicity, each scenario depicted here includes members with only one enrollment period. The following examples also assume that the MP6 algorithm has already restricted the cohort to members with and/or without a condition of interest (as specified in the Inclusion/Exclusion Conditions File) and that no additional codes have been included in the Incident Event File to refine incidence criteria.

Figure 6 illustrates how the MP6 algorithm identifies incidence events and lookup periods using the minimum incidence option.

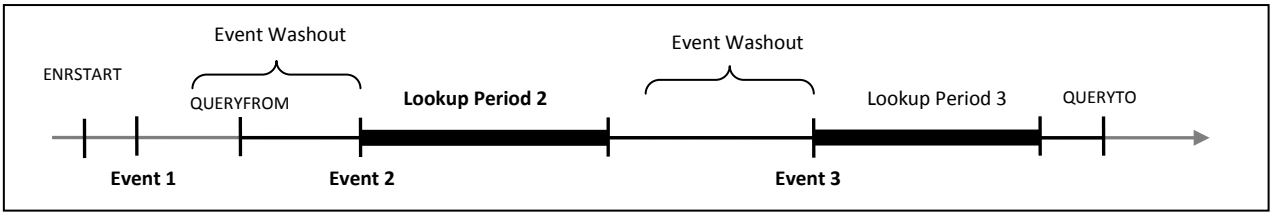
Figure 6: Incident Event and Lookup Period Identification Using the Minimum Incidence Option



In Figure 6, ENRSTART indicates the member's start of enrollment in pharmacy and medical benefits. Event 1 would be selected as the incident event in this scenario, as the member satisfies enrollment criteria and has no event before Event 1. Event 2 also satisfies the enrollment conditions, but the prior event excludes this period from being considered incident under the minimum incidence option. In this

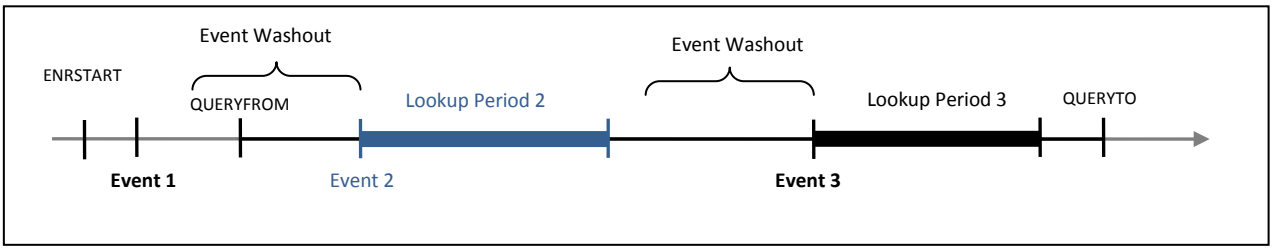
example, Event 1 and therefore Lookup Period 1 will be included in the incident analysis. Figure 7 depicts a scenario where a member does not have an incident event under the minimum incidence option.

Figure 7: No Incident Event and Lookup Period Using the Minimum Incidence Option



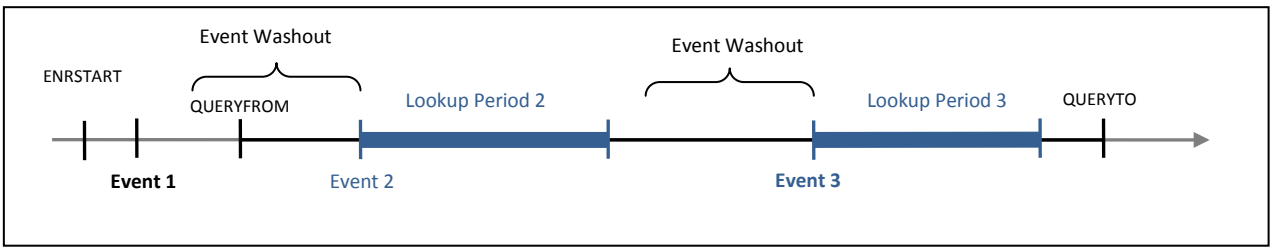
In this scenario Event 1 is not considered incident since it did not occur within the query period. While Events 2 and 3 satisfy enrollment criteria, the presence of Event 1 before the query period, but during the member's history, excludes these as incident events under the minimum incidence option. In this example, no event and therefore no lookup period will be included in the incident analysis. Figure 8 illustrates how MP6 identifies incidence events and lookup periods using the single incidence option.

Figure 8: Incident Event Lookup Period Identification Using the Single Incidence Option



In the scenario depicted in Figure 8, Event 2 would be selected as the incident event, as the member satisfies enrollment criteria and has no event claim in the WASHPER days before the Event 2 claim date. The presence of Event 1 in this scenario is irrelevant, as it does not occur during the query period or the WASHPER days before the Event 2 claim date. While Event 3 also satisfies enrollment criteria, the prior Event 2 excludes this event from being considered incident under the single incidence option. In this example, Event 2 and therefore Lookup Period 2 will be included in the incident analysis.

Figure 9: Incident Event and Lookup Period Identification Using the Multiple Incidence Option



In Figure 9, Events 2 and 3 will be considered incident using the multiple incidence option since a washout period free of any event or Incident Event File claim is observed and both satisfy enrollment criteria. Subsequently, Lookup Periods 2 and 3 will be included in the incident analysis.

2. Incident with Respect to Treatment Episode

To be considered incident, an event must also be incident with respect to treatment episodes as defined by the Post-Event Treatment File. Incident treatment episodes can be defined in two different ways by the requester, using either the minimum or multiple incidence type options.

a) Minimum Incidence (MIN) for Treatment Episode

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

1. Member is continuously enrolled in both pharmacy and medical benefits at least WASHPER days (specified by the Washout Period parameter in the Post-Event Treatment File) before the index date (*i.e.*, event date/lookup period start date).
2. Member has no evidence of treatment(s) of interest during any considered enrollment period before the index date (*i.e.*, event date/lookup period start date). That is, the MP6 algorithm queries the set of data available before the index date (regardless of the specified query period) to ensure that no treatment(s) of interest are observed during enrollment periods with drug and medical coverage. "Treatment(s)" includes those defined in both the Post-Event Treatment File and the Incident Post-Event Treatment File.

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).

b) Multiple Incidence (MULT) for Treatment Episode

Under the multiple incidence option a member can have multiple incident treatment episodes as long as each episode meets the following incidence conditions:

1. Member is continuously enrolled in pharmacy and medical benefits at least WASHPER days (specified by the Washout Period parameter in the Post-Event Treatment File) before the index date (*i.e.*, event date/lookup period start date).
2. Member has no evidence of treatment(s) of interest during the WASHPER days before the index date (*i.e.*, event date/lookup period start date). This includes treatments defined in both the Post-Event Treatment File and the Incident Post-Event Treatment File.

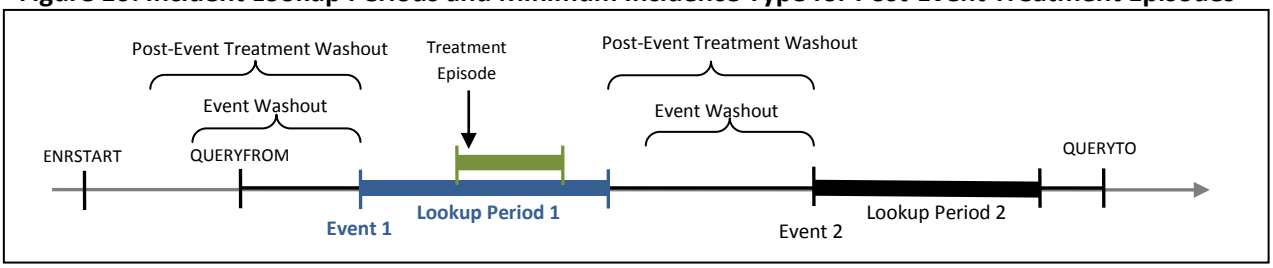
c) Examples

The following examples illustrate the implications of post-event treatment episode incidence type options. While the MP6 algorithm can evaluate multiple enrollment periods per member, for simplicity, each scenario depicted here includes members with only one enrollment period. The following examples also assume that the MP6 algorithm has already restricted the cohort to members with and/or without a condition of interest (as specified in the Inclusion/Exclusion Conditions File) and that no

additional codes have been included in the Incident Post-Event Treatment File to refine the incidence definition.

Assuming the multiple incidence type was chosen for the *event*, Figure 10 illustrates the implications of using the minimum incidence type for the *treatment episode*.

Figure 10: Incident Lookup Periods and Minimum Incidence Type for Post-Event Treatment Episodes



In Figure 10, the member satisfies the enrollment condition before the Event 1 and Event 2 claim date. However, only Event 1 will be considered incident as no other treatment episode is present before Event 1. This is not the case for Event 2, since a treatment episode has occurred during the Event 1 Lookup Period. While both Event 1 and Event 2 are considered incident based on the specified multiple incidence type for the event, selecting the minimum incidence type for the post-event treatment episodes leads the MP6 algorithm to retain only Event 1 (and Lookup Period 1).

If the multiple incidence option was selected for the post-event treatment episodes, both Event 1 and 2 would be incident and Lookup Periods 1 and 2 would be included in analyses.

d) Summary

Table 11 illustrates the implications of selecting combinations of incidence type options for the event and post-event treatment on the potential number of lookup periods and treatment episodes per member.

Table 11: Implications of Event and Post-Event Treatment Incidence Type Selection*

	Post-Event Treatment File **Minimum Incidence**	**Post-Event Treatment File** **Multiple Incidence**
Event File **Minimum Incidence**	At most, one incident event/lookup period.	At most, one incident event/lookup period.
	Incident event (used to define the lookup period) must be the first observed during member's history.	Incident event (used to define the lookup period) must be the first observed during member's history.
	Multiple treatment episodes may be initiated during the lookup period, but only if the first treatment episode is the first observed during the member's history.	Multiple treatment episodes may be initiated during the lookup period, but only if there are WASHPER days of continuous enrollment without the treatment of interest prior to the event date (*i.e.*, index date).
Event File **Single Incidence**	At most, one incident event/lookup period.	At most, one incident event/lookup period.
	Incident event (used to define the lookup period) must have WASHPER days of continuous enrollment prior to the event date (*i.e.*, index date).	Incident event (used to define the lookup period) must have WASHPER days of continuous enrollment prior to the event date (*i.e.*, index date).

	Post-Event Treatment File **Minimum Incidence**	Post-Event Treatment File **Multiple Incidence**
	Multiple treatment episodes may be initiated during the lookup period, but only if the first treatment episode is the first observed during the member's history.	Multiple treatment episodes may be initiated during the lookup period, but only if there are WASHPER days of continuous enrollment without the treatment of interest prior to the event date (*i.e.*, index date).
Event File **Multiple Incidence**	Multiple incident events/lookup periods possible. Incident events (used to define the lookup periods) must have WASHPER days of continuous enrollment prior to the event date(s) (*i.e.*, index date(s)).	Multiple incident events/lookup periods possible. Incident events (used to define the lookup periods) must have WASHPER days of continuous enrollment prior to the event date(s) (*i.e.*, index date(s)).
	Multiple treatment episodes may be initiated during a lookup period, but only if the first treatment episode is the first observed during the member's history.	Multiple treatment episodes may be initiated during each lookup period, but only if there are WASHPER days of continuous enrollment without the treatment of interest prior to the event date (*i.e.*, index date).

*Multiple treatment episodes may be captured per lookup period.

F. COHORT INCLUSION OR EXCLUSION BASED ON CONDITIONS OF INTEREST

The requester can restrict the cohort with inclusion and/or exclusion criteria using the optional Inclusion/Exclusion Conditions File. Members can be included or excluded from the cohort if certain conditions are recorded during a specific lookback period. Conditions can be defined by any combination of valid diagnoses, procedures and/or NDCs.

The condition lookback period is defined by a combination of start and end dates (expressed in terms of days from index date, where day zero refers to the index date). Note that the start and end dates can include and go beyond the index date (Day 0 of the interval). For example, if start =-30 and end=30 the MP6 algorithm will search for conditions in the period starting 30 days before the index date and ending 30 days after.

The lookback period can also be defined at the code level. For example, the requester could require members to have a code for diabetes in the 183 days before index date OR a code for AMI in the 365 days before index date.

The presence of a claim with one of the desired inclusion condition codes is a sufficient condition to meet the inclusion criterion. However, in the case of exclusions, the absence of any claims with one of the desired exclusion condition codes is a necessary but not sufficient condition to meet the exclusion criterion. To fully satisfy the exclusion criterion the member also needs to be continuously enrolled for medical and/or drug coverage for the complete exclusion lookback period. For example, if a member is free of an exclusion claim in the -180 to -90 days before the index date, but was only enrolled from days -120 to -90, the MP algorithm cannot classify this member "free of the exclusion claims" since there is no way to know whether an exclusion claim would have been recorded during days -180 to -121.

VI. DENOMINATORS, RATES, AND POST-EVENT TREATMENT INTENSITY

In addition to metrics on event(s) and treatment episode(s) of interest, output tables include metrics on denominators associated with each result stratum (See Section IX). Denominator metrics include (1)

count of eligible members and (2) eligible member days. These metrics are different for the prevalence-based vs. incidence-based cohort. The members included in any denominator metrics are all the "eligible" members, *i.e.,* members who can potentially be identified by the MP algorithm (*i.e.*, either prevalent or incident).

Prevalence-Based Cohort: Eligible Members and Member-Days

The eligible member count for the prevalence-based cohort is composed of all members with at least one day of enrollment in pharmacy and medical benefit coverage during the query period. If inclusion/exclusion conditions are specified, the member must also satisfy the condition requirements to be included. Eligible member days for this cohort are the sum of all such enrolled days during the query period for the eligible members.

Incidence-Based Cohort: Eligible Members and Member-Days

Eligible members are those who meet the following conditions on at least one day during the query period. These members have the potential to have at least one valid event.

1. Event Incidence Condition

    a. Single or Multiple Event Incidence: enrolled for at least WASHPER+1 days in pharmacy and medical benefit coverage (*i.e.*, WASHPER days for the event incidence requirement and an additional day for the potential event to be observed). Members reported must be free of event claims or claims from event(s) found in the Incident Event File during the WASHPER days.
    b. Minimum Event Incidence: enrolled for at least WASHPER+1 days in pharmacy and medical benefit coverage (*i.e.*, WASHPER days for the event incidence requirement and an additional day for the potential event to be observed). Members reported must be free of event claims or claims from event(s) found in the Incident Event File during the WASHPER days and during any prior enrollment period considered by the program.

2. Post-Event Treatment Incidence Condition

    a. Multiple Exposure Incidence: enrolled for at least WASHPER+1 days in pharmacy and medical benefit coverage (*i.e.*, WASHPER days for the post-event treatment incidence requirement and an additional day for the potential treatment to be observed). Members reported must be free of post-event treatment claims or claims from post-event treatment(s) found in the Incident Post-Event Treatment File during the WASHPER days.
    b. Minimum Exposure Incidence: enrolled for at least WASHPER+1 days in pharmacy and medical benefit coverage (*i.e.*, WASHPER days for the post-event treatment incidence requirement and an additional day for the potential treatment to be observed). Members reported must be free of post-event treatment claims or claims from post-event treatment(s) found in the Incident Post-Event Treatment File during the WASHPER days and during any prior enrollment period considered by the program.

3. Inclusion/Exclusion Conditions Condition (Optional): if the optional condition inclusion/exclusion feature is requested, all eligible members to be reported must also meet all inclusion/exclusion

condition(s) criteria in addition to the event and post-event treatment incident criteria described above.

Eligible member days reported are equal to the total number of days meeting all criteria for the eligible members above and falling between the start and end dates of the query period.

Background Rates

Once denominator metrics are available, MP6 allows for the calculation of background rates for each Event Group specified. For example, the requester can calculate the proportion and rate of new events for Event Group Z. The proportion of new events would be defined as the number of members with an incident event (*i.e.*, the numerator) per X eligible members (*i.e.*, the denominator), whereas the rate of new events would be defined as the number of members with an incident event per Y person-time (*e.g.*, person-years, member-days). Due to how incident events are defined (*i.e.*, with respect to both the event and the post-event treatment), "background rates" should be interpreted with caution and with respect to the incidence criteria requested.

Post-Event Treatment Intensity Ratio

The post-event intensity ratio is defined as the sum of post-event treatment days across all members during a valid lookup period divided by the sum of all lookup period durations during the query period. The purpose of this metric is to determine the percentage of days treated during an event lookup period. For example, this metric can be used to define the percentage of days of beta-blocker use (post-event treatment) during the 365 days after an acute myocardial infarction (index date) among patients with a history of diabetes (inclusion condition).

Mean Time to Treatment

The mean time to treatment is the average number of days between the start of an event lookup period (index date) and the first treatment episode claim.

VII. PROGRAM STEPS

The general program steps are the following:

1. Process the seven input files
2. Extract medical claims from the diagnosis and procedure tables
3. Recode claims that occurred during an inpatient stay as inpatient
4. Extract drug claims from the outpatient pharmacy file and lab records from the laboratory file
5. Apply stockpiling algorithm to drug claims
6. Identify members with events during the query period
7. Reconciliation of enrollment episodes (gaps in enrollment less than ENROLGAP and correct coverage type)
8. Create post-event treatment episodes
9. Create lookup periods and assess their incidence status
10. Link post-event treatment episodes with lookup periods and calculate treatment days
11. If required, filter lookup periods according to the presence of inclusion/exclusion conditions

12. Determine if lookup periods are incident with respect to the post-event drug/procedures/labs
13. Compute denominator member counts
14. Calculate age and identify sex for each cohort member
15. Create output tables with denominators

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 12 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.

Table 12: Environment Variable Definitions

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.
Procedures Table Name	PROCTABLE	Enter the name of the MSCDM Procedures table.
Encounter Table Name	ENCTABLE	Enter the name of the MSCDM Encounter table.
Laboratory Table Name	LABTABLE	Enter the name of the MSCDM Laboratory table.
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.
Libname of the MSCDM	INDATA	Enter the path where the MSCDM data is saved.

IX. OUTPUT TABLES

Fifty-two output tables are created by the modular program and are each output in both .sas7bdat and .csv formats. Twenty-five output tables each are created for the incident-based cohort and the prevalence-based cohort and are stratified by age, sex, year and year/month. Additionally, numerator

and denominator tables are output containing the full query summary statistics. Tables can be identified by the following suffixes:

- _ITABLEX
- _PTABLEX
- _ITABLEXAG
- _PTABLEXAG
- _ITABLEXG
- _PTABLEXG
- _ITABLEXY
- _PTABLEXY
- _ITABLEXYM
- _PTABLEXYM
- _DENTABLE0
- _NUMTAB0

The "I" and "P" correspond to incident and prevalent tables, respectively, and the "X" corresponds to the table number and takes the values 1 to 5. Each TABLEX is output with no stratification and are additionally output stratified by sex, age group, year and year/month (five versions of each table are created). Each table is identified by the suffixes "AG" for age group, "G" for gender/sex, "Y" for year and "YM" for year/month. There is only one denominator table (DENTABLE0) and one numerator table (NUMTAB0). Below are examples of the incident output tables, produced using the multiple incidence type option for both the event and post-event treatment.

The output for the first four tables below is an example examining hip replacement (post-event procedure) following a fall (event diagnosis) in members with osteoporosis (inclusion condition). The output for the fifth table is an example investigating the occurrence of an HgbA1C test (post-event lab) in the 365 days following a diagnosis of diabetes. Note that the fifth table is only populated if the post-event treatment of interest is the occurrence of a lab test. Only output for the incidence-based cohort is presented.

Output TABLE 1: Summary of Incident Events, Post-Event Treatment, and Eligible Members (part 1)

Event Group	Post-Event Group	Unique Members w/ Lookup Period	Lookup Periods	Event Claims	Lookup Period Duration	Unique Members w/ Post-Event Treatment
FALL1	HIP1	1,463	1,477	1,879	353,741	21

Output TABLE 1: Summary of Incident Events, Post-Event Treatment, and Eligible Members (part 2)

Event Group	Post-Event Group	Post-Event Treatment Claims	Post-Event Treatment Duration	Post-Event Treatment Days Supplied	Post-Event Treatment Amount Supplied	Eligible Members	Member Days
FALL1	HIP1	28	22	22		88,155	26,823,691

Interpretation of Output TABLE 1: Within the QUERYFROM to QUERYTO period, 1,463 members had at least one incident diagnosis of fall. For these members, a total of 1,477 incident lookup periods were observed for a total of 1,879 claims and a total lookup period duration of 353,741 days. Among the 1,463 members having at least one incident lookup period, 21 members had at least one hip

replacement following a fall. These post-fall episodes cumulated a total of 28 hip replacement procedure codes. Finally, a total of 88,155 members could potentially have had an incident fall diagnosis for a total of 26,823,691 eligible days.

While not as relevant for procedure-based treatment, the metrics for total treatment episode duration (22 days) and total days of supply (22) are displayed here. These metrics would be more directly interpretable for drug-based treatment.

This table is repeated four times to stratify results by year, year/month, sex, and age group.

PTABLE1 for the prevalence-based cohort would have similar interpretation, but would represent prevalent lookup periods and prevalent post-event treatment.

Output TABLE 2: Post-Event Treatment Intensity

Event Group	Post-Event Group	Unique Members w/ Post-Event Treatment	Proportion of Unique Members with Post-Event Treatment	Post-Event Days Treated	Post-Event Treatment Intensity
FALL1	HIP1	21	0.014	22	<0.0001

Interpretation of Output TABLE 2: Within the QUERYFROM to QUERYTO period, 21 members had at least one hip replacement following a fall (1.4%).The treatment intensity ratio is defined as the number of procedures occurring during a lookup period (n=22) divided by lookup period duration in days (n=353,741). The post-event treatment intensity in this example is <0.01%.

This table is repeated four times to stratify results by year, year/month, sex, and age group.

Output TABLE 3: Distribution of Post-Event Treatment Intensity, Members with Post-Event Treatment (part 1)

Event Group	Post-Event Group	Unique Members w/ Post-Event Treatment	Mean Post-Event Treatment Intensity	SD Post-Event Treatment Intensity
FALL1	HIP1	21	0.005	0.004

Output TABLE 3: Distribution of Post-Event Treatment Intensity, Members with Post-Event Treatment (part 2)

Event Group	Post-Event Group	Min Post-Event Treatment Intensity	Median Post-Event Treatment Intensity	Max Post-Event Treatment Intensity
FALL1	HIP1	0.003	0.003	0.016

Interpretation of Output TABLE 3: Within the QUERYFROM to QUERYTO period, 21 members had at least one hip replacement following a fall. The mean post-event treatment intensity ratio for these members was 0.005, the standard deviation of the ratio was 0.003, the minimum ratio was 0.003, the median ratio was 0.003 and the maximum ratio was 0.016. This is calculated per member as number of procedures occurring during a lookup period divided by lookup period duration in days. As shown, the minimum ratio is 0.003, which represents a member with 1 procedure during a lookup period and a 365 day lookup period duration (1/365=0.003).

This table is repeated four times to stratify results by year, year/month, sex, and age group.

Output TABLE 4: Distribution of Time to Treatment (TTT) Per Member

Event Group	Post-Event Group	Unique Members w/ Post-Event Treatment	Mean TTT	SD TTT	Min TTT	Median TTT	Max TTT
FALL1	HIP1	21	49.9	85.2	0	0	302

Interpretation of Output TABLE 4: Within the QUERYFROM to QUERYTO period, 21 members had at least one hip replacement following a fall. For these members, the mean number of days between the fall and the hip replacement was 49.9 days, with a standard deviation of 85.2 and a minimum, median and maximum of 0, 0, and 302, respectively. A TTT of 0 indicates that the fall and the hip replacement codes occurred on the same day.

This table is repeated four times to stratify results by year, year/month, sex, and age group.

Output TABLE 5: Number of Post-Event Treatment Labs per Member

Event Group	Post-Event Group	Number of Labs	Unique Members with Post-Event Lab	Denominator
DIABETES1	HGBA1C1	0	856	1211
DIABETES1	HGBA1C1	1	29	1211
DIABETES1	HGBA1C1	2-3	48	1211
DIABETES1	HGBA1C1	4+	278	1211

Interpretation of Output TABLE 5: Of the 1,211 members with a diabetes diagnosis, 856 members did not have a resulted HGBA1C test in the 365 days following the diagnosis within the QUERYFROM to QUERYTO period. Twenty-nine members had 1 resulted HGBA1c test, 48 had 2-3 tests, and 278 had four or more tests.

This table is repeated four times to stratify results by year, year/month, sex, and age group.

Note: this table is only populated if the post-event treatment of interest is a lab test.

X. EXAMPLE

Tables 13-17 below show partially-populated examples of the Event, Post-Event Treatment, Inclusion/Exclusion Condition, and Output Table Selection files used to create the TABLE 1 – TABLE 4 output described in Section IX:

Table 13: Example of Event File

Group	SubGroup	CodeType	Code	Principal	CareSetting	WashTyp	WashPer	EnrDays	LookupPer	MinFollowPer
FALL1	FALL1	DX09	E880	NO		MULT	365	730	365	0
FALL1	FALL1	DX09	E8800	NO		MULT	365	730	365	0
FALL1	FALL1	DX09	E8801	NO		MULT	365	730	365	0

Table 14: Example of Post-Event Treatment File

Group	PostDiagGroup	SubGroup	CodeType	Code	WashTyp	WashPer	EpisodeGap
FALL1	HIP1	FALL1	PX09	0074	MULT	0	0

Group	PostDiagGroup	SubGroup	CodeType	Code	WashTyp	WashPer	EpisodeGap
FALL1	HIP1	FALL1	PX09	0075	MULT	0	0
FALL1	HIP1	FALL1	PX09	0076	MULT	0	0

Table 15: Example of Inclusion/Exclusion Conditions File

Group	SubGroup	CodeType	Code	Inclusion	CondFrom	CondTo	Principal	CareSetting
FALL1	BoneDis	DX09	733	1	-365	-1	NO	
FALL1	BoneDis	DX09	7332	1	-365	-1	NO	
FALL1	BoneDis	DX09	7334	1	-365	-1	NO	

Table 16: Example of Output Table Selection File

DOCTABNAME	DOCTABDESCR	TABNAME	TAB-REQUIRED
	Global Denominators	dentable0	Y
	Global Numerators	numtable0	Y
ITable1	Incident Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group and PostDiagGroup	itable1	Y
ITable1ag	Incident Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup and Age Group	itable1ag	Y
ITable1g	Incident Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup and Sex	itable1g	Y
ITable1y	Incident Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup and Year	itable1y	Y
ITable1ym	Incident Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup, Year and Month	itable1ym	Y
ITable2	Incident Concomitance Intensity stratified by Group and PostDiagGroup	itable2	Y
ITable2ag	Incident Concomitance Intensity stratified by Group, PostDiagGroup and Age Group	itable2ag	Y
ITable2g	Incident Concomitance Intensity stratified by Group, PostDiagGroup and Sex	itable2g	Y
ITable2y	Incident Concomitance Intensity stratified by Group, PostDiagGroup and Year	itable2y	Y
ITable2ym	Incident Concomitance Intensity stratified by Group, PostDiagGroup, Year and Month	itable2ym	Y
ITable3	Incident Concomitance Intensity Distribution stratified by Group and PostDiagGroup	itable3	Y
ITable3ag	Incident Concomitance Intensity Distribution stratified by Group, PostDiagGroup and Age Group	itable3ag	Y
ITable3g	Incident Concomitance Intensity Distribution stratified by Group, PostDiagGroup and Sex	itable3g	Y
ITable3y	Incident Concomitance Intensity Distribution stratified by Group, PostDiagGroup and Year	itable3y	Y
ITable3ym	Incident Concomitance Intensity Distribution stratified by Group, PostDiagGroup, Year and Month	itable3ym	Y
ITable4	Incident Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group and PostDiagGroup	itable4	Y
ITable4ag	Incident Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup and Age Group	itable4ag	Y
ITable4g	Incident Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup and Sex	itable4g	Y
ITable4y	Incident Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup and Year	itable4y	Y
ITable4ym	Incident Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup, Year and Month	itable4ym	Y

DOCTABNAME	DOCTABDESCR	TABNAME	TAB-REQUIRED
ITable5	Incident Counts of Members in Post-Diagnosis categories stratified by Group and PostDiagGroup	itable5	Y
ITable5ag	Incident Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup and Age Group	itable5ag	Y
ITable5g	Incident Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup and Sex	itable5g	Y
ITable5y	Incident Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup and Year	itable5y	Y
ITable5ym	Incident Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup, Year and Month	itable5ym	Y
PTable1	Prevalent Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group and PostDiagGroup	ptable1	N
PTable1ag	Prevalent Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup and Age Group	ptable1ag	N
PTable1g	Prevalent Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup and Sex	ptable1g	N
PTable1y	Prevalent Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup and Year	ptable1y	N
PTable1ym	Prevalent Counts of Members, Episodes, Dispensing and Days of Supply stratified by Group, PostDiagGroup, Year and Month	ptable1ym	N
PTable2	Prevalent Concomitance Intensity stratified by Group and PostDiagGroup	ptable2	N
PTable2ag	Prevalent Concomitance Intensity stratified by Group, PostDiagGroup and Age Group	ptable2ag	N
PTable2g	Prevalent Concomitance Intensity stratified by Group, PostDiagGroup and Sex	ptable2g	N
PTable2y	Prevalent Concomitance Intensity stratified by Group, PostDiagGroup and Year	ptable2y	N
PTable2ym	Prevalent Concomitance Intensity stratified by Group, PostDiagGroup, Year and Month	ptable2ym	N
PTable3	Prevalent Concomitance Intensity Distribution stratified by Group and PostDiagGroup	ptable3	N
PTable3ag	Prevalent Concomitance Intensity Distribution stratified by Group, PostDiagGroup and Age Group	ptable3ag	N
PTable3g	Prevalent Concomitance Intensity Distribution stratified by Group, PostDiagGroup and Sex	ptable3g	N
PTable3y	Prevalent Concomitance Intensity Distribution stratified by Group, PostDiagGroup and Year	ptable3y	N
PTable3ym	Prevalent Concomitance Intensity Distribution stratified by Group, PostDiagGroup, Year and Month	ptable3ym	N
PTable4	Prevalent Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group and PostDiagGroup	ptable4	N
PTable4ag	Prevalent Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup and Age Group	ptable4ag	N
PTable4g	Prevalent Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup and Sex	ptable4g	N
PTable4y	Prevalent Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup and Year	ptable4y	N
PTable4ym	Prevalent Days between Query/Post-Diagnosis Dispensings Distribution stratified by Group, PostDiagGroup, Year and Month	ptable4ym	N
PTable5	Prevalent Counts of Members in Post-Diagnosis categories stratified by Group and PostDiagGroup	ptable5	N
PTable5ag	Prevalent Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup and Age Group	ptable5ag	N
PTable5g	Prevalent Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup and Sex	ptable5g	N

DOCTABNAME	DOCTABDESCR	TABNAME	TAB-REQUIRED
PTable5y	Prevalent Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup and Year	ptable5y	N
PTable5ym	Prevalent Counts of Members in Post-Diagnosis categories stratified by Group, PostDiagGroup, Year and Month	ptable5ym	N

Table 17: Example of Dispensing Processing File

Group	SameDay	SupRange	AmtRange	PercentDays
QGRP1	aa	0<-HIGH	0<-HIGH	0

In this example, the Inclusion/Exclusion Conditions File requires that each Primary Group be restricted to members with a code for a condition of interest in the 365 days prior to the index date. Furthermore, the requester specified the following parameters to be used:

- To be selected members need to have both medical and drug coverage
- Any enrollment gap of less than 45 days is considered administrative and must be ignored
- For incident scenarios members need to have at least 720 days of enrollment of correct coverage type prior to HOI index date
- The query period spans the years 2005 to 2010
- The results should be included for members 65+
- Only certain output tables should be preserved

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

```
%MODULARPROGRAM6 (
                    REQUESTID=mpr01,
                    RUNID=r01,
                    COVERAGE=MD,
                    ENROLGAP=45,
                    QUERYFROM=01/01/2005,
                    QUERYTO=12/31/2010,
                    QUERYFILE=event.sas7bdat,
                    INCQUERYFILE=,
                    POSTDIAGFILE= posteventtx.sas7bdat,
                    INCPOSTDIAGFILE=,
                    CONDFILE= cond.sas7bdat,
                    OUTTABLESFILE= output.sas7bdat,
                    AGESTRAT=65+
                    );
```