

Appendix B1: Structured Reporting Template (word version)

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## ADMINISTRATIVE INFORMATION

**Protocol Title:**

New initiator, active comparator cohort study of Drug A versus Drug B on risk of Outcome Y

**Objective:**

*Include PICOTS (Patient, Intervention, Comparator, Outcome, Time-Horizon, Setting)*

To evaluate the comparative risk of Outcome Y within 183 days of initiating Drug A versus Drug B in commercially insured patients

Protocol registration:	Registration number	Registration site
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EUPAS1234	<a href="http://www.encepp.eu/encepp/studiesDatabase.jsp">http://www.encepp.eu/encepp/studiesDatabase.jsp</a>
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Protocol version:	Version number	Version date
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v3	15-Apr-19
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Protocol Contributors:	Name	Role	Affiliation
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Jane Smith	Principal Investigator	ABC School of Medicine
John Doe	Co-Investigator	Alphabet Agency
...		

Funding:	Grant number	Source
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XYZ99999	Alphabet Agency
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Data Use Agreement (DUA)	DUA number	Data vendor
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Not applicable	IBM Truven Health MarketScan
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Institutional Review Board (IRB)	IRB number	IRB Name
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ABC123	ABC School of Medicine IRB
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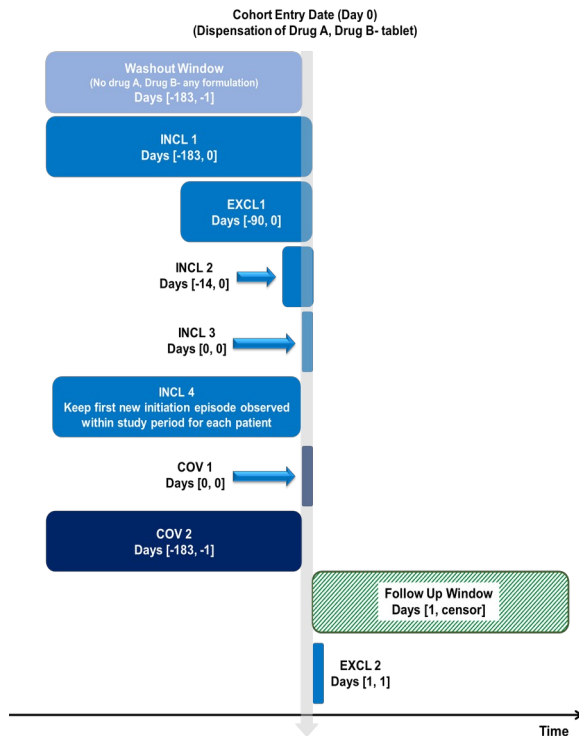
**VERSION HISTORY**

<b>Version Date</b>	<b>Version Number</b>	<b>Change Log</b>	<b>Rationale for Change</b>
November 12, 2018	v2	Added covariate: "co-prescription of Drug C" measured in days [-183, 0] in any care setting and diagnosis position	Added because of concern that Drug C may interact with effect of Drug A and B
April 15, 2019	v3	Changed covariate assessment window from days [-183, -1] to [-183, 0]	Changed assessment window to include day 0, due to concern that important diagnoses occurring on the day of drug dispensation may be missed

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# DESIGN DIAGRAM

New initiator, active comparator cohort design  
 Example: Drug A versus Drug B on risk of Outcome Y



**INCL/EXCL = Inclusion/Exclusion Assessment Window**

- INCL1**  
Medical and Drug coverage (45 day gaps allowed)
- INCL2**  
Community acquired pneumonia diagnosis and chest radiography
- INCL3**  
Age between 18-65
- INCL4**  
Keep first new initiator episode
- EXCL1**  
Inpatient hospitalization
- EXCL2**  
Censored on day follow up starts

**COV = Covariate Assessment Window**

- COV1**
  - Age (continuous)
  - Gender
  - Co-prescription of beta-lactam
- COV2**
  - Metastatic cancer
  - Tumor
  - Arrhythmia
  - Congestive heart failure
  - Dementia
  - Renal failure
  - Weight loss
  - Hemiplegia
  - Alcohol abuse
  - Pulmonary disease
  - Coagulopathy
  - Complicated diabetes
  - Anemia
  - Fluid and electrolyte disorder
  - Liver disease
  - Peripheral vascular disorder
  - Psychosis
  - Pulmonary circulation disorders
  - HIV/AIDS
  - Hypertension
  - Degenerative disease of central nervous system
  - Durable medical equipment
  - Vaccine administration
  - Screening examinations and disease management training
  - Pap smear
  - HPV DNA test
  - Mammogram
  - Fecal occult blood test
  - Colonoscopy
  - PSA test
  - Number of inpatient hospitalizations
  - Number of outpatient visits
  - Number of emergency department visits
  - Number of unique generics
  - Prior prescription of penicillins
  - Prior prescription of cephalosporins
  - Prior prescription of sulfonamides
  - Prior prescription of tetracyclines
  - Prior prescription of aminoglycosides
  - Pregnancy at time of initiation
  - Empirically selected

**Censoring**

- 183 days
- 30-Sep-15
- Discharged dead
- Disenroll medical or drug coverage (45-day gaps allowed)

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ATTRITION TABLE	Less Excluded Patients	Remaining Patients
All patients		
Did not meet cohort entry criteria (dispensation of drug A or drug B)		
Excluded due to insufficient prior enrollment (<183 days with 45-day gaps allowed)		
Excluded due to prior use of referent (Drug B)		
Excluded due to prior use of exposure (Drug A)		
Excluded because patient qualified in >1 exposure category		
Excluded based on Age <18		
Excluded based on Age ≥65		
Excluded based on Gender (unknown)		
Excluded based on Drug supply ≤0 days		
Excluded based on Drug A (additional formulations and combinations not included in exposure)		
Excluded based on Drug B (additional formulations and combinations not included in referent)		
Excluded based on absence of community acquired pneumonia diagnosis within 14 days prior to index date		
Excluded based on absence of chest x-ray within 14 days prior to index date		
Excluded based on inpatient admission within 90 days prior to index date		
Excluded if censored on day 1		
Final cohort		
	Drug A initiators N =	
	Drug B initiators N =	

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**Power and Sample Size Calculation Specifications for Protocol: *Example 1 Drug A versus Drug B***

Software: powerandsamplesize.com  
 Calculate: Power to compare 2 proportions: 2-Sample, 2-Sided Equality

Assumptions	Primary	Range	Source for estimated parameters
Total sample size	<input type="text"/>	<input type="text"/>	<input type="text"/>
Incidence in exposed group	<input type="text"/>	<input type="text"/>	<input type="text"/>
Incidence in comparator group	<input type="text"/>	<input type="text"/>	<input type="text"/>
Ratio of exposed to comparator	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other (specify):	<input type="text"/>	<input type="text"/>	<input type="text"/>
Statistical parameters:			
Type 1 error rate	<input type="text"/>	<input type="text"/>	
Type 2 error rate	<input type="text"/>	<input type="text"/>	

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<b>ANALYSIS SPECIFICATIONS</b>					
<b>Analyses</b>					
	<b>Primary</b>	<b>Secondary 1</b>	<b>Secondary 2</b>	<b>Subgroup</b>	<b>Sensitivity</b>
<b>Outcome:</b>	Myocardial infarction	Stroke	TIA	n/a	Myocardial infarction
<b>Software:</b>	SAS 9.4: PHREG, PROC LOGISTIC, Pharmacoepi Toolbox nearest neighbor matching macro ( <a href="http://www.drugepi.org/dope-downloads/">http://www.drugepi.org/dope-downloads/</a> )	SAS 9.4: PHREG, PROC LOGISTIC, Pharmacoepi Toolbox nearest neighbor matching macro ( <a href="http://www.drugepi.org/dope-downloads/">http://www.drugepi.org/dope-downloads/</a> )	SAS 9.4: PHREG, PROC LOGISTIC, Pharmacoepi Toolbox nearest neighbor matching macro ( <a href="http://www.drugepi.org/dope-downloads/">http://www.drugepi.org/dope-downloads/</a> )		SAS 9.4: PHREG, PROC LOGISTIC, Pharmacoepi Toolbox nearest neighbor matching macro ( <a href="http://www.drugepi.org/dope-downloads/">http://www.drugepi.org/dope-downloads/</a> )
<b>Model(s):</b>	Outcome: Cox proportional hazards model, Propensity score: logistic regression	Outcome: Cox proportional hazards model, Propensity score: logistic regression	Outcome: Cox proportional hazards model, Propensity score: logistic regression		Outcome: Cox proportional hazards model, Propensity score: logistic regression
<b>Confounding Adjustment</b> <i>(check all that apply and provide details, where requested)</i>					
<b>Bivariate</b>					
<b>Multivariable</b>					
<b>Propensity Score Matching</b>	X	X	X		
<i>(specify matching algorithm, ratio, and caliper)</i>	Nearest neighbor, Ratio = fixed 1:1, Caliper = 0.025	Nearest neighbor, Ratio = fixed 1:1, Caliper = 0.025	Nearest neighbor, Ratio = fixed 1:1, Caliper = 0.025		
<b>Propensity Score Weighting</b>					X

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<b>ANALYSIS SPECIFICATIONS</b>					
<b>Analyses</b>					
	<b>Primary</b>	<b>Secondary 1</b>	<b>Secondary 2</b>	<b>Subgroup</b>	<b>Sensitivity</b>
<b>Confounding Adjustment</b> <i>(check all that apply and provide details, where requested)</i>					
<i>(specify weight formula, trimming, truncation decisions)</i>					Exposed weight = 1, Comparator weight = PS/(1-PS), 1% asymmetrical trim
<b>Propensity Score Stratification</b>					
<i>(specify strata definition)</i>					
<b>Other</b>					
<i>(specify details)</i>					
<b>Missing Data Methods (check all that apply)</b>					
Missing Indicators					
Complete Case					
Last Value Carried Forward					
Multiple Imputation					
Other (please specify)...					



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<b>GLOSSARY</b>	
<b>Term</b>	<b>Definition</b>
Confounder	Variable other than the exposure of interest or outcome under investigation that is: 1) associated with exposure; 2) a risk factor for the outcome; and 3) not on the causal pathway between the exposure and the outcome. A confounder can artificially inflate or reduce the magnitude of association between an exposure and outcome.
Covariates	Variables that are neither exposure nor outcome of interest but are measured to describe a population or because they may be a confounder to account for in analyses.
Data Extraction Date	The date when the data were extracted from the dynamic healthcare database.
Days Supplied	Number of days supplied for a dispensed prescription.
Eligible Cohort Entry Period	Calendar time frame, during which cohort entry dates are identified.
Empirically-Defined Covariates	Covariates that are not prespecified by the investigator. The selection of these covariates is based on applying algorithms to the data. The algorithms for covariate selection may be tuned by investigator-specified parameters.
Enrollment/Coverage	For insurance claims data, this may refer to periods of enrollment in medical and/or drug plans. For electronic health record databases, this may refer to algorithms designed to identify patients whose healthcare contacts are likely to be covered within the healthcare system.
Enrollment Gap	Maximum number of days allowed between two consecutive enrollment periods to still be considered "continuously enrolled."
Follow-Up Window	The interval during which occurrence of the outcome of interest in the study population will be included in the analysis.
Grace Window	Number of days added to days' supply to allow for non-adherence or account for the hypothesized biologic exposure risk window. Operationally, this could be defined as the number of extra days added to the end of a days' supply to extend time counted as "exposed." This grace may bridge the gap between dispensations, where the days' supply dispensed does not cover all days until the refill.
Index Date	The date when subjects enter the study population (cohort entry date, outcome event date). It is defined based on events in the patient's longitudinal timeline; other windows are defined relative to the index date.
Assessment Window	Interval during which a patient is required to have evidence of a pre-existing condition (diagnosis/procedure/drug dispensing). May be used for washout of exposure or outcome, exclusion assessment, or covariate assessment.
Predefined Covariates	Covariates that are prespecified and defined by the investigator in the protocol.
Principal Diagnosis	Diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital.
Source Data Range	The calendar time range covered by a data source that is available.
Stockpiling Algorithm	Algorithm defining how early refills are handled when determining length of exposure follow up.

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<b>GLOSSARY</b>	
<b>Term</b>	<b>Definition</b>
Study Period	Calendar time interval of data available for study, including pre-index date assessment windows and post-index follow up.
Treatment Episode	Continuous period of exposure, defined by using dispensation date + days' supply and applying stockpiling algorithms and/or grace windows.
Washout Window	Minimum number of days a patient is required to have no evidence of prior exposure and/or outcome.
Wildcard	Symbol used to represent any single alphanumeric digit in code algorithms. For example, 410.*1, where * is the wildcard.

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**Appendix A: Study Population Entry Criteria**

<b>Study Entry Criterion</b>	<b>NDC</b>	<b>Generic Name</b>	<b>Brand Name</b>	<b>Route</b>	<b>Strength</b>
Drug A	00003016050	drug A	Awesome Drug	tablet	250mg
Drug B	00003016050	drug B	Really Cool Drug	tablet	250mg

## Appendix B1: Structured Reporting Template (word version)

**Appendix B: Drug, Diagnosis, and Procedure-Based Inclusion/Exclusion Criteria**

Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
Drug A	00003016050	drug A	NDC	Awesome Drug	tablet	250mg
Drug B	00003016050	drug B	NDC	Really Cool Drug	tablet	250mg
Drug A	01003016050	drug A	NDC	Awesome Drug oral	oral suspension	5 ml
Drug B	00803016050	drug B	NDC	Really Cool Drug injectable	injectable	5 y injectable
Chest radiography	87.44	PX	09	Routine chest x-ray, so described		
Chest radiography	87.49	PX	09	Other chest x-ray		
Chest radiography	71010	PX	C4	Radiologic examination, chest; single view, frontal		
Chest radiography	71015	PX	C4	Radiologic examination, chest; stereo, frontal		
Chest radiography	71020	PX	C4	Radiologic examination, chest, 2 views, frontal and lateral / Radiologic examination, chest, 2 views, frontal and lateral; / Radiologic examination, chest, two views, frontal and lateral		
Chest radiography	71021	PX	C4	Radiologic examination, chest, 2 views, frontal and lateral; with apical lordotic procedure / Radiologic examination, chest, two views, frontal and lateral; with apical lordotic procedure		
Chest radiography	71022	PX	C4	Radiologic examination, chest, 2 views, frontal and lateral; with oblique projections / Radiologic examination, chest, two views, frontal and lateral; with oblique projections		
Chest radiography	71023	PX	C4	Radiologic examination, chest, 2 views, frontal and lateral; with fluoroscopy / Radiologic examination, chest, two views, frontal and lateral; with fluoroscopy		
Chest radiography	71030	PX	C4	Radiologic examination, chest, complete, minimum of 4 views / Radiologic examination, chest, complete, minimum of 4 views; / Radiologic examination, chest, complete, minimum of four views		

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Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
Chest radiography	71034	PX	C4	Radiologic examination, chest, complete, minimum of 4 views; with fluoroscopy / Radiologic examination, chest, complete, minimum of four views; with fluoroscopy		
Chest radiography	71035	PX	C4	Radiologic examination, chest, special views (e.g., lateral decubitus, Bucky studies)		
Community-acquired pneumonia	480	DX	09	VIRAL PNEUMONIA		
Community-acquired pneumonia	480.0	DX	09	PNEUMONIA DUE TO ADENOVIRUS		
Community-acquired pneumonia	480.1	DX	09	PNEUMONIA DUE TO RESPIRATORY SYNCYTIAL VIRUS		
Community-acquired pneumonia	480.2	DX	09	PNEUMONIA DUE TO PARAINFLUENZA VIRUS		
Community-acquired pneumonia	480.3	DX	09	PNEUMONIA DUE TO SARS-ASSOCIATED CORONAVIRUS		
Community-acquired pneumonia	480.8	DX	09	PNEUMONIA DUE TO OTHER VIRUS NOT ELSEWHERE CLASSIFIED		
Community-acquired pneumonia	480.9	DX	09	VIRAL PNEUMONIA UNSPECIFIED		
Community-acquired pneumonia	481	DX	09	PNEUMOCOCCAL PNEUMONIA [STREPTOCOCCUS PNEUMONIAE PNEUMONIA]		
Community-	482	DX	09	OTHER BACTERIAL PNEUMONIA		

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Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
acquired pneumonia						
Community-acquired pneumonia	482.0	DX	09	PNEUMONIA DUE TO KLEBSIELLA PNEUMONIAE		
Community-acquired pneumonia	482.1	DX	09	PNEUMONIA DUE TO PSEUDOMONAS		
Community-acquired pneumonia	482.2	DX	09	PNEUMONIA DUE TO HEMOPHILUS INFLUENZAE (H. INFLUENZAE)		
Community-acquired pneumonia	482.3	DX	09	PNEUMONIA DUE TO STREPTOCOCCUS		
Community-acquired pneumonia	482.30	DX	09	PNEUMONIA DUE TO STREPTOCOCCUS UNSPECIFIED		
Community-acquired pneumonia	482.31	DX	09	PNEUMONIA DUE TO STREPTOCOCCUS GROUP A		
Community-acquired pneumonia	482.32	DX	09	PNEUMONIA DUE TO STREPTOCOCCUS GROUP B		
Community-acquired pneumonia	482.39	DX	09	PNEUMONIA DUE TO OTHER STREPTOCOCCUS		
Community-acquired pneumonia	482.4	DX	09	PNEUMONIA DUE TO STAPHYLOCOCCUS		
Community-	482.40	DX	09	PNEUMONIA DUE TO STAPHYLOCOCCUS UNSPECIFIED		

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Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
acquired pneumonia						
Community-acquired pneumonia	482.41	DX	09	METHICILLIN SUSCEPTIBLE PNEUMONIA DUE TO STAPHYLOCOCCUS AUREUS		
Community-acquired pneumonia	482.42	DX	09	METHICILLIN RESISTANT PNEUMONIA DUE TO STAPHYLOCOCCUS AUREUS		
Community-acquired pneumonia	482.49	DX	09	OTHER STAPHYLOCOCCUS PNEUMONIA		
Community-acquired pneumonia	482.8	DX	09	PNEUMONIA DUE TO OTHER SPECIFIED BACTERIA		
Community-acquired pneumonia	482.81	DX	09	PNEUMONIA DUE TO ANAEROBES		
Community-acquired pneumonia	482.82	DX	09	PNEUMONIA DUE TO ESCHERICHIA COLI [E.COLI]		
Community-acquired pneumonia	482.83	DX	09	PNEUMONIA DUE TO OTHER GRAM-NEGATIVE BACTERIA		
Community-acquired pneumonia	482.84	DX	09	PNEUMONIA DUE TO LEGIONNAIRES' DISEASE		
Community-acquired pneumonia	482.89	DX	09	PNEUMONIA DUE TO OTHER SPECIFIED BACTERIA		
Community-	482.9	DX	09	BACTERIAL PNEUMONIA UNSPECIFIED		

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Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
acquired pneumonia						
Community-acquired pneumonia	483	DX	09	PNEUMONIA DUE TO OTHER SPECIFIED ORGANISM		
Community-acquired pneumonia	483.0	DX	09	PNEUMONIA DUE TO MYCOPLASMA PNEUMONIAE		
Community-acquired pneumonia	483.1	DX	09	PNEUMONIA DUE TO CHLAMYDIA		
Community-acquired pneumonia	483.8	DX	09	PNEUMONIA DUE TO OTHER SPECIFIED ORGANISM		
Community-acquired pneumonia	484	DX	09	PNEUMONIA IN INFECTIOUS DISEASES CLASSIFIED ELSEWHERE		
Community-acquired pneumonia	484.1	DX	09	PNEUMONIA IN CYTOMEGALIC INCLUSION DISEASE		
Community-acquired pneumonia	484.3	DX	09	PNEUMONIA IN WHOOPING COUGH		
Community-acquired pneumonia	484.5	DX	09	PNEUMONIA IN ANTHRAX		
Community-acquired pneumonia	484.6	DX	09	PNEUMONIA IN ASPERGILLOSIS		
Community-	484.7	DX	09	PNEUMONIA IN OTHER SYSTEMIC MYCOSES		



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Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
acquired pneumonia						
Community-acquired pneumonia	484.8	DX	09	PNEUMONIA IN OTHER INFECTIOUS DISEASES CLASSIFIED ELSEWHERE		
Community-acquired pneumonia	485	DX	09	BRONCHOPNEUMONIA ORGANISM UNSPECIFIED		
Community-acquired pneumonia	486	DX	09	PNEUMONIA ORGANISM UNSPECIFIED		
Community-acquired pneumonia	487	DX	09	INFLUENZA		
Community-acquired pneumonia	487.0	DX	09	INFLUENZA WITH PNEUMONIA		
Community-acquired pneumonia	487.1	DX	09	INFLUENZA WITH OTHER RESPIRATORY MANIFESTATIONS		
Community-acquired pneumonia	487.8	DX	09	INFLUENZA WITH OTHER MANIFESTATIONS		
Community-acquired pneumonia	038.0	DX	09	STREPTOCOCCAL SEPTICEMIA		
Community-acquired pneumonia	038.2	DX	09	PNEUMOCOCCAL SEPTICEMIA		
Community-	041.0	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED		

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Exclusion Criteria	Code	Code Category	Code Type	Description	Route	Strength
acquired pneumonia				ELSEWHERE AND OF UNSPECIFIED SITE		
Community-acquired pneumonia	041.00	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE STREPTOCOCCUS UNSPECIFIED		
Community-acquired pneumonia	041.01	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE STREPTOCOCCUS GROUP A		
Community-acquired pneumonia	041.02	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE STREPTOCOCCUS GROUP B		
Community-acquired pneumonia	041.03	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE STREPTOCOCCUS GROUP C		
Community-acquired pneumonia	041.04	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE STREPTOCOCCUS GROUP D [ENTEROCOCCUS]		
Community-acquired pneumonia	041.05	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE STREPTOCOCCUS GROUP G		
Community-acquired pneumonia	041.09	DX	09	STREPTOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE OTHER STREPTOCOCCUS		
Community-acquired pneumonia	041.2	DX	09	PNEUMOCOCCUS INFECTION IN CONDITIONS CLASSIFIED ELSEWHERE AND OF UNSPECIFIED SITE		
Community-acquired pneumonia	320.1	DX	09	PNEUMOCOCCAL MENINGITIS		

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**Appendix C: Drug, Diagnosis, and Procedures, Based on Covariates**

(Note: as the file is extensive, we provide the first few covariates, here, only; for the full list, please visit the excel document).

Covariate	Code	Code Category	Code Type	Description	Strength	Dose
Degenerative disease of central nervous system	330	DX	09	CEREBRAL DEGENERATIONS USUALLY MANIFEST IN CHILDHOOD		
Degenerative disease of central nervous system	330.0	DX	09	LEUKODYSTROPHY		
Degenerative disease of central nervous system	330.1	DX	09	CEREBRAL LIPIDOSES		
Degenerative disease of central nervous system	330.2	DX	09	CEREBRAL DEGENERATION IN GENERALIZED LIPIDOSES		
Degenerative disease of central nervous system	330.3	DX	09	CEREBRAL DEGENERATION OF CHILDHOOD IN OTHER DISEASES CLASSIFIED ELSEWHERE		
Degenerative disease of central nervous system	330.8	DX	09	OTHER SPECIFIED CEREBRAL DEGENERATIONS IN CHILDHOOD		
Degenerative disease of central nervous system	330.9	DX	09	UNSPECIFIED CEREBRAL DEGENERATION IN CHILDHOOD		
Degenerative disease of central nervous system	331	DX	09	OTHER CEREBRAL DEGENERATIONS		
Degenerative disease of central nervous system	331.0	DX	09	ALZHEIMER'S DISEASE		
Degenerative disease of central nervous system	331.1	DX	09	FRONTOTEMPORAL DEMENTIA		
Degenerative disease of central nervous system	331.11	DX	09	PICK'S DISEASE		
Degenerative disease of central nervous system	331.19	DX	09	OTHER FRONTOTEMPORAL DEMENTIA		
Degenerative disease of central nervous system	331.2	DX	09	SENILE DEGENERATION OF BRAIN		
Degenerative disease of central nervous system	331.3	DX	09	COMMUNICATING HYDROCEPHALUS		

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<b>Covariate</b>	<b>Code</b>	<b>Code Category</b>	<b>Code Type</b>	<b>Description</b>	<b>Strength</b>	<b>Dose</b>
Degenerative disease of central nervous system	331.4	DX	09	OBSTRUCTIVE HYDROCEPHALUS		
Degenerative disease of central nervous system	331.5	DX	09	IDIOPATHIC NORMAL PRESSURE HYDROCEPHALUS (INPH)		
Degenerative disease of central nervous system	331.6	DX	09	CORTICOBASAL DEGENERATION		
Degenerative disease of central nervous system	331.7	DX	09	CEREBRAL DEGENERATION IN DISEASES CLASSIFIED ELSEWHERE		
Degenerative disease of central nervous system	331.8	DX	09	OTHER CEREBRAL DEGENERATION		
Degenerative disease of central nervous system	331.81	DX	09	REYE'S SYNDROME		
Degenerative disease of central nervous system	331.82	DX	09	DEMENTIA WITH LEWY BODIES		
Degenerative disease of central nervous system	331.83	DX	09	MILD COGNITIVE IMPAIRMENT SO STATED		
Degenerative disease of central nervous system	331.89	DX	09	OTHER CEREBRAL DEGENERATION		
Degenerative disease of central nervous system	331.9	DX	09	CEREBRAL DEGENERATION UNSPECIFIED		
Degenerative disease of central nervous system	332	DX	09	PARKINSON'S DISEASE		
Degenerative disease of central nervous system	332.0	DX	09	PARALYSIS AGITANS		
Degenerative disease of central nervous system	332.1	DX	09	SECONDARY PARKINSONISM		
Degenerative disease of central nervous system	333	DX	09	OTHER EXTRAPYRAMIDAL DISEASE AND ABNORMAL MOVEMENT DISORDERS		
Degenerative disease of central nervous system	333.0	DX	09	OTHER DEGENERATIVE DISEASES OF THE BASAL GANGLIA		
Degenerative disease of	333.1	DX	09	ESSENTIAL AND OTHER SPECIFIED FORMS OF TREMOR		

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Covariate	Code	Code Category	Code Type	Description	Strength	Dose
central nervous system						
Degenerative disease of central nervous system	333.2	DX	09	MYOCLONUS		
Degenerative disease of central nervous system	333.3	DX	09	TICS OF ORGANIC ORIGIN		
Degenerative disease of central nervous system	333.4	DX	09	HUNTINGTON'S CHOREA		
Degenerative disease of central nervous system	333.5	DX	09	OTHER CHOREAS		
Degenerative disease of central nervous system	333.6	DX	09	GENETIC TORSION DYSTONIA		
Degenerative disease of central nervous system	333.7	DX	09	ACQUIRED TORSION DYSTONIA		
Degenerative disease of central nervous system	333.71	DX	09	ATHETOID CEREBRAL PALSY		
Degenerative disease of central nervous system	333.72	DX	09	ACUTE DYSTONIA DUE TO DRUGS		
Degenerative disease of central nervous system	333.79	DX	09	OTHER ACQUIRED TORSION DYSTONIA		
Degenerative disease of central nervous system	333.8	DX	09	FRAGMENTS OF TORSION DYSTONIA		
Degenerative disease of central nervous system	333.81	DX	09	BLEPHAROSPASM		
Degenerative disease of central nervous system	333.82	DX	09	OROFACIAL DYSKINESIA		
Degenerative disease of central nervous system	333.83	DX	09	SPASMODIC TORTICOLLIS		

Appendix B1: Structured Reporting Template (word version)

**Appendix D: Outcome**

<b>Outcome</b>	<b>Code</b>	<b>Code Category</b>	<b>Code Type</b>	<b>Description</b>
Myocardial Infarction	41001	DX	ICD9	Acute myocardial infarction of anterolateral wall, initial episode of care

Appendix B1: Structured Reporting Template (word version)

**Appendix E: Care Setting**

<b>CARE SETTING</b>		
IP = inpatient	All claims in the MarketScan inpatient admissions table and inpatient services are coded as IP; primary diagnosis is defined by the inpatient admissions primary diagnosis, only.	
ED = emergency department	Any encounters in the inpatient service or outpatient service table with SVCSCAT ending in '20' or STDPLAC in ('23', '41', '42').	
AV = ambulatory visit	Based on outpatient service table values for STDPLAC (see below).	
IS = institutional stay	Based on outpatient service table values for STDPLAC (see below).	
OA = other ambulatory visit	Based on outpatient service table values for STDPLAC (see below).	
STDPLAC		
Value	Label	Care Setting
1	Pharmacy	AV
3	School	AV
4	Homeless Shelter	AV
11	Office	AV
12	Patient Home	AV
13	Assisted Living Facility	IS
14	Group Home	IS
15	Mobile Unit	AV
16	Temporary Lodging	AV
17	Walk-In Retail Health Clinic	AV
18	Place of Employment - Worksite	AV
20	Urgent Care Facility	AV
21	Inpatient Hospital	AV
22	Outpatient Hospital	AV
23	Emergency Room - Hospital	ED
24	Ambulatory Surgical Center	AV
25	Birth Center	AV
26	Military Treatment Facility	AV



## Appendix B1: Structured Reporting Template (word version)

<b>CARE SETTING</b>		
Value	Label	Care Setting
27	Inpatient Long-Term Care (NEC)	IS
28	Other Inpatient Care (NEC)	IS
31	Skilled Nursing Facility	IS
32	Nursing Facility	IS
33	Custodial Care Facility	IS
34	Hospice	IS
35	Adult Living Care Facility	IS
41	Ambulance (land)	ED
42	Ambulance (air or water)	ED
49	Independent Clinic	AV
50	Federally Qualified Health Center	AV
51	Inpatient Psychiatric Facility	AV
52	Psych Facility Partial Hospital	AV
53	Community Mental Health Center	AV
54	Intermed Care/Mental Retarded	AV
55	Residential Substance Abuse Facility	AV
56	Psych Residential Treatment Center	AV
57	Non-Resident Substance Abuse Facility	AV
60	Mass Immunization Center	AV
61	Comprehensive Inpatient Rehab Facility	AV
62	Comprehensive Outpatient Rehab Facility	AV
65	End-Stage Renal Disease Facility	AV
71	State/Local Public Health Clinic	AV
72	Rural Health Clinic	AV
81	Independent Laboratory	AV
95	Outpatient (NEC)	AV
98	Pharmacy	AV
99	Other Unlisted Facility	OA