MINI-SENTINEL MODULAR PROGRAMS

MODULAR PROGRAM 3: FREQUENCY OF SELECT EVENTS DURING EXPOSURE TO A DRUG/PROCEDURE GROUP OF INTEREST

Documentation version: 7.5

Prepared by the Mini-Sentinel Operations Center
For use with Modular Program 3 version 7.5
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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
7.5	09/11/2014	• Up-versioned due to increment from mp3_7.4.sas to mp3_7.5.sas to improve efficiency. No change to documentation text.	Mini-Sentinel Operations Center
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7.2	05/02/2014	• Integrated Mini-Sentinel Toolkit Combo Tool macro, to allow the specification of complex event algorithms and to query laboratory result data • Added additional macro parameters for workplan and request identification	Mini-Sentinel Operations Center
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7.0	12/17/2013	• Added Query File parameter “COHORTDEF” and removed Query File parameter “WASHTYP” • Added Event File parameter “EVENTCOUNT” • Removed Event File parameter “WASHTYP” • Added Incident Query File parameter “INCTRUNC” • Removed all text describing WASHTYP parameter values • Updated output tables to include amount supplied metrics • Added output tables (13 and 14) capturing information on multiple events and number of events per treatment episode • Added specifications for and an example of optional “Dispensing Processing File” • Added macro parameter “RunID”	Mini-Sentinel Operations Center
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6.0	8/28/2013	• Added Macro parameter “COVERAGE” • Added Query File parameter “ENRDAYS” • Added “CARESETTINGPRINCIPAL” parameter to Query File and Incident Query File • Updated Attrition Table Tool to break out enrollment episode exclusions by coverage type • Added parameter “DESCR” to Query, Incident	Mini-Sentinel Operations Center

		Query, Event, Incident Event and Inclusion/Exclusion Conditions files	
5.0	5/16/2013	• Added standard attrition table available by default for each run. • Revised to allow either exact code match and/or wildcard match. • Added optional Output Table Selection module to instruct the MP 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	• Added Change in BMI Stratification module functionality, file, and output descriptions. • Revised Event, Incident Event, and Inclusion/Exclusion Conditions Files to include new CareSettingPrincipal parameter, allowing the requester to query any combination of care setting and principal diagnosis status. This new parameter replaced the existing CareSetting and Principal parameters in these files. • Added optional IRR calculation tool description.	Mini-Sentinel Operations Center
3.0	1/25/2013	• Added Charlson Comorbidity Index and Medical Utilization module functionality, file, and output descriptions. • 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
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I. OVERVIEW

Mini-Sentinel modular programs (MPs) allow rapid implementation of standard queries across the Mini-Sentinel Distributed Database (MSDD). MPs are designed to run against the Mini-Sentinel Common Data Model (MSCDM).[1] They are written in SAS and can be customized using various parameter settings that define exposures, outcomes, date ranges, age ranges, and other implementation details. This document describes the key program specifications and main assumptions underlying each of the query parameters for Modular Program 3 version 7.5. 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 throughout this document 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 terms "exposure" and “exposure of interest” are used to represent exposure to a medical product or procedure as defined by the MP requester. An exposure can be defined using any set of NDC, procedure and/or diagnosis codes found in the MSCDM. For example, exposure to a drug product dispensed in the outpatient setting can be defined as observation of one or more National Drug Codes (NDCs) in the pharmacy dispensing file, whereas exposure to a vaccine can be defined based on observation of specific procedure codes in the procedure file.

The terms "event" and “event of interest” are used to represent the occurrence of a diagnosis, procedure and/or dispensing as defined by the MP requester. An event can therefore be defined using any set of diagnosis, procedure and/or NDCs found in the MSCDM.

The term “condition” is used to represent a medical code (or a group of codes) that identify a medical condition of interest.

The term “claim” is used to represent an outpatient pharmacy dispensing or medical encounter/record with any of the codes for the exposure(s), event(s) or condition(s) of interest.

A “treatment episode” or “episode” is a period of continuous treatment defined using outpatient pharmacy dispensings, procedures and/or diagnoses. For dispensings, a treatment episode is a dispensing sequence that has no interruption in days supplied greater than an allowable “gap”. The allowable gap is the number of days used to bridge dispensings to create a continuous treatment episode.

The term “member” is used to represent an individual with relevant criteria for enrollment, exposure(s), event(s), and condition(s) (as specified by the MP parameters). A member can be further defined as a “user” if evidence of use of exposure(s) of interest is observed. Whenever a user is identified, the service date on the claim of the first exposure of interest observed during the relevant period of interest is labeled the “index date”.

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

The execution of MP3 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 one scenario to be tested.

III. PROGRAM SUMMARY

MP3 is used to characterize the frequency of select event(s) among a cohort of members newly treated with exposure(s) of interest during a period defined by a start and an end date (*i.e.*, the query period). Continuous treatment episodes are created using various parameters in the treatment episode algorithm (*e.g.*, pre-initiation washout period, minimum episode duration, maximum allowable gap in days supply to bridge two claims into a single treatment episode, episode extension days). MP3 can also restrict the analysis to a subset of treatment episodes during the query period (*e.g.*, all valid episodes, the first valid episode). Select event(s) of interest must be identified during treatment episodes.

MP3 has several 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 the user to define how days supply and amount supplied on each dispensing should be processed by the MP. Another module allows MP3 to output a subset of result tables generated, reducing workload to compile and review results that are not relevant to a specific request. Additional modules allow results to be stratified by range of Charlson Comorbidity Index (CCI) scores, range of number of medical utilization visits, and range of change in Body Mass Index (BMI).

An optional output analysis tool is also available that can calculate incident rates (IRs) and incident rate ratios (IRRs) using the output generated by MP3. See Section IX for additional details.

One run of MP3 generates a total of twenty-five result tables. Five tables contain metrics on exposure utilization: one table with information overall for the entire query period (*i.e.*, no stratification), and four tables each stratified by year, year/month, age group, and sex. The metrics reported in these five tables are the number of users, number of treatment episodes, number of claims used to build treatment episodes, and the days and amount supplied from these claims. Two additional tables contain metrics on number of events and days at risk: one overall for the entire query period and another stratified by year. Each of these seven tables also contains enrollment information, *i.e.*, the total number of members and number of eligible member days. Three additional tables contain information on numerators and denominators for combinations of the aforementioned stratification options. Combining the information from all these tables allows the requester to generate population-based background rates (Section VI) for all stratifications. Two additional tables contain information on the number of events per treatment episode and stratify the number of treatment episodes by the number of events. One table details the number of dispensings excluded from consideration by the MP based on user-defined parameters in the Dispensing Processing File. Another table allows the requester to assess the attrition of the cohort of interest after each selection criterion is applied. The final eleven tables provide metrics on exposure utilization and number of days at risk for the CCI, medical utilization, and change in BMI stratifications. For more details on result tables, please see Section IX.

MP3 requires the specification of several parameters to define a scenario. These include program parameters to specify project and workplan identifiers, query period, age range(s), coverage type requirements, and enrollment criteria. The names of all required input files (built as SAS datasets)

containing several parameters must also be specified. All parameters and input file specifications are described in Section IV.

IV. PROGRAM PARAMETER AND INPUT FILE SPECIFICATIONS

A. PROGRAM PARAMETER SPECIFICATIONS

There are several main program parameters that must be specified. These include project and workplan identifiers, 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 the names of all input files.

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

Table 1: Main Program Parameter Specification

Parameter	Field Name	Description
Project Identifier	MSPROJID	**Details**: project identifier for internal MSOC identification and tracking. **Note 1:** should follow the format to##_[*ActivityAcronym*]_[*SubactivityAcronym*]. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric **Example**: MSPROJID=to16_cap
Work Plan Type	MSWPTYPE	**Details**: work plan type for internal MSOC identification and tracking. **Note 1:** should follow the format specified in the MSOC internal naming conventions document. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric **Example**: MSWPTYPE=mpl1r
Work Plan Identifier	MSWPID	**Details**: work plan identifier for internal MSOC identification and tracking. **Note 1:** should follow the format [wp###]. **Note 2:** should be used to uniquely identify a modular program request. **Defined by:** Request programmer **Input type:** Required

Parameter	Field Name	Description
		Format: Alphanumeric **Example**: MSWPID= wp001
Version Identifier	MSVERID	**Details**: version identifier for internal MSOC identification and tracking. Should track each re-distribution of the package (if multiple distributions are required). **Note 1:** should follow the format [v##]. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric **Example**: MSVERID =v01
Run Identifier	RUNID	**Details**: run identifier for internal MSOC identification and tracking. Should uniquely identify each execution of a modular program within the same work plan. **Note 1:** should follow the format [r##]. **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric **Example**: RUNID =r01
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 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)
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.

Parameter	Field Name	Description
		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 Query 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
Query Start Date	QUERYFROM	**Details:** date for the start of the query identification period. If QUERYFROM =03/01/2008, only treatment episodes initiated 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 treatment episodes initiated before this date will be considered. **Note 1:** QUERYTO only binds treatment episode start dates. Treatment episodes 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
Query File	QUERYFILE	**Details:** name of the SAS dataset defining the query exposure(s) of interest. It lists the codes of interest and various parameters to

Parameter	Field Name	Description
		specify how each code must be queried by MP3. The file name, including its extension, must be entered. For specific details on the content of this file, please see Section IV.B.1. **Named by:** Request programmer **Input type:** Required **Format: .**sas7bdat or .cport file format **Example:** QUERYFILE=query.sas7bdat or query.cport
Incident Query File	INCQUERYFILE	**Details:** name of the SAS dataset refining the incident exposure definition(s). It contains additional codes and various parameters to further refine how incident use of each exposure 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 Query File, see Section IV.B.2. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** INCQUERYFILE=incquery.sas7bdat or incquery.cport
Event File	QUERYEVENTFILE	**Details:** name of the SAS dataset defining the query event(s) of interest. It lists the codes of interest and various parameters to specify how each code must be queried by MP3. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.3. **Named by:** Request programmer **Input type:** Required **Format: .**sas7bdat or .cport file format **Example:** QUERYEVENTFILE=event.sas7bdat or event.cport
Incident Event File	INCEVENTFILE	**Details:** name of the SAS dataset refining the incident event definition(s). It contains additional codes and various parameters to further refine how incident events 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.4. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** INCEVENTFILE=incevent.sas7bdat or incevent.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.5.

Parameter	Field Name	Description
		Named by: Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** CONDFILE =cond.sas7bdat or cond.cport
Charlson Comorbidity Index File	CCIFILE	**Details:** name of the SAS dataset defining the Charlson Comorbidity Index parameters. It lists various parameters to specify how the CCI must be defined and queried. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.6. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** CCIFILE=cci.sas7bdat or cci.cport
Medical Utilization Stratification File	UTILFILE	**Details:** name of the SAS dataset defining the medical utilization stratification parameters. It lists various parameters to specify how medical utilization must be defined and queried. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.7. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** UTILFILE =util.sas7bdat or util.cport
Change in BMI Stratification File	BMIKIDSFILE	**Details:** name of the SAS dataset defining the change in body mass index (BMI) stratification parameters. It lists various parameters to specify how change in BMI must be evaluated. The file name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.8. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** BMIKIDSFILE =bmi.sas7bdat or bmi.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.9. **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

Parameter	Field Name	Description
		name, including its extension, must be entered. For specific details on the content of this file, see Section IV.B.10. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat or .cport file format **Example:** STOCKPILINGFILE = stockpil.sas7bdat or stockpil.cport
Combo Input File	COMBOFILE	**Details:** name of the SAS dataset used to specify the algorithms used to define complex events. Specifying a COMBOFILE value signals the modular program to call the Mini-Sentinel Toolkit Combo Tool macro. See the Combo Tool documentation for details and specifications for this file. **Note 1:** the MP3 COMBOFILE is identical to the Combo Tool COMBFILE. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat **Example:** COMBOFILE=combofile
Lab Code Map File	LABSCODEMAP	**Details:** name of the SAS dataset defining lab codes used to query the Laboratory Result table. Specifying a LABSCODEMAP value signals the modular program to call the Mini-Sentinel Toolkit Combo Tool macro. See the Combo Tool documentation for details and specifications for this file. **Named by:** Request programmer **Input type:** Optional **Format: .**sas7bdat **Example:** LABSCODEMAP =Lab_Lookup
Age Groups	AGESTRAT	**Details:** age group categories for reporting. Specifying this parameter will (1) restrict to certain age groups and (2) specify how age groups will be stratified in the result tables. For example, to have results stratified by 20 year increments for members 40-99 years of age, AGESTRAT=40-59 60-79 80-99 would be entered. **Note 1:** age is determined at the index date. **Note 2:** various units of time can be used. Valid values are: • **D**: days • **W**: weeks • **Q**: quarters • **M**: months • **Y**: years (default value)

Parameter	Field Name	Description
		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 input files.

1. Query File

The Query File is required. It contains the comprehensive set of codes used to define the exposure(s) of interest used to create treatment episodes. NDCs, International Classification of Diseases (ICD) procedure and diagnosis codes, Healthcare Common Procedure Coding System (HCPCS) codes, and/or laboratory result values can be used to define exposure(s) of interest. Exposure(s) can be defined using a combination of allowed code types.

The structure of the Query File must reflect how codes should be queried to define a unique exposure. The GROUP field is used by the request programmer to group all codes pertaining to a given exposure of interest. For example, a group for "Exposure1" could be defined by all NDCs for any oral forms of anti-diabetic medications, a group for "Exposure2" by a mix of NDC and HCPCS codes for certain insulin products, and another group for "Exposure3" by only those NDCs for a recently approved oral form of anti-diabetic medication.

The GROUP field is also used by the request programmer to define a unique scenario (*i.e.,* a unique combination of parameters across all input files). For example, if a requester wants to examine exposure to "Exposure1" and risk for "Event A" *and* "Event B" (two scenarios), the two "Exposure1" requests would each need a unique GROUP name (*e.g.*, "Exposure 1_Event A" and Exposure 1_Event B"). Request programmers must ensure that when choosing GROUP names they represent both a unique exposure *and* a unique scenario. Table 2 describes specifications for the Query File.

Table 2: Query File Specification

Parameter	Field Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried.

Parameter	Field Name	Description
		Note 1: multiple exposures/query groups can be defined within the same Query File. In this case all exposures are queried independently and results are reported separately and labeled using each query GROUP name specified. **Named by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $30; no special characters (*e.g.*, commas, periods, hyphens, etc.) allowed, and underscores must be used to mark spaces. **Example:** Insulin
Name of Query Subgroup	SUBGROUP	**Details:** standardized name used to refer to a specific exposure of interest within a given query GROUP. **Note 1:** the SUBGROUP field is used by the stockpiling algorithm as group categories to adjust claim service dates. See Section V.B.1 for more details. **Note 2:** useful when a query GROUP contains multiple exposures of interest. For example, if GROUP= "Insulin" SUBGROUP could take values of "Insulin_Oral" and "Insulin_Injectable". **Note 3:** SUBGROUP values must match between the Query File and the Incident Query File. **Note 4:** 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:** Insulin_Oral
Query 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 diagnosis • **DX10**: ICD-10-CM diagnosis • **DX11**: ICD-11-CM diagnosis • **RX11**: 11-digit NDC • **RX09**: 9-digit NDC

Parameter	Field Name	Description
		• **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 • **PXC2**: CPT Category II • **PXC3**: CPT Category III **Note 1**: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below). **Request Programmer Note 2:** exposures defined using laboratory result values must be created using the Combo Tool (see Combo Tool documentation for details). **Note 3:** when querying a combination item ("combo code") generated by the Combo Tool module, the following code types should be used: • **RXCB**: combo item behaving like a dispensing • **PXCB**: combo item behaving like a procedure • **DXCB**: combo item behaving like a diagnosis **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4. **Example:** RX11
Query Codes of Interest	CODE	**Details:** NDC, ICD, and HCPCS code values for the exposure(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**: 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.*, MP3 will not find any valid matches in the data for CODETYPE=RX11 and a 9-digit NDC value).

Parameter	Field Name	Description
		Note 5: duplicate CODETYPE-CODE combinations in a given query GROUP are removed by the MP3 algorithm. **Named by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11. **Example:** 12345678911
Query 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 Query File) **Defined by:** Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Cohort Definition	COHORTDEF	**Details:** indicates how the cohort will be defined. As detailed in Section V.C., the cohort definition parameter can take the values: • **01:** Cohort includes only the first valid incident treatment episode during the query period • **02:** Cohort includes all valid incident treatment episodes during the query period • **03:** Cohort includes all valid incident treatment episodes during the query period until an event occurs **Note 1:** COHORTDEF parameter is used in conjunction with the Query Washout Period (below) to define a valid incident treatment episode(s). **Named by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $2 **Example:** 01
Query Washout Period	WASHPER	**Details:** length of washout period in days. The washout period is a period of time before the treatment episode index date during which a member cannot have any evidence of the exposure(s) of interest or any other exposure(s) specified in the Incident Query File.

Parameter	Field Name	Description
		Note 1: length of washout period days must be the same within a given query GROUP. **Note 2**: used in conjunction with the COHORTDEF parameter. **Note 3:** the MP algorithm may use days before QUERYFROM to determine if continuous enrollment and incidence criteria are met. **Note 4**: in conjunction with the ENROLGAP, COVERAGE, and ENRDAYS parameters, the WASHPER 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, the ENRDAYS parameter value is only binding if ENRDAYS > WASHPER (See Section V.A). If enrollment requirements prior to index date are not met, treatment episode incidence cannot be determined and thus the episode is excluded from output metrics. **Note 5**: **special case**: when WASHPER = missing the program requires ENRDAYS of continuous enrollment but only considers a treatment episode valid if, at index date, the member has no evidence of exposure in their entire available enrollment history. **Named by:** Requester **Input type:** Optional **Format:** Numeric **Example:** 183
Minimum Pre-Index Enrollment Days	ENRDAYS	**Details:** optional parameter to further restrict the number of days of continuous enrollment prior to start of new incident treatment episode 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 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, the ENRDAYS parameter value is only binding if ENRDAYS >

Parameter	Field Name	Description
		WASHPER (See Section V.A). If enrollment requirements prior to index date are not met, treatment episode incidence cannot be determined and thus the episode is excluded from output metrics. **Named by:** Requester **Input type:** Optional (default value is 0) **Format:** Numeric **Example:** 365
Treatment Episode Gap	EPISODEGAP	**Details:** sets the number of days allowed between two consecutive claims to consider them as part of the same treatment episode. For a given claim, a gap of more than EPISODEGAP days between the claim date and the date of last day of supply of the previous claim triggers a new treatment episode. For example, if EPISODEGAP=10, claim1's last day of supply is on 1/31/2012 and claim2's start date is 2/12/2012, the MP algorithm starts a new treatment episode on 2/12/2012 because there are more than 10 days between the two claims. **Note 1:** gap days bridged are included in the days at risk metrics. See Section V.B.3 for more details. **Note 2:** gaps are assessed and bridged before the application of episode extensions (EXPEXTPER; below). **Named by:** Requester **Input type:** Required (0 must be entered if no EPISODEGAP is required) **Format:** Numeric **Example:** 10
Episode Extension Period	EXPEXTPER	**Details:** extends the length of the treatment episode by specified number of days. A treatment episode can be extended EXPEXTPER days after the last day of supply of the treatment episode's last claim. **Note 1:** extension days are added after the stockpiling algorithm has been applied and treatment episodes are created. See Section V.B.1 and Section V.B.3 for details. **Note 2:** extensions days are added after any episode gaps have been bridged (see EPISODEGAP parameter; above). **Note 3:** extension days are included in the days at risk

Parameter	Field Name	Description
		metrics. See Section V.B.3 for details. **Named by:** Requester **Input type:** Required (0 must be entered if no EXPEXTPER is required) **Format:** Numeric **Example:** 15
Minimum Episode Duration	MINEPISDUR	**Details:** rejects treatment episodes of fewer than MINEPISDUR days. **Note 1:** criterion applied after any gaps are bridged and extension days added to the length of the treatment episode. **Named by:** Requester **Input type:** Required (0 must be entered if no MINEPISDUR is required) **Format:** Numeric **Example:** 10
Minimum Days Supplied	MINDAYSUPP	**Details:** rejects treatment episodes where less than MINDAYSUPP days supplied were used to build the episode. **Named by:** Requester **Input type:** Required (0 must be entered if no MINDAYSUPP is required) **Format:** Numeric **Example:** 10
Query Care Setting and Principal Diagnosis Indicator	CARESETTINGPRINCIPAL	**Details:** defines the care setting and principal diagnosis requirements applied to the exposure(s) of interest. This field uses combination(s) of the MSCDM variables care setting (EncType) and principal diagnosis flag (PDX) to restrict valid events to those in the requested care settings and with the requested principal diagnosis flag. If no restrictions are required (*e.g.*, requester wants all care settings and any value of PDX), leave the field blank. The following are valid entries; all entries must be in single quotes and separated by a space: • **IPP:** inpatient hospital stays, principal diagnoses • **IPS:** inpatient hospital stays, secondary diagnoses • **IPX:** inpatient hospital stays, unclassified diagnoses • **IP.:** inpatient hospital stays, PDX blank • **ISP:** non-acute institutional stays, principal diagnoses • **ISS:** non-acute institutional stays, secondary diagnoses

Parameter	Field Name	Description
		• **ISX:** non-acute institutional stays, unclassified diagnoses • **IS.:** non-acute institutional stays, PDX blank • **EDP:** emergency department, principal diagnoses • **EDS:** emergency department, secondary diagnoses • **EDX:** emergency department, unclassified diagnoses • **ED.:** emergency department, PDX blank • **AVP:** ambulatory visit, principal diagnoses • **AVS:** ambulatory visit, secondary diagnoses • **AVX:** ambulatory visit, unclassified diagnoses • **AV.:** ambulatory visit, PDX blank • **OAP:** other ambulatory visit, principal diagnoses • **OAS:** other ambulatory visit, secondary diagnoses • **OAX:** other ambulatory visit, unclassified diagnoses • **OA.:** other ambulatory visit, PDX blank **Request Programmer Note 1:** the wildcard symbol (*) can be used to represent "any" values of either care setting or principal diagnosis flag. For example, CARESETTINGPRINCIPAL = 'IP*' will restrict events to inpatient events irrespective of the principal diagnosis flag. CARESETTINGPRINCIPAL = '**P' will restrict diagnosis-defined events to only principal diagnoses, irrespective of the care setting. **Request Programmer Note 2:** the principal diagnosis flag is only relevant for events defined using diagnosis codes. If an event is defined using a procedure code, the third digit of the CARESETTINGPRINCIPAL field must be set to * (*i.e.*, wildcard value). **Note 3:** CARESETTINGPRINCIPAL is allowed to vary between CODEs within the same GROUP. For example, CARESETTINGPRINCIPAL is allowed to equal 'IPP' for one diagnosis code and 'IPP' 'EDP' for another diagnosis code *in the same GROUP*. **Named by:** Requester **Input type:** Optional; Default: blank (*i.e.*, no restrictions) **Format:** Alphanumeric **Example:** 'IPX' 'ED*' '**P'

2. Incident Query File

The Incident Query File is optional. If defined, the file contains the comprehensive set of codes used to refine the incidence definition of the exposure(s) of interest. Just like the Query File, exposure(s) of interest can be defined using a combination of the following allowed code types: NDCs, ICD procedure and diagnosis codes, HCPCS codes, and/or laboratory result values.

The query group structure of the Incident Query File must match that of the Query File. That is, for each GROUP defined in the Incident Query File a matching GROUP must be found in the Query File.

By default, for a given query group, MP3 uses the list of codes included in the Query File to determine the incident status of identified exposure (as of the treatment episode index date). That is, incidence is defined as no exposure of interest in the WASHPER days before the start of the treatment episode. The Incident Query File is used to refine incidence based on a set of codes different than those used to define the exposure of interest in the Query File. Table 3 contains detailed specifications for the Incident Query File.

Table 3: Incident Query File Specification

Parameter	Field Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Request Programmer Note 1**: in many cases value must match GROUP values from the Query File. In the case where all codes in the Incident Query File are used to assess incidence for all GROUPs in the Query 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:** Insulin
Name of Query SubGroup	SUBGROUP	**Details:** standardized name used to refer to a specific exposure of interest within a given query GROUP. **Note 1:** the SUBGROUP field is used by the stockpiling algorithm as group categories to adjust claim service dates. See Section V.B.1 for more details. **Note 2:** useful when a query GROUP contains multiple exposures of interest. For example, if GROUP= “Insulin” SUBGROUP could take values of “Insulin_Oral” and “Insulin_Injectable”. **Note 3:** SUBGROUP values must match between the Query

Parameter	Field Name	Description
		File and the Incident Query File. **Note 4:** 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:** Insulin_Oral
Incident Only Query Code Type	CODETYPE	**Details:** type of each procedure and/or drug code value included in the CODE field (below) of this file. Valid values are: • **DX09**: ICD-9-CM diagnosis • **DX10**: ICD-10-CM diagnosis • **DX11**: ICD-11-CM diagnosis • **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 **Note 1**: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below). **Request Programmer Note 2:** exposures defined using laboratory result values must be created using the Combo Tool (see Combo Tool documentation for details). **Note 3:** when querying a combination item ("combo code") generated by the Combo Tool module, the following code types should be used: • **RXCB**: combo item behaving like a dispensing • **PXCB**: combo item behaving like a procedure • **DXCB**: combo item behaving like a diagnosis **Defined by:** Request programmer

Parameter	Field Name	Description
		Input type: Required **Format:** Alphanumeric; SAS character $4 **Example:** RX11
Incident Only Query Codes	CODE	**Details:** NDC, ICD, and HCPCS code values to be used to refine the incident definition for the exposure(s) of interest. For example, if a requester is examining the occurrence of PROCEDURE X but wants incidence of PROCEDURE X to be defined with respect to PROCEDURE X *and* PROCEDURE Y, the Incident Only Query Code field would include PROCEDURE Y 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. **Note 3**: CODETYPE must be consistent with the expected format of the CODE value (*e.g.*, MP3 will not find any valid matches in the data for CODETYPE=PXC4 and a 3-digit code value). **Note 4**: duplicate CODETYPE-CODE combinations in a given query GROUP are removed by the MP3 algorithm. **Named by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11 **Example:** J3490
Incident Query 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 Query File) **Defined by:** Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** Insulin Lispro
Treatment Episode	INCTRUNC	**Details:** indicates whether observation of the incident query code during follow-up requires truncation of valid treatment

Parameter	Field Name	Description
Truncation Indicator		episodes. Valid values are: • **Y**: treatment episodes should be truncated at the first occurrence of an incident query code • **N:** treatment episodes should not be truncated at the occurrence of the incident query code **Note 1**: INCTRUNC is allowed to vary between CODEs within the same GROUP. For example, INCTRUNC is allowed to equal 'Y' for one code and 'N' for another code *in the same GROUP*. **Note 2**: default value is 'N'. **Defined by**: Requester **Input type**: Required **Format**: SAS character $1 **Example**: N
Incident Query Care Setting and Principal Diagnosis Indicator	CARESETTINGPRINCIPAL	**Details:** defines the care setting and principal diagnosis requirements applied to the incident exposure(s) of interest. This field uses combination(s) of the MSCDM variables care setting (EncType) and principal diagnosis flag (PDX) to restrict valid events to those in the requested care settings and with the requested principal diagnosis flag. If no restrictions are required (*e.g.*, requester wants all care settings and any value of PDX), leave the field blank. The following are valid entries; all entries must be in single quotes and separated by a space: • **IPP:** inpatient hospital stays, principal diagnoses • **IPS:** inpatient hospital stays, secondary diagnoses • **IPX:** inpatient hospital stays, unclassified diagnoses • **IP.:** inpatient hospital stays, PDX blank • **ISP:** non-acute institutional stays, principal diagnoses • **ISS:** non-acute institutional stays, secondary diagnoses • **ISX:** non-acute institutional stays, unclassified diagnoses • **IS.:** non-acute institutional stays, PDX blank • **EDP:** emergency department, principal diagnoses • **EDS:** emergency department, secondary diagnoses • **EDX:** emergency department, unclassified diagnoses • **ED.:** emergency department, PDX blank • **AVP:** ambulatory visit, principal diagnoses • **AVS:** ambulatory visit, secondary diagnoses • **AVX:** ambulatory visit, unclassified diagnoses • **AV.:** ambulatory visit, PDX blank

Parameter	Field Name	Description
		• **OAP:** other ambulatory visit, principal diagnoses • **OAS:** other ambulatory visit, secondary diagnoses • **OAX:** other ambulatory visit, unclassified diagnoses • **OA.:** other ambulatory visit, PDX blank **Request Programmer Note 1:** the wildcard symbol (*) can be used to represent "any" values of either care setting or principal diagnosis flag. For example, CARESETTINGPRINCIPAL = 'IP*' will restrict events to inpatient events irrespective of the principal diagnosis flag. CARESETTINGPRINCIPAL = '**P' will restrict diagnosis-defined events to only principal diagnoses, irrespective of the care setting. **Request Programmer Note 2:** the principal diagnosis flag is only relevant for events defined using diagnosis codes. If an event is defined using a procedure code, the third digit of the CARESETTINGPRINCIPAL field must be set to * (*i.e.*, wildcard value). **Note 3:** CARESETTINGPRINCIPAL is allowed to vary between CODEs within the same GROUP. For example, CARESETTINGPRINCIPAL is allowed to equal 'IPP' for one diagnosis code and 'IPP' 'EDP' for another diagnosis code *in the same GROUP*. **Named by:** Requester **Input type:** Optional; Default: blank (*i.e.*, no restrictions) **Format:** Alphanumeric **Example:** 'IPX' 'ED*' '**P'

3. Event File

The Event File is required. It contains the comprehensive set of codes used to define the event(s) of interest. NDCs, ICD-9-CM procedure and diagnosis codes, HCPCS codes, and/or laboratory result values can be used to define events of interest, in combination with a care setting and a principal diagnosis indicator (diagnosis codes only). Events can be defined using any mix of allowed code types.

The query group structure of the Event File must match that of the Query File. That is, for each GROUP defined in the Query File a matching GROUP must be found in the Event File to define an event (or group of events).

Table 4: Event File Specification

Parameter	Variable Name	Description
Name of Query	GROUP	**Details:** standardized name used to refer to a query GROUP for

Parameter	Variable Name	Description
Group		event(s) of interest to be queried. **Note 1**: must match a GROUP value from the Query File. **Note 2**: if multiple codes are needed to define an event, they need to be grouped using the same GROUP value. **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:** AMI
Name of Event Subgroup	SUBGROUP	**Details:** contains names of subgroups of event codes in this file. This variable is not used by the MP algorithm but it is useful for tracking purposes. **Note 1:** SUBGROUP values must match between the Event File and the Incident Event File. **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:** Subendocardial_infarction
Event Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this Event File. Valid values are: • **DX09**: ICD-9-CM diagnosis • **DX10**: ICD-10-CM diagnosis • **DX11**: ICD-11-CM diagnosis • **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 **Note 1**: for CODETYPE=RX09, a nine-digit NDC value must be

Parameter	Variable Name	Description
		included in the CODE field (below). **Request Programmer Note 2:** outcomes defined using laboratory result values must be created using the Combo Tool (see Combo Tool documentation for details). **Note 3:** when querying a combination item ("combo code") generated by the Combo Tool module, the following code types should be used: • **RXCB**: combo item behaving like a dispensing • **PXCB**: combo item behaving like a procedure • **DXCB**: combo item behaving like a diagnosis **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4. **Example:** DX09
Event Codes of Interest	CODE	**Details:** code values to be used to define events. **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.*, MP3 will not find any valid matches in the data for CODETYPE=PXC4 and a 3-digit code value). **Note 4**: duplicate CODETYPE-CODE combinations are removed by the MP3 algorithm. **Defined by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11. **Example:** J3490
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	Variable Name	Description
		Defined by: Request Programmer **Input type:** Optional **Format:** SAS character $30. **Example:** AMI subendocardial infarction
Event Washout Period	WASHPER	**Details:** length of event washout period in days. The washout period is a period before an incident treatment episode during which a member cannot have any evidence of event(s) of interest or any other event(s) specified in the Incident Event File. **Note 1**: the event washout period looks back from the *treatment episode* index date. **Note 2**: length of event washout period days must be the same within a given GROUP. **Note 3:** the MP algorithm may use days before QUERYFROM to determine if continuous enrollment and incidence criteria are met. **Note 4**: in conjunction with the ENROLGAP, COVERAGE, and ENRDAYS parameters, the WASHPER 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, the ENRDAYS parameter value is only 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 treatment episode is excluded from output metrics. **Note 5**: **special case**: when WASHPER = missing the program requires ENRDAYS of continuous enrollment but only considers a treatment episode valid if, at index date, the member has no evidence of an event in their entire available enrollment history. **Named by:** Requester **Input type:** Required (0 must be entered if no WASHPER is required) **Format:** Numeric **Example:** 365
Event De-duplication Process	EVENTCOUNT	**Details:** specifies how events are counted by the MP algorithm. Valid values are: • **0:** counts all occurrences of an event group code of interest. • **1:** de-duplicates occurrences of the *same event code* on the same day (i.e., de-duplicates at the exact match code

Parameter	Variable Name	Description
		level). • **2:** de-duplicates occurrences of the *same event group code* on the same day (e.g., de-duplicates at the GROUP level). Consider the example where the event of interest is defined with ICD-9-CM diagnosis codes 250.01 and 250.11 in any care setting. A member has an occurrence of code=250.01 on two separate AV records and of code=250.11 on another AV record on the same date during his/her incident treatment episode. EVENTCOUNT=0 will identify three events. EVENTCOUNT=1 will identify two events. EVENTCOUNT=2 will identify one event. **Note 1:** MP output metrics report total events and the number of treatment episodes with at least one event. **Note 2:** days-at-risk during a valid treatment episode stop accruing after the occurrence of the first event. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $1. **Example:** 2
Event Care Setting and Principal Diagnosis Indicator	CARESETTINGPRINCIPAL	**Details:** defines the care setting and principal diagnosis requirements applied to the event(s) of interest. This field uses combination(s) of the MSCDM variables care setting (EncType) and principal diagnosis flag (PDX) to restrict valid events to those in the requested care settings and with the requested principal diagnosis flag. If no restrictions are required (*e.g.*, requester wants all care settings and any value of PDX), leave the field blank. The following are valid entries; all entries must be in single quotes and separated by a space: • **IPP:** inpatient hospital stays, principal diagnoses • **IPS:** inpatient hospital stays, secondary diagnoses • **IPX:** inpatient hospital stays, unclassified diagnoses • **IP.:** inpatient hospital stays, PDX blank • **ISP:** non-acute institutional stays, principal diagnoses • **ISS:** non-acute institutional stays, secondary diagnoses • **ISX:** non-acute institutional stays, unclassified diagnoses • **IS.:** non-acute institutional stays, PDX blank • **EDP:** emergency department, principal diagnoses • **EDS:** emergency department, secondary diagnoses • **EDX:** emergency department, unclassified diagnoses • **ED.:** emergency department, PDX blank

Parameter	Variable Name	Description
		• **AVP:** ambulatory visit, principal diagnoses • **AVS:** ambulatory visit, secondary diagnoses • **AVX:** ambulatory visit, unclassified diagnoses • **AV.:** ambulatory visit, PDX blank • **OAP:** other ambulatory visit, principal diagnoses • **OAS:** other ambulatory visit, secondary diagnoses • **OAX:** other ambulatory visit, unclassified diagnoses • **OA.:** other ambulatory visit, PDX blank **Request Programmer Note 1:** the wildcard symbol (*) can be used to represent "any" values of either care setting or principal diagnosis flag. For example, CARESETTINGPRINCIPAL = 'IP*' will restrict events to inpatient events irrespective of the principal diagnosis flag. CARESETTINGPRINCIPAL = '**P' will restrict diagnosis-defined events to only principal diagnoses, irrespective of the care setting. **Request Programmer Note 2:** the principal diagnosis flag is only relevant for events defined using diagnosis codes. If an event is defined using a procedure code, the third digit of the CARESETTINGPRINCIPAL field must be set to * (*i.e.*, wildcard value). **Note 3:** CARESETTINGPRINCIPAL is allowed to vary between CODEs within the same GROUP. For example, CARESETTINGPRINCIPAL is allowed to equal 'IPP' for one diagnosis code and 'IPP' 'EDP' for another diagnosis code *in the same GROUP*. **Named by:** Requester **Input type:** Optional; Default: blank (*i.e.*, no restrictions) **Format:** Alphanumeric **Example:** 'IPX' 'ED*' '**P'
Event Blackout Period	BLACKOUTPER	**Details:** the event blackout period in days. The requester can specify a period at the start of a treatment episode during which valid events found by the MP3 algorithm are ignored. That is, the at-risk period starts at the end of the blackout period. Moreover, if an event occurs during the blackout period, the episode will not be considered incident with respect to the event (and thus excluded from output metrics). See Section V.B.3 for more details. **Note 1**: this allows requester to exclude "same-day" events by setting the BLACKOUTPER to 1. **Named by:** Requester **Input type:** Required (0 must be entered if no BLACKOUTPER is required)

Parameter	Variable Name	Description
		Format: Numeric **Example:** 7

4. Incident Event File

The Incident Event File is optional. It contains the comprehensive set of codes used to refine the incidence definition of the event(s) of interest. Just like the Event File, NDCs, ICD procedure and diagnosis codes, HCPCS codes, and/or laboratory result values can be used to define incident events of interest, in combination with a care setting and a principal diagnosis indicator (diagnosis codes only). Incident events can be defined using any mix of allowed code types.

The query 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 event(s) of interest.

By default, for a given query group MP3 uses the list of codes included in the Event File to determine the incident status of event(s) of interest (as of the treatment episode index date). That is, incidence is defined as no event of interest in the WASHPER days before the start of the treatment episode. 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 event(s) of interest in the Event File. For example, a requester may want to evaluate the occurrence of incident principal AMI diagnoses in the inpatient and ED settings, but define incidence as *any* prior AMI diagnoses in *any* care setting. Table 5 contains detailed specifications for the Incident Event File.

Table 5: Incident Event File Specification

Parameter	Field Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Note 1**: must match GROUP values from the Query File. **Named by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $30; no special characters allowed; underscores must be used to mark spaces. **Example:** Insulin
Name of Event Subgroup	SUBGROUP	**Details:** contains names of subgroups of event codes in this file. This variable is not used by the MP algorithm but it is useful for tracking purposes. **Note 1:** SUBGROUP values must match between the Event File and the Incident Event File. **Named by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $30; special characters

Parameter	Field Name	Description
		(*e.g.*, commas, periods, hyphens, etc.) allowed and underscores must be used to mark spaces. **Example:** Anxiety, Dizziness
Incident Only Event Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this Incident Event File. Valid values are: • **DX09**: ICD-9-CM diagnosis • **DX10**: ICD-10-CM diagnosis • **DX11**: ICD-11-CM diagnosis • **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 **Note 1**: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below). **Request Programmer Note 2:** outcomes defined using laboratory result values must be created using the Combo Tool (see Combo Tool documentation for details). **Note 3:** when querying a combination item ("combo code") generated by the Combo Tool module, the following code types should be used: • **RXCB**: combo item behaving like a dispensing • **PXCB**: combo item behaving like a procedure • **DXCB**: combo item behaving like a diagnosis **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4. **Example:** DX09
Incident Only Event Codes	CODE	**Details:** code values used to refine the incident definition for the event of interest. 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

Parameter	Field Name	Description
		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. **Note 3**: CODETYPE must be consistent with the expected format of the CODE value (*e.g.*, MP3 will not find any valid matches in the data for CODETYPE =PXC4 and a 3-digit code value). **Note 4**: duplicate CODETYPE-CODE combinations are removed by the MP3 algorithm. **Named by:** Requester, with support from MSOC as needed **Input type:** Required **Format:** Alphanumeric; SAS character $11 **Example:** J3490
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:** AMI subendocardial infarction
Incident Event Care Setting and Principal Diagnosis Indicator	CARESETTINGPRINCIPAL	**Details:** defines the care setting and principal diagnosis requirements applied to the incident event(s) of interest. This field uses combination(s) of the MSCDM variables care setting (EncType) and principal diagnosis flag (PDX) to restrict valid incident events to those in the requested care settings and with the requested principal diagnosis flag. If no restrictions are required (*e.g.*, requester wants all care settings and any value of PDX), leave the field blank. The following are valid entries; all entries must be in single quotes and separated by a space: • **IPP:** inpatient hospital stays, principal diagnoses

Parameter	Field Name	Description
		• **IPS:** inpatient hospital stays, secondary diagnoses • **IPX:** inpatient hospital stays, unclassified diagnoses • **IP.:** inpatient hospital stays, PDX blank • **ISP:** non-acute institutional stays, principal diagnoses • **ISS:** non-acute institutional stays, secondary diagnoses • **ISX:** non-acute institutional stays, unclassified diagnoses • **IS.:** non-acute institutional stays, PDX blank • **EDP:** emergency department, principal diagnoses • **EDS:** emergency department, secondary diagnoses • **EDX:** emergency department, unclassified diagnoses • **ED.:** emergency department, PDX blank • **AVP:** ambulatory visit, principal diagnoses • **AVS:** ambulatory visit, secondary diagnoses • **AVX:** ambulatory visit, unclassified diagnoses • **AV.:** ambulatory visit, PDX blank • **OAP:** other ambulatory visit, principal diagnoses • **OAS:** other ambulatory visit, secondary diagnoses • **OAX:** other ambulatory visit, unclassified diagnoses • **OA.:** other ambulatory visit, PDX blank **Request Programmer Note 1:** the wildcard symbol (*) can be used to represent "any" values of either care setting or principal diagnosis flag. For example, CARESETTINGPRINCIPAL = 'IP*' will restrict incident events to inpatient incident events irrespective of the principal diagnosis flag. CARESETTINGPRINCIPAL = '**P' will restrict diagnosis-defined incident events to only principal diagnoses, irrespective of the care setting. **Request Programmer Note 2:** the principal diagnosis flag is only relevant for incident events defined using diagnosis codes. If an incident event is defined using a procedure code, the third digit of the CARESETTINGPRINCIPAL field must be set to * (*i.e.*, wildcard value). **Note 3:** CARESETTINGPRINCIPAL is allowed to vary between CODEs within the same GROUP. For example, CARESETTINGPRINCIPAL is allowed to equal 'IPP' for one diagnosis code and 'IPP' 'EDP' for another diagnosis code in the same GROUP. **Named by:** Requester **Input type:** Optional; Default: blank (*i.e.*, no restrictions) **Format:** Alphanumeric **Example:** 'IPX' 'ED*' '**P'

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 MP3 Inclusion/Exclusion Conditions File allows restrictions based on the following code types: NDCs, ICD diagnosis and procedure codes, HCPCS codes, and/or laboratory result values can be used to define condition(s) of interest. Condition(s) can be defined using any mix of these allowed code types. A lookback period can be defined for each condition code specified.

A condition may be specified for each query GROUP in the Query File. Values of the GROUP fields must match between the Query File and the Inclusion/Exclusion Conditions File. Table 6 contains detailed specifications for the Inclusion/Exclusion Conditions File.

Table 6: Inclusion/Exclusion Conditions File Specification

Parameter	Variable Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Note 1**: must match GROUP values from the Query 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:** Insulin
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 MP 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:** Diabetes
Condition Code Type	CODETYPE	**Details:** type of each code value included in the CODE field (below) of this file.

Parameter	Variable Name	Description
		Valid values are: • **DX09**: ICD-9-CM diagnosis • **DX10**: ICD-10-CM diagnosis • **DX11**: ICD-11-CM diagnosis • **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 **Note 1**: for CODETYPE=RX09, a nine-digit NDC value must be included in the CODE field (below). **Request Programmer Note 2:** inclusion/exclusions defined using laboratory result values must be created using the Combo Tool (see Combo Tool documentation for details). **Note 3:** when querying a combination item ("combo code") generated by the Combo Tool module, the following code types should be used: • **RXCB**: combo item behaving like a dispensing • **PXCB**: combo item behaving like a procedure • **DXCB**: combo item behaving like a diagnosis **Defined by:** Request programmer **Input type:** Required **Format:** Alphanumeric; SAS character $4 **Example:** PX09
Condition Code	CODE	**Details:** code values to be used 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.

Parameter	Variable Name	Description
		Note 3: CODETYPE must be consistent with the expected format of the CODE value (*e.g.*, MP3 will not find any valid matches in the data for CODETYPE=PXC4 and a 3-digit CODE value). **Note 4**: duplicate CODETYPE - CODE combinations are removed by the MP3 algorithm. **Defined by:** Requester, with support from MSOC as needed **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 (the MP9 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:** Diabetes with ketoacidosis
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
Lookback Period Start	CONDFROM	**Details:** used in combination with CONDTO. CONDFROM defines the start of the lookback period for each condition code specified, expressed in terms of “days from Index Date”. 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 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 condition code, the index date is included in the lookback

Parameter	Variable Name	Description
		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:** used in combination with CONDFROM. CONDTO defines the end of the lookback period for each condition code specified, expressed in terms of "days from Index Date". 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 condition code the index date is included in the lookback period. **Named by:** Requester **Input type:** Required **Format:** Numeric **Example:** -1
Condition Care Setting and Principal Diagnosis Indicator	CARESETTINGPRINCIPAL	**Details:** defines the care setting and principal diagnosis requirements applied to the condition(s) of interest. This field uses combination(s) of the MSCDM variables care setting (EncType) and principal diagnosis flag (PDX) to restrict valid conditions to those in the requested care settings and with the requested principal diagnosis flag. If no restrictions are required (*e.g.*, requester wants all care settings and any value of PDX), leave the field blank. The following are valid entries; all entries must be in single quotes and separated by a space: • **IPP:** inpatient hospital stays, principal diagnoses • **IPS:** inpatient hospital stays, secondary diagnoses • **IPX:** inpatient hospital stays, unclassified diagnoses • **IP.:** inpatient hospital stays, PDX blank • **ISP:** non-acute institutional stays, principal diagnoses • **ISS:** non-acute institutional stays, secondary

Parameter	Variable Name	Description
		diagnoses • **ISX:** non-acute institutional stays, unclassified diagnoses • **IS.:** non-acute institutional stays, PDX blank • **EDP:** emergency department, principal diagnoses • **EDS:** emergency department, secondary diagnoses • **EDX:** emergency department, unclassified diagnoses • **ED.:** emergency department, PDX blank • **AVP:** ambulatory visit, principal diagnoses • **AVS:** ambulatory visit, secondary diagnoses • **AVX:** ambulatory visit, unclassified diagnoses • **AV.:** ambulatory visit, PDX blank • **OAP:** other ambulatory visit, principal diagnoses • **OAS:** other ambulatory visit, secondary diagnoses • **OAX:** other ambulatory visit, unclassified diagnoses • **OA.:** other ambulatory visit, PDX blank **Request Programmer Note 1:** the wildcard symbol (*) can be used to represent "any" values of either care setting or principal diagnosis flag. For example, CARESETTINGPRINCIPAL = 'IP*' will restrict conditions to inpatient conditions irrespective of the principal diagnosis flag. CARESETTINGPRINCIPAL = '**P' will restrict diagnosis-defined conditions to only principal diagnoses, irrespective of the care setting. **Request Programmer Note 2:** the principal diagnosis flag is only relevant for conditions defined using diagnosis codes. If a condition is defined using a procedure code or NDC, the third digit of the CARESETTINGPRINCIPAL field must be set to * (*i.e.*, wildcard value). **Note 3:** CARESETTINGPRINCIPAL is allowed to vary between CODEs within the same GROUP. For example, CARESETTINGPRINCIPAL is allowed to equal 'IPP' for one diagnosis code and 'IPP' 'EDP' for another diagnosis code *in the same GROUP*. **Named by:** Requester **Input type:** Optional; Default: blank (*i.e.*, no restrictions) **Format:** Alphanumeric **Example:** 'IPX' 'ED*' '**P'

6. Charlson Comorbidity Index File

The Charlson Comorbidity Index (CCI) File is optional. It is used to stratify results based on ranges of CCI scores. Three CCI scores are calculated (pre-index period CCI, index period CCI, and a pre-index + index period CCI), each of which uses different lookup periods and comorbidities to calculate the score. The "index period" is a period that starts and ends immediately before (or a user-defined period that is close to) the index date, and the "pre-index period" is a period that precedes the index period. The CCI module uses three parameters, PRIORDAYS, INDEXDAYS, and INCLINDEX, to define "pre-index" and "index" periods for observing comorbidities of interest and calculating the three CCI scores. Section V.E describes the three parameters and the three CCI calculations in detail.

If the CCI file is defined, it contains the comprehensive set of parameters used to define how CCI scores should be calculated and how results should be stratified.

A range of CCI scores may be specified for each query GROUP in the CCI File. Values of the GROUP fields must match between the Query File and the CCI File . Table 7 contains detailed specifications for the CCI File.

Table 7: Charlson Comorbidity Index File Specification

Parameter	Variable Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Note 1**: must match GROUP values from the Query 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:** Insulin
Raw Number of Pre-Index Days	PRIORDAYS	**Details:** used in conjunction with INDEXDAYS to define the pre-index period length. PRIORDAYS is not used to define the index period length. The pre-index and index periods are used to define the lookup period for observing conditions of interest (see Section V.E). **Note 1:** the pre-index period length is defined as PRIORDAYS-INDEXDAYS. Therefore, if INDEXDAYS=0, PRIORDAYS is equal to the pre-index period length. **Note 2**: PRIORDAYS must be >= to INDEXDAYS. **Note3:** if a member does not have PRIORDAYS +INDEXDAYS + INCLINDEX days of continuous enrollment, they are included in the cohort but the CCI score is not calculated. **Named by:** Requester

Parameter	Variable Name	Description
		Input type: Required **Format:** Numeric **Example:** 365
Raw Number of Index Days	INDEXDAYS	**Details:** used in conjunction with INCLINDEX to define the index period length and used in conjunction with PRIORDAYS to define the pre-index period length. The pre-index and index periods are used to define the lookup period for observing conditions of interest (see Section V.E). **Note 1:** the index period length is defined as INDEXDAYS+INCLINDEX. Therefore, if INCLINDEX=0, INDEXDAYS is equal to the index period length. **Note 2:** the pre-index period length is defined as PRIORDAYS-INDEXDAYS. Therefore, if INDEXDAYS=0, PRIORDAYS is equal to the pre-index period length. **Note 3**: PRIORDAYS must be >= to INDEXDAYS. **Note 4:** if a member does not have PRIORDAYS +INDEXDAYS + INCLINDEX days of continuous enrollment, they are included in the cohort but the CCI score is not calculated. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** 30
Include Index Date	INCLINDEX	**Details:** instructs the MP to include the index date or days after the index date in the definition of the index lookup period. Used in conjunction with the INDEXDAYS to define the index period length (see Section V.E). INCLINDEX is not used to define the pre-index period length. **Note 1:** the index period length is defined as INDEXDAYS+INCLINDEX **Note 2**: INCLINDEX=0 excludes the index date and INCLINDEX=1 includes the index date in the index period. INCLINDEX >1 will include days beyond the index date. For example, if Index Date=01/08/2009 and INCLINDEX is set to 5, the MP algorithm will start looking for that condition code on 01/12/2009. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** 0
CCI Group	CCIGROUP	**Details:** range of CCI scores to be used for result stratification.

Parameter	Variable Name	Description
Stratification		**Note 1:** each *range* needs to be separated by a space; use "+" if the last group is open ended. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $20. **Example:** 0 1 2-3 4-7 8+
Keep Comorbidity-level Indicators	KEEPALLDUM	**Details:** instructs the MP to preserve additional comorbidity-level indicators in the output files (*e.g.*, AMI, CHF, PVD, etc.). If additional output for comorbidity-level indicators are requested, KEEPALLDUM=1; else KEEPALLDUM=0. **Defined by:** Request programmer **Input type:** Required **Format:** Numeric **Example:** 0

7. Medical Utilization Stratification File

The Medical Utilization Stratification File is optional. It is used to add result stratification options based on ranges of number of medical visits counted during a user-defined period of time. If defined, it contains the comprehensive set of parameters used to define what medical visits should be counted (*e.g.*, what care setting) and how results should be stratified based on specified ranges.

A range of number of medical visits may be specified for each query GROUP in the Medical Utilization Stratification File. Values of the GROUP fields must match between the Query File and the Medical Utilization Stratification File. Table 8 contains detailed specifications for the Medical Utilization Stratification File.

Table 8: Medical Utilization Stratification File Specification

Parameter	Variable Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Note 1**: must match GROUP values from the Query 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:** Insulin
Length of Lookup Period	PRIORDAYS	**Details:** number of days defining the length of lookup period before treatment initiation to calculate the number of medical visits of

Parameter	Variable Name	Description
before Index Date		specified care setting(s). **Note 1:** used in conjunction with the INCLINDEX parameter (which defines the length of lookup period *on or after* the Index Date) to determine entire lookup period length. **Named by:** Requester **Input type:** Required **Format:** Numeric **Example:** 365
Care Settings to Define Medical Visits	CARESETTINGS	**Details:** the MSCDM encounter types to identify and count medical visits. Valid values 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**: combining care settings generates counts for all settings combined, not separate counts by setting. If results stratified by multiple settings are needed the module must be invoked multiple times. **Note 2**: a member cannot have more than one medical visit per day. For example, if CARESETTINGS = 'IP' 'ED' 'OA' and a member has >=1 record of each (*e.g.*, one for IP, two for ED, and five for OA) with the same admission date (ADate) the module will aggregate all records as one visit for that day. **Note 3**: for inpatient visits (IP), length of stay is not taken into account. In other words, the module will count the number of inpatient admissions as reported in the data. Moreover, inpatient episodes that may overlap are not combined by the module. **Defined by:** Requester **Input type:** Required **Format:** Alphanumeric; SAS character $20. **Example:** 'ED' 'IP'
Counts of Medical Visits Group Stratification	CSSTRAT	**Details:** range of counts of medical visits to be used for result stratification. **Note 1:** needs to be separated by a space; use "+" if the last group is open ended. **Defined by:** Requester

Parameter	Variable Name	Description
		Input type: Required **Format:** Alphanumeric; SAS character $20. **Example:** 0 1 2-7 8+
Include Index Date	INCLINDEX	**Details:** instructs the MP to include the index date in the definition of the index lookup period. **Note 1**: INCLINDEX=0 excludes the index date and INCLINDEX=1 includes the index date. INCLINDEX >1 will include days beyond the index date. For example, if Index Date=01/08/2009, PRIORDAYS=10, and INCLINDEX =5, the MP algorithm will look for medical visits from 12/29/2008 to 01/12/2009. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** INCLINDEX=1

8. Change in Body Mass Index (BMI) Stratification File

The Change in Body Mass Index (BMI) Stratification File is optional. It is used to add result stratification options based on ranges of change in BMI z-score among members age 2-19 years during a user-defined period of time. If defined, it contains parameters used to define how baseline and follow-up BMI are evaluated.

Values of the GROUP fields must match between the Query File and the Change in BMI Stratification File. Table 9 contains detailed specifications for the Change in BMI Stratification File.

Table 9: Change in BMI Stratification File Specification

Parameter	Variable Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Note 1**: must match GROUP values from the Query 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:** Insulin
End of Pre-index period to define baseline BMI	PREINDEXEND	**Details:** number of days, relative to the index date, defining the end of the baseline BMI evaluation period. PREINDEXEND is used in conjunction with PREDAYS (below) to define the baseline BMI evaluation period.

Parameter	Variable Name	Description
		Example: if the index date is 1/1/2007 and PREINDEXEND=3, the last day allowed for the evaluation of baseline BMI will be 1/3/2007 (index date is day 1). **Note 1:** value may be negative if a pre-index period end date before the index date is requested. **Named by:** Requester **Input type:** Required **Format:** Numeric **Example:** PREINDEXEND=3
Number of Days in the Pre-index Period	PREDAYS	**Details:** total number of days, relative to PREINDEXEND, defining the duration of the baseline BMI evaluation period. PREDAYS is used in conjunction with PREINDEXEND (above) to define the baseline BMI evaluation period. **Example:** if the index date is 1/1/2007, PREINDEXEND=3, and PREDAYS=30, the baseline BMI evaluation period will be 12/5/2006-1/3/2007 (*i.e.*, the thirty days prior to and including 1/3/2007). **Request Programmer Note 1:** while PREDAYS will always be "looking back" from the pre-index end date, the parameter only accepts positive values. That is, to look back 30 days PREDAYS should equal 30, not -30. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** PREDAYS=30
Start of Post-index Period to define follow-up BMI	POSTINDEXSTART	**Details:** number of days, relative to the index date, defining the start of the follow-up BMI evaluation period. POSTINDEXSTART is used in conjunction with POSTDAYS (below) to define the follow-up BMI evaluation period. **Example:** if the index date is 1/1/2007 and POSTINDEXSTART=4, the first day of the follow-up BMI evaluation period will be will be 1/4/2007 (index date is day 1). **Note 1:** POSTINDEXSTART must be greater than PREINDEXEND. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** POSTINDEXSTART =4
Number of Days in the Post-index	POSTDAYS	**Details:** total number of days, relative to POSTINDEXSTART, defining the duration of the follow-up BMI evaluation period. POSTDAYS is used in conjunction with POSTINDEXSTART (above) to define the

Parameter	Variable Name	Description
Period		follow-up BMI evaluation period. **Example:** if the index date is 1/1/2007, POSTINDEXSTART=4, and POSTDAYS=45, the follow-up BMI evaluation period will be 1/4/2007 – 2/17/2007 (*i.e.*, the fort-five days following and including 1/4/2007). **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** POSTINDEXSTART = 45
Height and Weight Measurement Lag	HTLAG	**Details:** number of days allowed between height and weight measurements for calculation of BMI. This parameter allows height and weight measurements not taken on the same day to be used to calculate BMI. **Note 1:** if HTLAG > 0 (*i.e.*, BMI is calculated using height and weight measurements that are not taken on the same day) the date of the weight measurement is used to assign the BMI value to the baseline or follow-up period. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** HTLAG = 0
Change in BMI Group Stratification	BMIGROUP	**Details:** stratification groups for change in BMI (z-score). Groups must be separated by a space; do not use "+" if the last group is open ended. **Note 1**: enter only positive values - the program will automatically create both positive and negative change groups. For example, if the request programmer enters 0 0.25 0.5, results will be stratified in the following manner: Low → -0.5 -0.5 → -0.25 -0.25 → 0 0 → 0.25 0.25 → 0.5 0.5 → High **Note 2:** in output, the lower bound is inclusive while the upper bound is not. Therefore, the stratum 0.25 → 0.5 includes 0.25 but does not include 0.5. The stratum 0.5 → High will include 0.5. **Note 3:** if BMI cannot be calculated for the baseline and the follow-

Parameter	Variable Name	Description
		up evaluation period, the change in z-score category will be blank. **Defined by:** Requester **Input type:** Required **Format:** Numeric **Example:** BMIGROUP = 0 0.25 0.5

9. 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 MP3. Table 10 contains detailed specifications for the Output Table Selection File, and a template is provided in Section X.

Table 10: 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 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, Incident Treatment Episodes, Total Dispensings and Days of Supply
Name of Table	TABNAME	**Details**: contains the name of the table generated by the modular

Parameter	Variable Name	Description
Generated by MP program		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

10. 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 treatment episodes (Section V.B.1). 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 11: Dispensing Processing File Specification

Parameter	Variable Name	Description
Name of Query Group	GROUP	**Details:** standardized name used to refer to a query GROUP for exposure(s) of interest to be queried. **Note 1**: must match GROUP values from the Query 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:** Insulin
Same Day	SAMEDAY	**Details**: defines how same day dispensings are processed. The first

Parameter	Variable Name	Description
Dispensing Processing Indicator		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”. **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.

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

V. COMBO TOOL

MP3 is integrated with the Combo Tool, a re-usable SAS macro that allows requesters to define MP3 exposures, events, and inclusion/exclusion criteria using complex algorithms.

The Combo Tool performs several functions, most notably the following:

- Queries the MSDD Laboratory Result table, to define exposures, outcomes, and inclusion/exclusion criteria based on (a range of) laboratory result values
- Combines NDCs, diagnoses, procedures, encounter types, and laboratory result values using "and" and/or "or" joins
- Uses same-day, same-encounter, or time intervals to define events (*e.g.,* diagnoses X and procedure Y within 2 weeks of each other)

Requesters are encouraged to define the algorithm of interest in the MP3 input form and work with an MSOC analyst to ensure that the query is specified correctly. For more information on how the Combo Tool functions and required inputs, please consult the combo tool documentation.

VI. KEY DEFINITIONS

A. ENROLLMENT REQUIREMENTS

All claims used by the MP algorithm to select members of interest and build treatment episodes 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 incident treatment episodes, and identification of events and other inclusion/exclusion criteria.

Since each treatment episode can only be considered incident with at least WASHPER days free of any of the exposure(s) of interest (or any other exposure(s) specified in the Incident Query 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 Query 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. TREATMENT EPISODES

A treatment episode is defined as an uninterrupted sequence of treatment with claims of the same query 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.B.2) defined by the requester.

For claims of drug code types (*i.e.*, RX09 and RX11) the days supply used by the MP algorithm are from the MSCDM outpatient pharmacy file. For other code types used to define query groups (*e.g.*, procedure code types for vaccination or injectables), the MP algorithm assigns a default value of one day of supply.

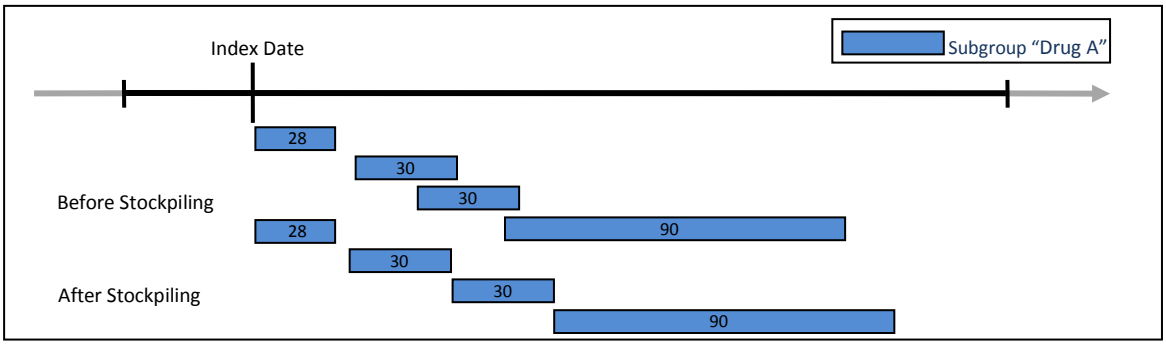
The only treatment episodes considered valid are those that meet the incident definition (based on requester-defined criteria such as query washout period, treatment episode gap, and minimum pre-index enrollment days) and occur during an enrollment period with the user-defined coverage requirements.

1. Stockpiling Algorithm

Because members may refill their drug prescriptions before the end of days supply of the prior prescription, a stockpiling algorithm is used to account for claims with overlapping days of supply of the same Query File or Incident Query File GROUP/SUBGROUP combination. Since this early-refill pattern may artificially reduce the length of the treatment episode and at-risk period (Section V.B.3), the dispensing date of the subsequent overlapping dispensing is adjusted. For example, all codes contained in subgroup "DRUG A" in exposure group "Exposure1"will be input together in the stockpiling algorithm to adjust claim service dates. Claims in subgroup "DRUG B" in exposure group "Exposure1" 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 "Exposure 1" claims with adjusted dates.

Figure 1 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 1: Stockpiling Algorithm

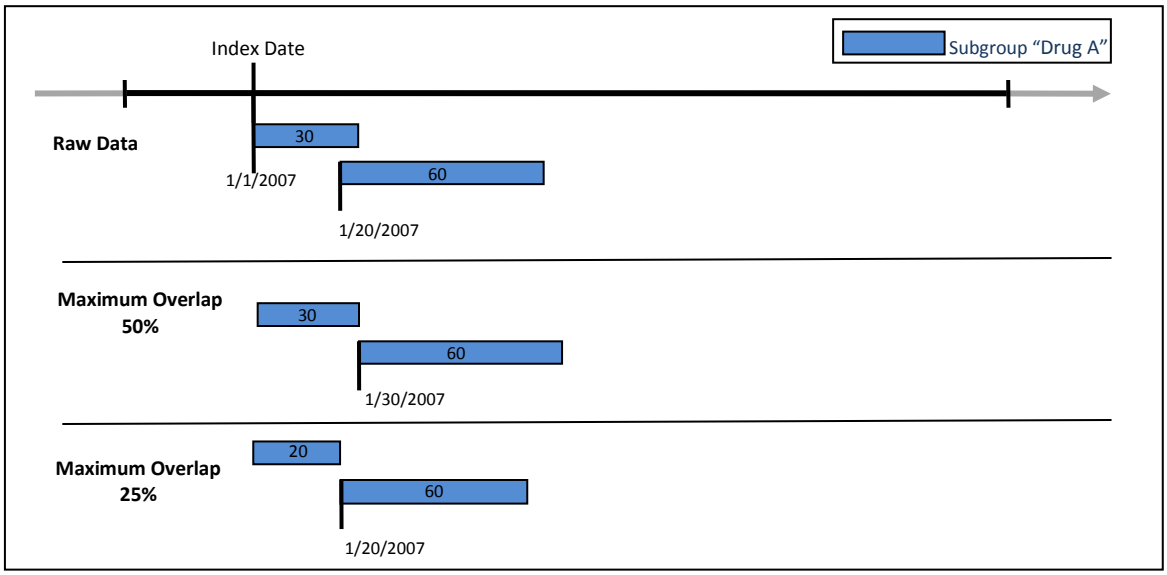


Requesters can specify which dispensings are considered by the MP and how dispensings are stockpiled. The Dispensing Processing File allows requesters to specify a range of allowable days supplied (RxSup in the MSCDM) and amount supplied (RxAmt in the MSCDM) that are considered by the stockpiling algorithm. 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 in the Dispensing Processing File. The PERCENTDAYS parameter sets a maximum percentage of overlap between two dispensings in order for dispensing dates to be adjusted. For example, consider the dispensing pattern in Figure 2, where the first dispensing and second dispensing overlap by 10 days.

Figure 2: Use of Maximum Percentage Overlap in Stockpiling Algorithm

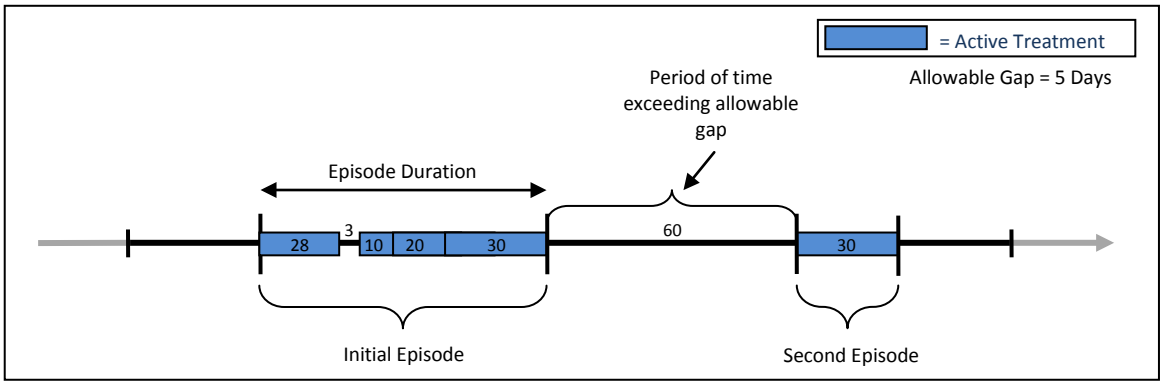


If a requester specifies a maximum overlap of 50%, the stockpiling algorithm will only augment dispensing dates if the number of days of overlap between the two dispensing is less than (30 days * .5) = 15 days. Since the dispensings overlap by 10 days (<15 days) the start date of the second dispensing 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 the EPISODEGAP parameter in the Query File) is the maximum number of days of interrupted days supply that can be found between two claims of the same query group to be considered part of the same treatment episode. If a gap of treatment between two claims of the same query group is smaller than or equal to the allowable gap, the MP3 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 end of first claim and a new treatment episode starts at the beginning of the second claim. The allowable gap is assessed after claim service dates are adjusted by the stockpiling algorithm. Figure 3 summarizes the treatment episode and allowable gap concepts.

Figure 3: Illustration of Treatment Episode and Allowable Gap of MP3



In Figure 3, 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 query 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 MP3 algorithm to create a single episode.

The treatment episode start date (or index date) is the service date on the first claim of the treatment episode. The treatment episode end date corresponds to the earliest of 1) date of the last day of supply preceding a treatment gap that is greater or equal to the "allowable gap" (as in Figure 3); 2) occurrence of a claim with a code for any of the exposure(s) specified in the Incident Query File (if INCTRUNC parameter in the Incident Query File = "Y"); 3) interruption in the member's enrollment; or 4) MSDD end date.

The length of a treatment episode is defined as the difference between the episode end date and the episode start date plus one.

3. Days at Risk and Events, Episode Extension, and Blackout Period

Once valid treatment episodes are created, MP3 assesses whether members had an event during exposure. A valid exposed event is identified when the algorithm can confirm the following two conditions:

1. A claim with a medical code defining the event of interest in the Event File is identified during the treatment episode; this claim must also meet conditions set by optional parameters such as care setting - principal diagnosis indicator combinations, and episode extension and blackout periods.
2. The member must meet enrollment and requester-defined incidence criteria, described further in Section V.C. below.

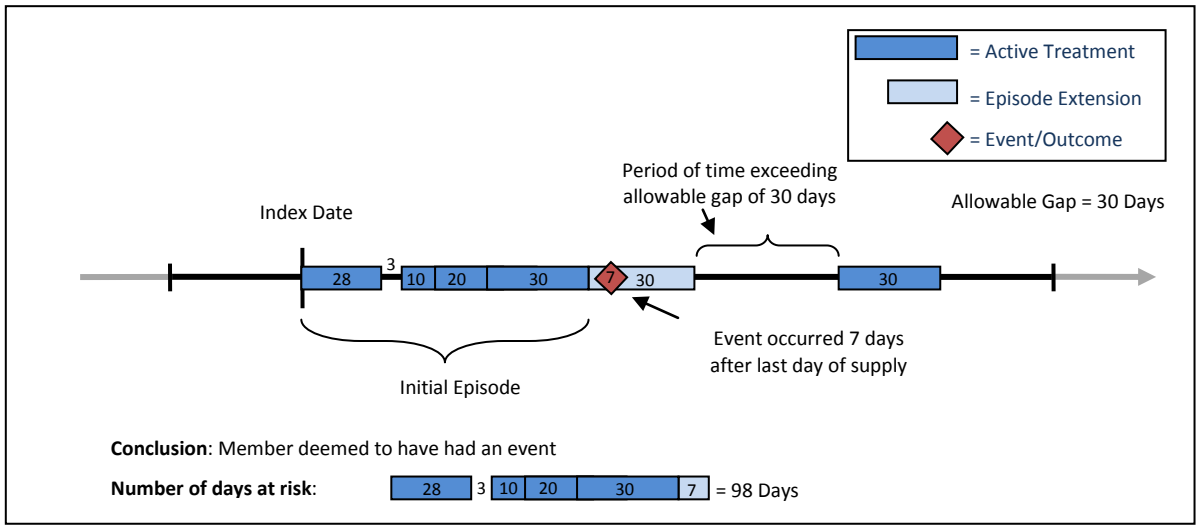
For each query group the number of days "at risk" for an exposed event are reported. Days at risk are based on the length of treatment exposure; days at-risk end upon identification of an exposed event of interest.

The number of days at risk may differ from the treatment episode length (after the stockpiling algorithm has been applied) if the requester makes use of the optional Episode Extension or Blackout Period features described below.

MP3 allows the requester to extend the treatment episode using the episode extension parameter. For example, if a treatment episode ends on December 31st, 2010 and an episode extension of 5 days is allowed, an event occurring between January 1st, 2011 and January 5th, 2011 will be considered valid (*i.e.*, exposed event).

Figure 4 illustrates the case where the allowable treatment gap and the episode extension are both set to 30 days.

Figure 4: Treatment Episode with an Episode Extension



In Figure 4, the active treatment ends on the last treatment day of the fourth dispensing because a gap of more than 30 days separates this date from the fifth dispensing. Since the episode extension is set to 30 days, the event occurring 7 days after the last day of supply of the fourth dispensing is considered valid by the MP3 algorithm.

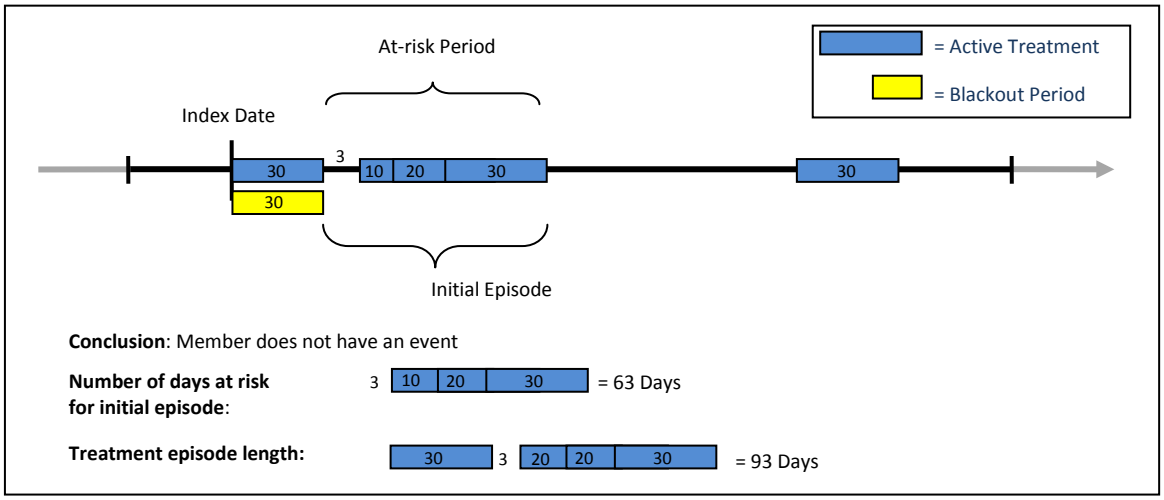
When an episode extension is used, the end date of the episode (and thus the episode length) is adjusted to reflect the additional days of extension. These additional days are also added to the days at risk metrics reported.

If an episode extension extends into another treatment episode (*i.e.*, episodes extension > allowable gap), the episode extension is truncated and no "bridging" of treatment episodes occurs. Under this condition, only events that occur before the start of the second treatment episode will be attributed to the first treatment episode.

MP3 permits a "blackout" period after the index date during which events are not counted. When a blackout period is defined, the effective start of the treatment episode remains the same, but the days at risk are reduced by BLACKOUTPER days. For example, if an episode starts on January 1st, 2010 and the blackout period is equal to 5 days, any events occurring between January 1st, 2010 and January 5th, 2010 will not be attributed to the treatment episode. The episode start date, however, will remain January 1st, 2010.

Figure 5 illustrates the case where a blackout period of 30 days is specified.

Figure 5: Treatment Episode with Blackout Period



In Figure 5, the number of days at risk begins accumulating at the end of the blackout period and extends until the last treatment date of the fourth dispensing. If an event of interest occurs during the blackout period the episode is no longer incident with respect to the event and is therefore excluded from analysis.

C. INCIDENT TREATMENT EPISODES

The MP algorithm will retain only incident treatment episodes. Valid incident episodes are those for which, as of the start of the episode (or index date), meet the specified incidence and enrollment criteria:

1. Member has the required number of days of continuous enrollment prior to index date (specified by the ENRDAYS parameter in the Query File)
2. Member does not have evidence of an exposure code of interest during the specified number of days prior to index date (specified by the WASHPER parameter in the Query File using the code lists included in the Query File and Incident Query File)
3. Member does not have evidence of an event code of interest during the specified number of days prior to index date (specified by the WASHPER parameter in the Event File using the code lists included in the Event File and Incident Event File)

Note that continuous enrollment is required during exposure and event washout periods. Therefore, should the ENRDAYS parameter be inadvertently set shorter than the user-defined exposure and event washout periods, the MP algorithm will require continuous enrollment for the greatest number of days specified by ENRDAYS, exposure WASHPER, and event WASHPER parameters.

The user has the option to define the incident cohort in several ways, using the COHORTDEF parameter in the Query File. Options include:

- Including only the first valid incident treatment episode during the Query Period
- Including all valid incident treatment episodes during the Query Period
- Including all valid incident treatment episodes during the Query Period until an event occurs

D. COHORT INCLUSION OR EXCLUSION BASED ON CONDITIONS OF INTEREST

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

The lookback period is defined by a combination of start and end dates (expressed in terms of days from treatment 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 MP 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.

E. CHARLSON COMORBIDITY INDEX STRATIFICATION

Using the optional Charlson Comorbidity Index (CCI) stratification module, the requester has access to additional result stratification options based on ranges of CCI score. Additional output tables containing metrics on exposure utilization and number of days at risk and events (broken down by range of CCI score as of index date) are provided for the subset of valid members identified by the main MP algorithm. Because those members may have multiple valid treatment episodes (in the case of multiple incidence for exposure) they could fall into multiple ranges of CCI and therefore may be counted in more than one CCI category. Section IX provides examples of output tables relevant to the optional CCI stratification module.

The module is based on a SAS program available from the National Cancer Institute (NCI) website.[2] The NCI program is an implementation of the Deyo[3] adaptation with modifications by Romano.[4] The Mini-Sentinel module enhances the NCI version with the following two features:

[2] National Cancer Institute (NCI). SEER-Medicare: Calculation of Comorbidity Weights, Version accessed 12/13/2012 http://healthservices.cancer.gov/seermedicare/program/comorbidity.html.

1. Inclusion of cancer as a comorbidity
2. Exclusion of the AMI-related hospital stays longer than one day (MEDPAR records)

Because some of the conditions included in the original CCI could be the result of post-operative complications rather than chronic conditions, the Deyo adaptation of the CCI enhances the original application by allowing the lookup period to contain two distinct periods: 1) an **index** period that starts and ends immediately before (or a user-defined period that is close to) the index date and 2) a **pre-index** period that precedes the index period. The adaption eliminates potentially non-chronic conditions from evaluation during the index period, and evaluates all conditions in the pre-index period, using *both* periods to compute a total score.

In addition to the Deyo adaptation of the original CCI, the CCI stratification module calculates a CCI score using the pre-index period only (Pre-Index CCI) and the index period only (Index CCI). The three scores differ by lookup period and the conditions used to calculate the score. Table 12 lists the conditions included in each CCI score and which conditions are included in index and pre-index periods.

Table 12: CCI Conditions by Score and Observation Period*

Condition	Index Period Score	Pre-Index Period Score	Deyo Adaptation of Original Charlson Score
Acute Myocardial Infarction		P	P
Old Myocardial Infarction	X	P	P or X
Congestive Heart Failure		P	P
Peripheral Vascular Disease	X	P	P or X
Cerebrovascular Disease		P	P
Chronic Pulmonary Disease	X	P	P or X
Dementia	X	P	P or X
Hemiplegia or Paraplegia		P	P
Diabetes	X	P	P or X
Chronic Renal Failure	X	P	P or X
Various Cirrhodites	X	P	P or X
Moderate-Severe Liver Disease	X	P	P or X
Acute Ulcer		P	P
Chronic Ulcer		P	
Rheumatologic Disease		P	
AIDS		P	
Cancer		P	P or X

*P indicates the condition is evaluated in the pre-index period; X indicates the condition is evaluated in the Index Period

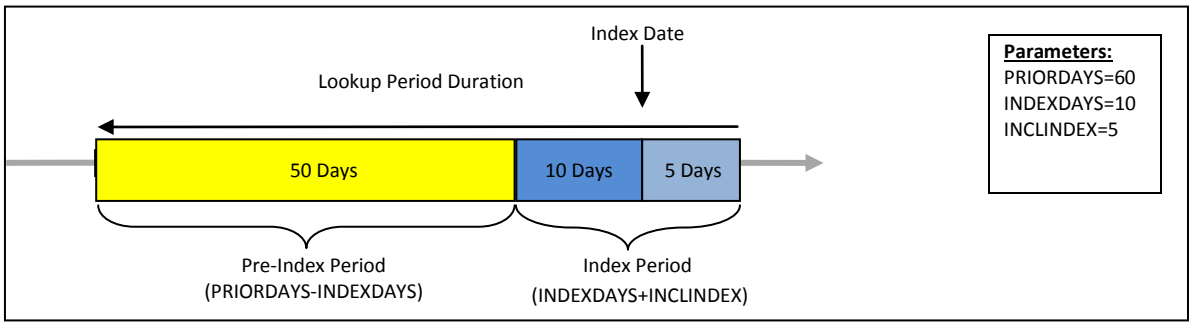
1. Deyo Adaptation of Original CCI

The Deyo adaptation of the original CCI evaluates the occurrence of a total of 14 comorbidities in the pre-index period and a subset of 9 comorbidities in the index period to calculate a total score (Table 12).

[3] Richard A. Deyo, Daniel C. Cherkin and Marcia A. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. Journal of Clinical Epidemiology, Volume 45, Issue 6, June 1992, Pages 613–619.
[4] Romano PS, Roos LL, Jollis JG. Adapting a clinical comorbidity index for use with ICD-9-CM administrative data: differing perspectives. Journal of Clinical Epidemiology, Volume 46, Issue 10, Oct 1993, Pages 1075–1090.

The length of the index and pre-index periods are user-defined by the parameters PRIORDAYS, INDEXDAYS, and INCLINDEX in the CCI File. INDEXDAYS + INCLINDEX define the length of the index period, and PRIORDAYS-INDEXDAYS define the pre-index period. INCLINDEX indicates whether the index date or any days after the index date are included in the index period (see CCI File for further details on these parameters). Figure 6 illustrates these concepts.

Figure 6: Illustration of Lookup and Observation Period Concepts for Deyo Adaptation of Original CCI

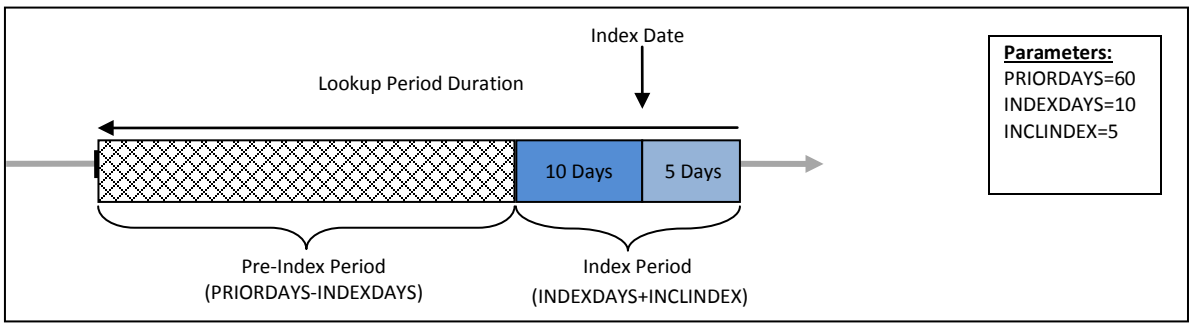


2. Index Period CCI

The Index period CCI evaluates the occurrence of a total of 8 comorbidities in the index period to calculate a total score (Table 12).

The length of the index period is user-defined by the parameters INDEXDAYS and INCLINDEX in the CCI File. INDEXDAYS+INCLINDEX define the index period. PRIORDAYS is irrelevant for Index Period CCI calculations (Figure 7).

Figure 7: Illustration of Lookup and Observation Period Concepts for Index Period CCI



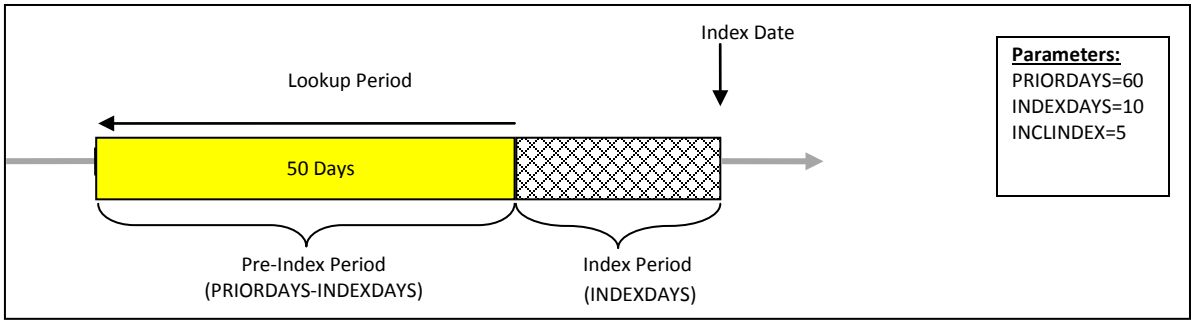
Note in Figure 7 that the Index CCI calculation does not search for evidence of conditions of interest during the Pre-Index Period.

3. Pre-Index Period CCI

The Pre-index period CCI evaluates the occurrence of a total of 17 comorbidities in the pre-index period to calculate a total score (Table 12).

The length of the pre-index period is user-defined by the parameters PRIORDAYS and INDEXDAYS in the CCI File. PRIORDAYS-INDEXDAYS defines the pre-index period. INCLINDEX is irrelevant for Pre-Index Period CCI calculations (Figure 8).

Figure 8: Illustration of Lookup and Observation Period Concepts for Pre-Index Period CCI



Note in Figure 8 that while INDEXDAYS is used to define the temporal relationship between the pre-index period and the index date, the Pre-Index CCI calculation does not search for evidence of conditions of interest during the Index Period.

The most intuitive way to use and interpret the results generated by the Pre-Index CCI is to set the INDEXDAYS and INCLINDEX parameters to zero and the PRIORDAYS parameter to the desired length of lookup period.

F. MEDICAL UTILIZATION STRATIFICATION

Using the optional Medical Utilization Stratification module, the requester has access to additional result stratification options based on ranges of number of medical visits counted during a pre-defined period of time. Additional output tables containing metrics on exposure utilization and number of days at risk and events (broken down by range of number of medical visits as of index date) are provided for the subset of valid members identified by the main MP algorithm. Because those members may have multiple valid treatment episodes (in the case of multiple incidence for exposure), they could fall into multiple ranges of number of medical visits and therefore may be counted in more than one number of medical visit categories. Section IX provides examples of output tables relevant to the optional Medical Utilization Stratification Module.

The requester must specify a length of a pre-index date lookup period during which medical visits should be counted. An optional parameter (INCLINDEX) in the Medical Utilization Stratification File also allows the index date (and days after the index date) to be included in the lookup period.

A range of number of medical visits can be specified (*e.g.*, 0 1-5 6-10 11+). The requester must specify what care settings (*e.g.*, emergency department, hospital inpatient) need to be used to define medical visits. One run of the MP algorithm aggregates counts of visits across all requested care settings (*i.e.*, strata by number of ED or IP visits), but results cannot be stratified by more than one group of care settings (*e.g.*, strata by number of ED and then by number of IP visits). Therefore, a member cannot have more than one medical visit per day. That is, the MP algorithm only counts one visit per member per day for all desired care settings. For example, if medical visits of either emergency department or

hospital inpatient are requested, a member with both an ED and an IP visit on the same day will be considered having only one IP+ED medical visit (of desired care settings).

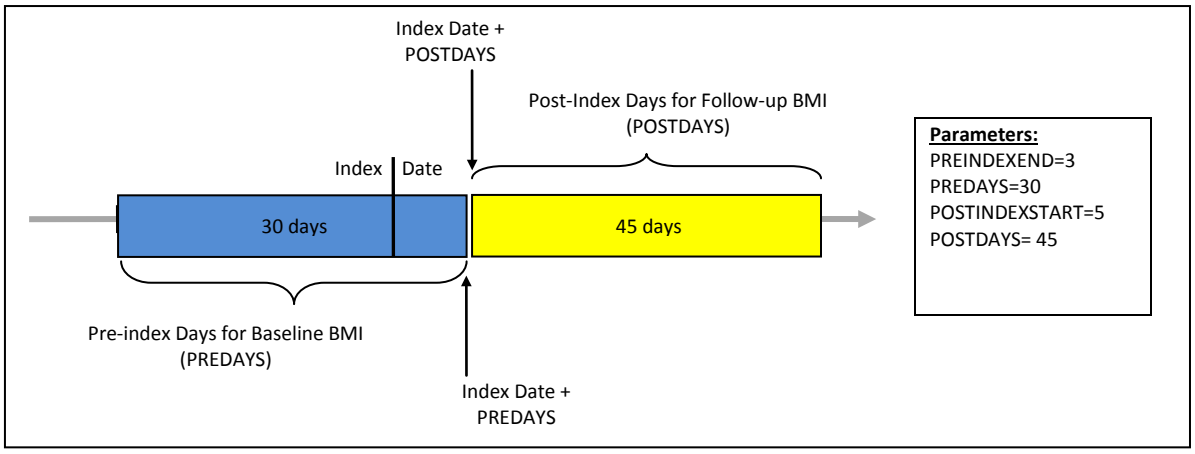
G. CHANGE IN BODY MASS INDEX (BMI) STRATIFICATION

Using the optional Change in BMI Stratification module, the requester has access to additional result stratification options based on changes in BMI z-score in members aged 2-19 years. One additional output table containing metrics on number of members, treatment episodes, events, and days at risk by change in BMI z-score is provided for the subset of valid members identified by the main MP algorithm. Because those members may have multiple valid treatment episodes (in the case of multiple incidence for exposure) they may be counted more than once in the same change in BMI z-score stratum. Section IX provides an example of the output table generated by the optional Change in BMI Stratification Module.

Using the Change in BMI Stratification File the requester must specify several parameters that instruct the module how to evaluate the change in BMI between baseline and follow-up periods: end of pre-index period (PREINDEXEND), pre index days (PREDAYS), start of post-index period (POSTINDEXSTART) and post-index days (POSTDAYS). PREINDEXEND is used in conjunction with PREDAYS to determine the start, end, and duration of the baseline BMI evaluation period. While PREDAYS determines the duration of the period, PREINDEXEND determines the end of the evaluation period *relative to the index date*. The combination of these two parameters allows the module to extrapolate a baseline period start date. POSTINDEXSTART is used in conjunction with POSTDAYS to determine the start, end, and duration of the follow-up BMI evaluation period. While POSTDAYS determines the duration of the period, POSTINDEXSTART determines the start of the evaluation period *relative to the index date*. The combination of these two parameters allows the module to extrapolate a follow-up period end date.

Figure 9 illustrates the four parameters used to define the baseline and follow-up evaluation periods, and how they interact.

Figure 9: Illustration of Parameters to Evaluate Baseline and Follow-up BMI



The module also allows BMI to be calculated for members with height and weight measurements not taken on the same day. The parameter HTLAG can be used to specify the number of days allowed between a height and weight measurement to calculate BMI for both the baseline and follow-up period.

Additionally, stratification categories may be user-defined depending on the requester's needs.

VII. DENOMINATORS AND BACKGROUND RATES

In addition to metrics on exposure(s) and event(s) of interest described in Section IX below, all output tables include metrics on denominators associated with each result stratum. Denominator metrics include (1) count of members and (2) eligible member days.

As MP3 only considers newly exposed patients who meet the incident exposure and event criteria, all denominator metrics are for members who meet these same criteria. That is, all members who can potentially be included in the cohort of newly exposed users (described below) during the query period (but are not necessarily exposed), as defined by various MP3 parameters, are included in denominators.

Eligible Members

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 treatment episode.

1. Member must be continuously enrolled for the required number of days (determined by whichever is longer: ENRDAYS parameter in the Query File, WASHPER parameter in the Query File, or WASHPER parameter in the Event File +1 [*i.e.*, required number of days of enrollment and an additional day for the potential exposure to be observed])
2. Member must be free of exposure claims or claims from exposure(s) found in the Incident Query File during the exposure washout period (determined by the WASHPER parameter in the Query File)
3. Member must be free of event claims or claims from event(s) found in the Incident Event File during the event washout period (determined by the WASHPER parameter in the Event File)
4. Member must meet all inclusion/exclusion condition(s) criteria specified in the Inclusion/Exclusion Conditions File (only applicable if optional inclusion/exclusion module is used)

Member Days

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, MP3 allows for the calculation of background rates for each Query Group specified. For example, the requester can calculate the proportion and rate of new treatment episodes for Query Group Z. The proportion of new users would be defined as the number of users with an incident treatment episode (*i.e.*, the numerator) per X eligible members (*i.e.*, the denominator), whereas the rate of new users would be defined as the number of users with an incident treatment episode per Y person-time (*e.g.*, person-years, member-days). Due to how incident treatment episodes are defined (*i.e.*, with respect to both the treatment episode and the event), "background rates" should be interpreted with caution and with respect to the incidence criteria requested.

VIII. PROGRAM STEPS

The general program steps are:

1. Process the two required input files (and all other optional ones if specified)
2. Extract medical claims from the diagnosis and procedure files
3. Recode claims that occurred during an inpatient stay as inpatient
4. Extract drug claims from the outpatient pharmacy file
5. Apply stockpiling algorithm to query group claims (drug and procedure)
6. Find which members have query group claims during the query period
7. Reconciliation of enrollment episodes (gaps in enrollment less than ENROLGAP and correct coverage type)
8. Create query group treatment episodes and retain only incident treatment episodes satisfying the minimum duration, minimum days of supply, and minimum pre-index enrollment days requirements
9. Filter treatment episodes according to inclusion/exclusion conditions
10. Add events and determine if the treatment episodes are incident with respect to the event
11. Compute denominator member counts and days exposed for each query group
12. Calculate age and identify sex for each cohort member
13. Create output tables with denominators and exposed days

IX. 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 13 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 13: 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.
Procedure Table Name	PROCTABLE	Enter the name of the MSCDM Procedures table.

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

X. OUTPUT TABLES AND ANALYSIS TOOLS

A. OUTPUT TABLES

Twenty-five output tables are created by the modular program. Twenty output tables are created for counts associated with incident treatment episodes and events; additionally, two numerator tables, one denominator table, one dispensing exclusion table, and one attrition table are also output. Tables can be identified by the following suffixes:

- _TABLEX
- _DENTABLE0
- _NUMTAB00
- _NUMTAB01
- _ATTRITIONTABLE
- _STOCKPILING_EXCL

The "X" corresponds to the table number. There is only one denominator table (DENTABLE0), two numerator tables (NUMTAB00, NUMTAB01; one for treatment episodes and one for events), one dispensing exclusion table (STOCKPILING_EXCL) and one attrition table (ATTRITIONTABLE). Below are examples of the output tables.

Output TABLE 1: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply

Query Group	Unique Members w/Treatment Episode	Treatment Episodes	# Dispensings	Days of Supply	Amount Supplied	Eligible Members	Member Days
QGRP1	7,729	8,307	30,959	1,183,897	1,755,432	471,990	290,424,580
QGRP2	208	213	323	11,078	14,991	477,319	296,513,379

Interpretation of Output TABLE 1: Within the QUERYFROM to QUERYTO period, 7,729 members had at least one incident treatment episode for any NDC or procedure in QGRP1. For these members, a total of 8,307 episodes were observed. These episodes accumulated a total of 30,959 dispensings for total days of supply of 1,183,897 and a total amount supplied (i.e., units dispensed) of 1,755,432. Finally, 471,990 members could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 for a total of 290,424,580 eligible member days.

Output TABLE 2: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Age Group

Query Group	Age Group	Unique Members w/Treatment Episode	Treatment Episodes	# Dispensings	Days of Supply	Amount Supplied	Eligible Members	Member Days
QGRP1	18 to 44	3,769	4,024	13,787	483,702	501,001	251,142	126,736,555
QGRP1	45 to 54	2,086	2,221	8,920	343,680	450,124	114,341	65,719,892
QGRP1	55 to 64	1,459	1,561	6,287	267,852	310,254	91,802	58,007,257
QGRP1	65+	473	501	1,965	88,663	99,665	53,218	40,007,782
QGRP2	18 to 44	81	83	113	3,689	4,109	253,404	128,968,127
QGRP2	45 to 54	70	73	123	4,081	4,561	116,311	67,569,719
QGRP2	55 to 64	43	43	70	2,745	3,199	93,294	59,542,638
QGRP2	65+	14	14	17	563	899	53,663	40,472,676

Interpretation of Output TABLE 2: Within the QUERYFROM to QUERYTO period, 3,769 members had at least one incident treatment episode for any NDC or procedure in QGRP1 while aged between 18 and 44 years. For these members, a total of 4,024 episodes were observed for a total of 13,787 dispensings, a total days supply of 483,702, and a total amount supplied (i.e., units dispensed) of 501,001. Finally, 251,142 members aged between 18 and 44 years old could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 for 126,736,555 eligible member days.

Output TABLE 3: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Sex

Query Group	Sex	Unique Members w/Treatment Episode	Treatment Episodes	# Dispensings	Days of Supply	Amount Supplied	Eligible Members	Member Days
QGRP1	F	5,293	5,703	21,698	836,369	911,206	247,896	153,636,054
QGRP1	M	2,436	2,604	9,261	347,528	399,701	224,094	136,788,526
QGRP2	F	113	116	177	6,165	6,999	251,663	157,941,662
QGRP2	M	95	97	146	4,913	5,610	225,656	138,571,717

Interpretation of Output TABLE 3: Within the QUERYFROM to QUERYTO period, 5,293 female members had at least one incident treatment episode for any NDC or procedure in QGRP1. For these members, a total of 5,703 episodes were observed for a total of 21,698 dispensings, total days of supply of 836,369, and total amount supplied (i.e., units dispensed) of 911,206. Finally, 247,896 female members could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 for a total of 153,636,054 eligible member days.

Output TABLE 4: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Year

Query Group	Year	Unique Members w/Treatment Episode	Treatment Episodes	# Dispensings	Days of Supply	Amount Supplied	Eligible Members	Member Days
QGRP1	2006	1,786	1,800	8,057	317,469	333,245	167,465	50,273,462
QGRP1	2007	1,700	1,709	7,332	287,664	310,225	233,271	61,410,911
QGRP2	2006	68	68	102	3,306	4,001	169,901	51,397,580
QGRP2	2007	34	35	52	1,754	2,106	236,675	62,706,730

Interpretation of Output TABLE 4: Within the QUERYFROM to QUERYTO period, 1,786 members had at least one incident treatment episode for any NDC or procedure in QGRP1 starting in 2006. For these

members, a total of 1,800 episodes started in 2006 and these episodes accumulated a total of 8,057 dispensings for total days of supply of 317,469 and total amount supplied (i.e., units dispensed) of 333,245. Finally, a total of 167,465 members could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 in 2006 for a total of 50,273,462 eligible member days.

Output TABLE 5: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Year/Month

Query Group	Year	Month	Unique Members w/Treatment Episode	Treatment Episodes	# Dispensings	Days of Supply	Amount Supplied	Eligible Members	Member Days
QGRP1	2006	1	169	169	587	22,715	27,509	189,938	5,878,989
QGRP1	2006	2	162	162	573	22,919	26,218	189,283	5,295,632
QGRP2	2006	1	4	4	5	142	185	193,764	5,999,868
QGRP2	2006	2	6	6	20	602	799	193,146	5,405,830

Interpretation of Output TABLE 5: Within the QUERYFROM to QUERYTO period, 169 members had at least one incident treatment episode for any NDC or procedure in QGRP1 starting in January 2006. For these members, a total of 169 episodes started in January 2006 and these episodes accumulated a total of 587 dispensings for total days of supply of 22,715 and total amount supplied (i.e., units dispensed) of 27,509. Finally, a total of 189,938 members could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 in January 2006 for a total of 5,878,989 eligible member days.

Output TABLE 6: Counts of Patients, Treatment Episodes, Events and Days at Risk

Query Group	Unique Members w/Treatment Episode	Treatment Episodes	# Events	# Episodes with Events	Days At Risk	Eligible Members	Member Days
QGRP1	7,729	8,307	29	26	1,406,829	471,990	290,424,580
QGRP2	208	213	0	0	17,305	477,319	296,513,379

Interpretation of Output TABLE 6: Within the QUERYFROM to QUERYTO period, 7,229 members had at least one incident treatment episode for any NDC or procedure in QGRP1. For these members, a total of 8,307 episodes were observed and 29 incident events occurred during these episodes. A total of 26 episodes had at least one event. The total days at risk (*i.e.*, days at risk for the event) was 1,406,829. Finally, 471,990 members could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 for a total of 290,424,580 eligible member days.

Output TABLE 7: Counts of Patients, Treatment Episodes, Events and Days at Risk by Year

Query Group	Year	Unique Members w/Treatment Episode	Treatment Episodes	# Events	# Episodes with Events	Days At Risk	Eligible Members	Member Days
QGRP1	2006	1,786	1,800	10	8	379,022	167,465	50,273,462
QGRP1	2007	1,700	1,709	9	8	341,059	233,271	61,410,911
QGRP2	2006	68	68	0	0	5,387	169,901	51,397,580
QGRP2	2007	34	35	0	0	2,846	236,675	62,706,730

Interpretation of Output TABLE 7: Within the QUERYFROM to QUERYTO period, 1,786 members had at least one incident treatment episode for any NDC or procedure in QGRP1 starting in 2006. For these

members, a total of 1,800 episodes started in 2006 and 10 incident events occurred during these episodes. A total of 8 episodes had at least one event. The total days at risk (*i.e.*, days at risk for the event) was 379,022. Finally, 167,465 members could potentially have had an incident treatment episode for any NDC or procedure in QGRP1 in 2006 for a total of 50,273,462 eligible member days.

Output TABLE 8: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of Count of Emergency Department or Hospital Inpatient Visits

Query Group	Number of Visits	Unique Members w/Treatment Episode	Treatment Episodes	Dispensings	Days of Supply	Amount Supplied
QGRP1	0	6,255	6,722	25,039	947,122	1,000,113
QGRP1	1	1,016	1,091	4,054	153,913	175,001
QGRP1	2-4	325	338	1,286	48,444	54,277
QGRP1	5+	133	156	580	34,418	42,327

Output TABLE 8 depicts a medical utilization stratification output table where the requester has specified 1) 180 days in the PRIORDAYS parameter; 2) 0 days in the INCLINDEX parameter; 3) 'IP' and 'ED' in the CARESETTINGS parameter; and 4) 0 1 2-4 5+ groupings in the CSSTRAT parameter in the Medical Utilization Stratification File.

Interpretation of Output TABLE8: Within the QUERYFROM to QUERYTO period, 6,255 members in QGRP1had at least one incident treatment episode and 0 'ED' or 'IP' visits in the 180 days before the index date. For these members, a total of 6,722 episodes with no 'IP' or 'ED' visit in the 180 days prior were observed. These episodes accumulated a total of 25,039 dispensings for total days of supply of 947,122 and total amount supplied (i.e., units dispensed) of 1,000,113.

Note that the number of visits is determined *per treatment episode*. If a member has multiple treatment episodes during the query period (*i.e.*, if multiple incidence for exposure is selected), the member may be counted in more than one 'Number of Visits' stratum.

Output TABLE 9_1: Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of Charlson Comorbidity Index Score (Pre-Index CCI example)

Query Group	PCharlson	Unique Members w/Treatment Episode	Treatment Episodes	# Dispensings	Days of Supply	Amount Supplied
QGRP1	0	6,250	6,717	25,034	947,117	1,000,995
QGRP1	1	1,011	1,086	4,049	153,908	178,646
QGRP1	2-4	320	343	1,281	48,439	57,231
QGRP1	5+	148	161	595	34,433	47,307

Output TABLE 9_1 depicts a Pre-Index CCI stratification output table where the requester has specified 1) 365 days in the PRIORDAYS parameter; 2) 0 days in the INDEXDAYS parameter; 3) 0 days in the INCLINDEX parameter; and 4) 0 1 2-4 5+ groupings in the CCIGROUP parameter in the Charlson Comorbidity Index File. This an example of one of four tables produced for counts of patients, treatment episodes, total dispensings, and days of supply by range of Charlson Comorbidity Index Score. In addition to TABLE 9_1, TABLES 9_2 and 9_3 are produced and include the same metrics for different

calculations of the CCI score (*i.e.*, Deyo adaptation of CCI, Index Period CCI) and TABLE 9 outputs these metrics by all combinations of the three CCI scores.

Interpretation of Output TABLE 9_1: Within the QUERYFROM to QUERYTO period, 6,250 members in QGRP1 had at least one incident treatment episode and a Pre-Index CCI score of 0 in the 365 days before the index date. For these members, a total of 6,717 episodes with a Pre-Index CCI of 0 were observed. These episodes accumulated 25,034 dispensings for total days of supply of 947,117 and total amount supplied (i.e., units dispensed) of 1,000,995.

Note that CCI is determined at index date *for each treatment episode*. If a member has multiple treatment episodes during the query period (*i.e.*, if multiple incidence for exposure is selected), the member may be counted in more than one 'PCharlson' stratum.

Output TABLE 10: Counts of Patients, Treatment Episodes, Number of Events, and Days at Risk by Range of Count of Emergency Department or Hospital Inpatient Visits

Query Group	Number of Visits	Unique Members w/Treatment Episode	Treatment Episodes	Events	Days at Risk
QGRP1	0	6,255	6,722	2,022	146,142
QGRP1	1	1,016	1091	501	52,044
QGRP1	2-4	325	338	125	10,444
QGRP1	5+	133	156	29	7,444

Output TABLE 10 depicts a medical utilization stratification output table where the requester has specified 1) 180 days in the PRIORDAYS parameter; 2) 0 days in the INCLINDEX parameter; 3) 'IP' and 'ED' in the CARESETTINGS parameter; and 4) 0 1 2-4 5+ groupings in the CSSTRAT parameter in the Medical Utilization Stratification File.

Interpretation of Output TABLE 10: Within the QUERYFROM to QUERYTO period, 6,255 members in QGRP1 had at least one incident treatment episode and 0 'ED' or 'IP' visits in the 180 days before the index date. For these members, a total of 6,722 episodes with no 'IP' or 'ED' visit in the 180 days prior were observed, and a total of 2,022 events of interest occurred during these episodes. There were a total of 146,142 days at risk for an event.

Note that the number of visits is determined *per treatment episode*. If a member has multiple treatment episodes during the query period (*i.e.*, if multiple incidence for exposure is selected), the member may be counted in more than one 'Number of Visits' stratum.

Output TABLE 11_1: Counts of Patients, Incident Treatment Episodes, Number of Events, and Days at Risk by Range of Charlson Comorbidity Index Score (Pre-Index CCI example)

Query Group	PCharlson	Unique Members w/Treatment Episode	Treatment Episodes	Events	Days at Risk
QGRP1	0	6,250	6,717	2,123	100,112
QGRP1	1	1,011	1,086	657	43,111
QGRP1	2-4	320	343	145	28,214
QGRP1	5+	148	161	78	10,999

Output TABLE 11_1 depicts a Pre-Index CCI stratification output table where the requester has specified 1) 365 days in the PRIORDAYS parameter; 2) 0 Days in the INCLINDEX parameter; 3) 0 days in the INDEXDAYS parameter; and 4) 0 1 2-4 5+ groupings in the CCIGROUP parameter in the Charlson Comorbidity Index File. This an example of one of four tables produced for counts of patients, incident treatment episodes, number of events, and days at risk by range of Charlson Comorbidity Index Score. In addition to TABLE 11_1, TABLES 11_2 and 11_3 are produced and include the same metrics for different calculations of the CCI score (*i.e.*, Deyo adaptation of CCI, Index Period CCI) and TABLE 11 outputs these metrics by all combinations of the three CCI scores.

Interpretation of Output TABLE 11_1: Within the QUERYFROM to QUERYTO period, 6,250 members in QGRP1had at least one incident treatment episode and a Pre-Index CCI score of 0 in the 365 days before the index date For these members, a total of 6,717 episodes with a Pre-Index CCI of 0 in the 365 days prior were observed, and a total of 2,123 events of interest occurred during these episodes. There was a total of 100,112 days at risk for an event.

Note that CCI is determined at index date *for each treatment episode*. If a member has multiple treatment episodes during the query period (*i.e.*, if multiple incidence for exposure is selected), the member may be counted in more than one 'PCharlson' stratum.

Output TABLE 12: Counts of Patients, Incident Treatment Episodes, Number of Events, and Days at Risk by Range of Change in BMI Z-score

Query Group	Change in Z-score Category	Unique Members w/Treatment Episode	Treatment Episodes	Events	Days at Risk
QGRP1		3,429	3,425	964	94.568
QGRP1	Low - -0.5	1,108	1,248	367	17,152
QGRP1	-0.5 - -0.25	942	1,012	359	14,233
QGRP1	-0.25 - 0	1,201	1,296	422	32,056
QGRP1	0 - 0.25	599	622	366	14,091
QGRP1	0.25 - .05	389	445	256	7,686
QGRP1	0.5 - high	241	259	269	2,650

Interpretation of Output TABLE 12: Within the QUERYFROM to QUERYTO period, 1,108 members in QGRP1 had at least one incident treatment episode and a change in BMI z-score of less than -0.5 after treatment initiation. For these members, a total of 1,248 episodes were observed, and a total of 367 events of interest occurred during these episodes. There was a total of 17,152 days at risk for an event. Note that if BMI cannot be calculated for the baseline *and* the follow-up evaluation period, the change in z-score category will be blank.

Output TABLE 13: Total Members by Number of Treatment Episodes and Number of Events

Query Group	Number of Treatment Episodes per Member	Total Events	Total Members
QGRP1	0	0	50,000
QGRP1	1	0	1,000
QGRP1	1	1	4,000
QGRP1	1	2	2,500
QGRP1	1	3	1,250

Query Group	Number of Treatment Episodes per Member	Total Events	Total Members
QGRP1	2	1	2,800
QGRP1	2	2	2,275
QGRP1	2	3	500
QGRP1	2	4	250
QGRP1	3	1	250
QGRP1	3	2	125
QGRP1	4	1	50

Interpretation of Output TABLE 13: There were 8,750 members with one treatment episode of interest in QGRP1 during the query period (1,000 + 4,000 + 2,500 + 1,250). Of these members, 1,000 experienced no events of interest, 4,000 had one event, 2,500 had two events, and 1,250 had 3 events.

Output TABLE 14: Total Members by Number of Treatment Episodes and Number of Events per Episode

Query Group	Total Number of Episodes	Events per Episode	Total Members
QGRP1	20,000	0	18,000
QGRP1	15,000	1	12,000
QGRP1	10,000	2	10,000
QGRP1	5,000	3	4,500
QGRP1	2,500	4	2,000

Interpretation of Output TABLE 14: In QGRP1, there were there were 15,000 valid treatment episodes that identified 1 event; 12,000 members contributed these episodes.

Output TABLE Stockpiling Exclusions: Number of Members and Dispensings Excluded from Output Metrics due to Dispensing Processing Restrictions

Query Group	Input File	Excluded Members	Excluded Dispensings	Excluded due to RxSup Conditions Only	Excluded due to RxAmt Conditions Only	Excluded due to RxSup and RxAmt Conditions
QGRP1	CONDITION	100	150	75	25	50
QGRP1	EVENT	0	0	0	0	0
QGRP1	QUERY	500	675	350	250	75

Interpretation of Output TABLE Stockpiling Exclusions: In QGRP1 there were 675 dispensings excluded from the creation of valid treatment episodes due to user-defined restrictions on dispensing processing. A total of 350 of these dispensings were excluded due to restrictions on the days supplied only, 250 dispensings were excluded due to restrictions on the amount supplied only, and 75 were excluded due to restrictions on both the days and amount supplied.

B. ANALYSIS TOOLS

1. Incidence Rate Ratios (IRR)

A standalone analysis tool that works in tandem with MP3 output is available to calculate the incidence rate ratios for two cohorts. The tool outputs a comparison of two user defined cohorts from the MP3 output (specifically _NUMTAB01) and provides both the unadjusted and adjusted incidence rate ratios and the corresponding 95% confidence intervals. The user can adjust for any combination of age, gender, year of event and data partner site in the adjusted incidence rate. One output table is generated that contains: number of new users, person-years of follow-up, number of outcome events, incidence per 1,000 persons and incidence rate per 1,000 person-years. Person-years of follow-up are estimated using days at risk standardized into years. Incidence per 1,000 persons is calculated as the number of event outcomes divided by the number of new users, standardized to 1,000 persons. Incidence rate per 1,000 person-years is calculated as the number of event outcomes divided by person-years of follow-up, standardized to 1,000 person-years. Please note that a separate input form is required for calculation of incidence rate ratios and will not be automatically generated from MP3.

2. Attrition Table

Another standalone analysis tool that is executed by default for each run of MP3 is the Attrition Table. This tool outputs a table containing the count of remaining and excluded members following application of inclusion and exclusion criteria. It allows the requester to see how the cohort of interest evolves after successively applying these criteria. The attrition table tool will enable the requester to summarize this information in a single output table.

Table 14: Example of Attrition Table:

Counts of Remaining and Excluded Members for Various Modular Program 3 Selection Criteria

Query Group	Criterion Number	Criterion Description	Members Remaining	Members Excluded
QGRP1	1	Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	10,000	
QGRP1	2	Exclusion – Members must be excluded if they only have episodes with DrugCov=N and MedCov=Y during the query period	10,000	0
QGRP1	3	Exclusion – Members must be excluded if they only have episodes with DrugCov=Y and MedCov=N during the query period	9,500	500
QGRP1	4	Exclusion – Members must be excluded if they only have episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	9,500	0
QGRP1	5	Exclusion - Members must satisfy the age range condition within the query period	9,000	500
QGRP1	6	Exclusion - Members must have at least one QUERYGROUP claim within the query period	5,000	4,000
QGRP1	7	Exclusion - members must have at least one QUERYGROUP episode with at least minimum days supplied (based on	4,500	500

Query Group	Criterion Number	Criterion Description	Members Remaining	Members Excluded
		MinDaysSupp criterion)		
QGRP1	8	Exclusion - members must have at least one QUERYGROUP episode with at least minimum days duration (based on MinEpisDur criterion)	4,500	0
QGRP1	9	Exclusion - Members must have at least one QUERYGROUP episode with more than blackout days duration	4,200	300
QGRP1	10	Exclusion - Members must have at least one QUERYGROUP episode satisfying the enrollment criterion specified by the 'EnrDays' parameter	3,200	1,000
	11	Exclusion - Members must have at least one QUERYGROUP episode satisfying the enrollment criterion specified by the Query 'WashPer' parameter	3,200	0
QGRP1	12	Exclusion - Members must have at least one QUERYGROUP episode satisfying the enrollment criterion specified by the Event 'WashPer' parameter	3,200	0
QGRP1	13	Exclusion - Members must have at least one QUERYGROUP episode that meets Query incidence criterion [no QUERYGROUP claim in the prior Query 'WashPer' days]	2,200	1,000
QGRP1	14	Exclusion - Members must have at least one QUERYGROUP episode that meets Event incidence criterion [no QUERYEVENTGROUP claim in the prior Event 'WashPer' days]	1,700	500
QGRP1	15	Exclusion - Members must have at least one QUERYGROUP episode satisfying the Exclusion enrollment requirement	1,700	0
QGRP1	16	Exclusion - Members must have at least one QUERYGROUP episode satisfying the Exclusion conditions	1,700	0
QGRP1	17	Exclusion - Members must have at least one QUERYGROUP episode satisfying the Inclusion conditions	1,600	100
QGRP1	18	Information - Members with at least one QUERYFILE claim with supply and/or amount outside specified ranges		107
QGRP1	19	Information - Members with at least one EVENTFILE claim with supply and/or amount outside specified ranges		0
QGRP1	20	Information - Members with at least one CONDFILE claim with supply and/or amount outside specified ranges		0

XI. EXAMPLE

Tables 15-24 show partially-populated examples of the Query, Incident Query, Event, Incident Event, Inclusion/Exclusion Conditions, Charlson Comorbidity Index, Medical Utilization Stratification, Change in BMI Stratification, Output Table Selection File, and Dispensing Processing files used to create the output for QGRP1 described in Section IX:

Table 15: Example of Query File

Group	Sub-Group	Code-Type	Code	Cohort-Def	Wash-Per	Enr-Days	Episode-Gap	ExpExt-Per	MinEpis-Dur	MinDay-Supp	CareSetting-Principal

Group	Sub-Group	Code-Type	Code	Cohort-Def	Wash-Per	Enr-Days	Episode-Gap	ExpExt-Per	MinEpis-Dur	MinDay-Supp	CareSetting-Principal
QGRP1	DRUGA	RX09	111111111	02	180	365	30	0	0	0	'IP*' 'ED*' 'IS*' 'AV*' 'OA*'

Table 16: Example of Incident Query File

Group	SubGroup	CodeType	Code	IncTrunc	CareSettingPrincipal
QGRP1	DRUGA	RX09	111111111	N	'IP*' 'ED*' 'IS*' 'AV*' 'OA*'
QGRP1	DRUGA	RX09	111111112	N	'IP*' 'ED*' 'IS*' 'AV*' 'OA*'

Table 17: Example of Event File

Group	SubGroup	CodeType	Code	WashPer	EventCount	BlackOutPer	CareSettingPrincipal
QGRP1	EVENTA	DX09	430	180	3	0	'IP*' 'ED*'

Table 18: Example of Incident Event File

Group	SubGroup	CodeType	Code	CareSettingPrincipal
QGRP1	EVENTA	DX09	430	
QGRP1	EVENTA	DX09	431	

Table 19: Example of Inclusion/Exclusion Conditions File

Group	SubGroup	CodeType	Code	Inclusion	CondFrom	CondTo	CareSettingPrincipal
QGRP1	INCL1	PXC4	99999	1	-180	10	

Table 20: Example of Charlson Comorbidity Index File

Group	PriorDays	IndexDays	InclIndex	CciGroup	KeepAllDum
QGRP1	365	0	0	0 1 2-4 5+	0

Table 21: Example of Medical Utilization Stratification File

Group	CareSettings	PriorDays	InclIndex	CsStrat
QGRP1	'ED' 'IP'	180	0	0 1 2-4 5+

Table 22: Example of Change in BMI Stratification File

Group	PreIndexEnd	PreDays	PostIndexStart	PostDays	HtLag	BMIGroup

Group	PreIndexEnd	PreDays	PostIndexStart	PostDays	HtLag	BMIGroup
QGRP1	2	33	14	365	33	0 0.25 0.5

Table 23: Example of Output Table Selection File

DOCTABNAME	DOCTABDESCR	TABNAME	TABREQUIRED
	Global Denominators	dentable0	Y
	Global Numerators With Treatment Episodes Information	numtab00	Y
	Global Numerators With Events Information	numtab01	Y
	Information About Inclusion/Exclusion Criteria	attritiontable	Y
Table1	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply	table1	Y
Table2	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Age Group	table2	N
Table3	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Sex	table3	Y
Table4	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Year	table4	Y
Table5	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Year/Month	table5	Y
Table6	Counts of Patients, Treatment Episodes, Events and Days at Risk	table6	Y
Table7	Counts of Patients, Treatment Episodes, Events and Days at Risk by Year	table7	Y
Table8	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of Count of Emergency Department or Hospital Inpatient Visits	table8	N
Table9	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of all 3 Charlson Comorbidity Index Score	table9	N
Table9_1	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of Prior Charlson Comorbidity Index Score	table9_1	N
Table9_2	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of Prior + Index Charlson Comorbidity Index Score	table9_2	N
Table9_3	Counts of Patients, Treatment Episodes, Total Dispensings and Days of Supply by Range of Index Charlson Comorbidity Index Score	table9_3	N
Table10	Counts of Patients, Treatment Episodes, Number of Events, and Days at Risk by Range of Count of Emergency Department or Hospital Inpatient Visits	table10	N
Table11	Counts of Patients, Incident Treatment Episodes, Number of Events, and Days at Risk by Range of all 3 Charlson Comorbidity Index Score	table11	N
Table11_1	Counts of Patients, Incident Treatment Episodes, Number of Events, and Days at Risk by Range of Prior Charlson Comorbidity Index Score	table11_1	N
Table11_2	Counts of Patients, Incident Treatment Episodes, Number	table11_2	N

DOCTABNAME	DOCTABDESCR	TABNAME	TABREQUIRED
	of Events, and Days at Risk by Range of Prior + Index Charlson Comorbidity Index Score		
Table11_3	Counts of Patients, Incident Treatment Episodes, Number of Events, and Days at Risk by Range of Index Charlson Comorbidity Index Score	table11_3	N
Table12	Counts of Patients, Incident Treatment Episodes, Number of Events, and Days at Risk by Range of Change in BMI Z-score	table12	N
Table13	Counts of members by the number of valid treatment episodes and total number of events	table13	N
Table14	Counts of valid treatment episodes by the number of events per episode and total number of members	table14	N
Stockpiling_excl	Information on claims excluded by the stockpiling algorithm	stockpiling_excl	Y

Table 24: Example of Dispensing Processing File

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

In the example above, the requester additionally instructed the request programmer to use the following SAS macro parameters:

- To be selected members need to have at least 365 days of medical and drug coverage during the pre-index period
- Any enrollment gap of less than 45 days is considered administrative and is ignored
- The query period spans the years 2006 to 2007
- Results should be stratified according to the following age groups: 18-44 45-54 55-64 65+
- Only certain output tables should be preserved
- Only dispensings with days or amount supplied >0 are considered by the program
- The Combo Tool should be used to define the outcome of interest using a complex algorithm

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

```
%MODULARPROGRAM3 (MSPROJID=to09msy5
                  MSWPTYPE=mpr,
                  MSWPID=wp01,
                  MSVERID=v01,
                  RUNID=01,
                  COVERAGE=MD,
                  ENROLGAP=45,
                  QUERYFROM=1/1/2006,
                  QUERYTO=12/31/2007,
                  QUERYFILE=query.sas7bdat,
                  INCQUERYFILE=incquery.sas7bdat,
                  QUERYEVENTFILE=event.sas7bdat,
                  INCEVENTFILE=incevent.sas7bdat,
```

```
CONDFILE=condfile.sas7bdat,
AGESTRAT=18-44 45-54 55-64 65,
CCIFILE=ccifile.sas7bdat,
UTILFILE=utilfile.sas7bdat,
BMIKIDSFILE=bmifile.sas7bdat,
OUTTABLESFILE=mp_output_select.sas7bdat,
STOCKPILINGFILE=stockpiling.sas7bdat,
COMBOFILE=complexevent.sas7bdat,
LABSCODEMAP=stockpiling.sas7bdat);
```