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TITLE:

Estimating Diabetes-Related Disparities in Health Care Use Trends with Healthcare Cost and Utilization Project and Medical Expenditure Panel Survey Data





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Summary of Changes (Optional)

Protocol Section	Change
List of	Added BRFSS to list of abbreviations
Abbreviations	
Protocol Summary	Removed rural/urban designation from Objective
	3/MEPS analysis, as variable only available through
	research data center
2	Removed rural/urban designation from Objective
	3/MEPS analysis as variable only available through
	research data center
4	Specified number of discharge diagnoses to be used in
	identifying diabetes disease state and comorbid
	conditions
4	Added criteria for determining Adult population without
	diabetes-disease state
4	Removed rural/urban designation from Objective
	3/MEPS analysis, as variable only available through
	research data center
4.2	Added diabetes-status to list of stratifications
4.2	Removed rural/urban designation from Objective
	3/MEPS analysis, as variable only available through
	research data center
5.1	Added information about BRFSS informed consent
	procedure
7.0	Replaced NHIS with BRFSS to analysis design to
	generate state-level demographic data and rate estimates
7.1	Added analysis by diabetes-status to objectives 1 and 2.
	Added rate standardization to rate calculation, fixed
	grammatical error at end of objective 2, removed
7.0 0	rural/urban from objective 3
7.2.3	Added limitation to using discharge diagnoses to identify
	patient population without diabetes, fixed grammatical
4 7: 5	error in limitation 3
Appendix 5.	Reformatted tables, replaced NHIS with BRFSS
Appendix 5.	Added table 7 for analysis with and without diabetes
Appendix 5.	Reformatted tables, updated age groups and regions
Appendix 6.	Reformatted tables, updated age groups and regions,
	renamed tables to account for new table
Appendix 7.	Updated race (reflecting sample size limitations) and
	region category, and removed rural/urban as data is not
	available in MEPS



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List of Abbreviations

NIS National Inpatient Sample

NEDS National Emergency Department Sample

SID State Inpatient Databases

SEDD State Emergency Department Databases

ICD-9 International Classification of Disease, 9th Modification

ICD-10 International Classification of Disease, 10th Modification

IRB Institutional Review Board

ED Emergency Department

PQI Prevention Quality Indicators

AHRQ US Agency for Health Research and Quality

BRFSS Behavioral Risk Factor Surveillance System

List of Definitions

Health Care Service Use	The utilization of the following healthcare services/products: Hospital Inpatient Stays/Hospitalizations, Emergency Department Visits, and Prescription Drugs,
cascade of care	diagnosis, linkage to care, achievement of individual treatment targets, and a composite of all individual targets





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Protocol summary

Title	Estimating Diabetes-Related Disparities in Health Care Use Trends with Healthcare Cost and Utilization Project Data and Medical Expenditure Panel Survey Data
Vendor/Collaborator	Emory Healthcare
Rationale	There exists limited data on the healthcare service utilization trends among people with diabetes by sociodemographic group. Identifying contributors to disparities in diabetes management will shed light on possible intervention targets to reduce these disparities and improve outcomes.
Primary Objective(s)	Objective 1. To describe trends in ED visit rates and inpatient use rates among adults with diabetes in the United States from 2005-2016 by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage. Objective 2. To describe trends in the rates of potentially preventable hospitalizations, as defined by, among adults with diabetes in the United States from 2005-2016 by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage. Objective 3. To describe trends of prescription drug usage (antihyperglycemic agents, antihyperlipidemic agents, antihypertensive agents, antiplatelet agents, and antidepressant/anxiolytic agents) among adults with diabetes in the United States from 2005-2016 by age, sex, race/ethnicity, , presence of comorbidities, geographic region, and health insurance coverage.
Study Design	Retrospective serial cross-sectional design using data from the AHRQ's Healthcare Cost and Utilization Project and Medical Expenditure Panel Survey
Study Population	U.S. non-institutionalized population aged 18+, diagnosed with diabetes
Study Duration	10 Years
Outcomes	Number and Rates of Hospital Stays and ED visits across sociodemographic groups, 2008-2016 Number and Rates of Potentially Preventable Hospitalizations across sociodemographic groups, 2008-2016 Number and rates of People with Diabetes Prescribed Cardiovascular Modifying Agents across sociodemographic groups, 2008-2016
Statistical Methods	Descriptive Statistics of Survey and Administrative Claims Data. Survey weights, calculation of mean and standard deviation, frequency tables, Taylor-Series linearization, and Jack-Knife methods will be used to generate estimates.
Limitations	 Generalizability issues arising from state selection and National Inpatient Sample sampling methods. Reliance on administrative claims data and clinician billing to identify diabetes-related claims. Generation of encounter-level estimates, rather than patient-level estimates Reliance on ICD codes provided by the AHRQ's Prevention Quality Indicators to define Potentially Preventable Hospitalizations



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Background and Rationale

1.1 Background

From 1990 to 2010, the number of people with a diabetes diagnosis more than tripled, from 6.5 million to 20.7 million. As of 2015, approximately 9.4% of the United States population have diabetes. The increased burden of diabetes bears large costs to society; the American Diabetes Association estimates the direct cost of diabetes at \$237 billion in 2017, or approximately 1 in 4 health care dollars spent in the United States.³

There exist wide-ranging disparities in diabetes prevalence, ^{4,5} quality of care, ^{6,7} and outcomes ^{8–10} in the United States. In terms of race, American Indians, Black, and Hispanic patients account for a disproportionate share of diabetes complications and worse disease-related outcomes, 11,12 whereas Whites have a higher risk of all-cause mortality and cardiovascular disease compared to ethnic minorities. Prevalence of diabetes has significantly increased in both White and Black residents of the southeastern Stroke Belt states, indicating regional variation.⁵ Further, diabetes is more prevalent and inadequately managed in rural areas. ^{13,14} Recent cost-saving trends towards high deductible health insurance plans disproportionately impact lower-income individuals, who may forego necessary care until the disease progresses. 15

Although studies reported an improvement in population achievement of diabetes treatment goals from 1990-2010 - recent data indicate there has not been an improvement from 2005 to 2016. 16,17 Currently, only an estimated 23% of those with diabetes engaged in health care and met four major care goals: blood pressure, cholesterol, lipoprotein cholesterol target, and smoking abstinence. ¹⁷ Clinicians may fail to escalate treatment to achieve treatment goals - even though patients are not reaching glycemic targets. 18 Termed clinical inertia, this inefficient care delivery may also be influenced by a patient's sociodemographic factors. Research suggests that older and White patients are more likely to have treatment intensified at lower HbA1c compared to younger and Black patients.¹⁹

Given the progressive nature of diabetes, quality care delivery along the care cascade—the process of diagnosis, linkage to care, and the achievement of treatment targets—is necessary to prevent the development of severe complications and comorbidities. Disparities exist along the diabetes care cascade, as young adults, women, non-Hispanic Blacks, and patients that were covered by Medicaid or uninsured are less likely to meet care goals. 17,20

Although interventions have been conducted to address clinical inertia and improve provider behavior,²¹ there still remains gaps in the literature in describing how health care use varies among those with diabetes. This project seeks to understand those utilization patterns and identify whether trends in health care use vary by sociodemographic groups. These data will serve to guide future research efforts and interventions towards improving the quality and equity along the diabetes care cascade.

1.2 Rationale





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Although trends in outpatient use, ED visits, and hospital discharges have been examined by race, age group, sex, complication type, and health insurance coverage, there has been no data published on trends by geographic region, rural/urban location. ^{22,23} Further, the aforementioned data describe trends until 2011. This provides an opportunity to both update and further describe healthcare utilization trends among people with diabetes

Further, existing data show distributions of healthcare use, but there are no data examining the same people linked across datasets and how they use health care in a given year. Using data that link individuals throughout the continuum of care, we can examine what differentiates individuals that are readmitted and those that are not.

Potentially preventable hospitalizations are defined as conditions for which good outpatient care can prevent the need for hospitalization, or for which early intervention can prevent complications or more serious disease. ²⁴ Recent research on trends in potentially preventable hospitalizations among people with diabetes has been stratified in terms of age, sex, health insurance coverage, income, region, conditions, and race.^{25–27}

This analysis will use criteria defined by the AHRQ's diabetes-related PQIs to define potentially preventable hospitalizations, with the expanded composite proposed by Tseng et al. functioning as parameters for a sensitivity analysis. 28 Using an expanded composite with HCUP data will test their validity at the national scale, whereas the original analysis was limited to Veteran's Administration data. We will also examine potentially preventable hospitalization trends stratified by geographic regions and rural/urban location, addressing the remaining gap in the literature.

No literature has been published which describes the trends in medications commonly prescribed (antihyperglycemic agents, antihyperlipidemic agents, antihypertensive agents, antiplatelet agents, and antidepressant/anxiolytic agents) among people with diabetes. We will fill this gap in the literature and determine if these patterns of use vary by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, or health insurance coverage. Identifying contributors to disparities in diabetes management will shed light on possible intervention targets to reduce these disparities and improve outcomes.

Objectives and Hypotheses

2.1 Primary Objective(s) & Hypothesis(es)

Objective 1. To describe trends in ED visit rates and inpatient use rates among adults with diabetes in the United States from 2005-2016.

Trends will be stratified by age, sex, race/ethnicity, rural/urban designation (as defined by the National Center for Health Statistics and described in Section 4: Variables), presence of comorbidities (microvascular, macrovascular, and depression/anxiety), geographic region, and health insurance coverage.





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Objective 2. To describe trends in the rates of potentially preventable diabetes-related hospitalizations, as defined by ICD-9 and ICD-10 codes for Prevention Quality Indicators 1, 3, 14, and 16 published by the AHRQ's Preventable Quality Indicators (described in Section 4: Variables) among adults with diabetes in the United States from 2005-2016.

Trends will be stratified by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage.

Objective 3. To describe trends of prescription drug usage (antihyperglycemic agents, antihyperlipidemic agents, antihypertensive agents, antiplatelet agents, and antidepressant/anxiolytic agents) among adults with diabetes in the United States from 2005-2016.

Trends will be stratified by age, sex, race/ethnicity, , presence of comorbidities, geographic region, and health insurance coverage.





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3 METHODOLOGY

3.1 Summary of Study Design

The analysis will be conducted using a retrospective serial cross-sectional design using data from the AHRQ's Healthcare Cost and Utilization Project. Specifically, data from the National Inpatient Sample, the Nationwide Emergency Department Sample, the State Inpatient Database, and the State Emergency Department Database, and the Medical Expenditure Panel Survey will be used for the analysis.

The AHRQ's Healthcare Cost and Utilization Project (HCUP) is the "largest collection of all payer, encounter-level hospital care data in the United States." There are multiple HCUP datasets: The National Inpatient Sample (NIS), the Nationwide Emergency Department Sample (NEDS), the State Inpatient Database (SID), and the State Emergency Department Database (SEDD). Each dataset contains hospital-level claims data. MEPS provides data from self-reported survey responses, physician claims data, hospital claims data, and pharmaceutical claims data.

NIS: The NIS contains a record of every non-psychiatric, non-federal hospital discharge from a nationally representative sample over a single year.

NEDD: The NEDD contains a record of every non-psychiatric, non-federal hospital emergency department discharge from a nationally representative sample over a single year.

SID: The SID contains a record of every non-psychiatric, non-federal hospital discharge in an individual state over a single year.

SEDD: The SEDD contains a record of ED visits at hospital-affiliated EDs that do not result in a hospital admission.

The National Inpatient Sample is a database of hospital inpatient stays derived from billing data by U.S community hospitals. Data are systematically sampled from the State Inpatient Databases.

Each year of the NIS includes over 7 million inpatient stays. The Nationwide Emergency Department Sample contains data from approximately 31 million ED visits per year and estimates roughly 143 million ED visits. These datasets are available for purchase through the HCUP website. The HCUP data use agreement requires that researchers do not attempt to discover the individual identity of anyone in the database. A powerful tool within these datasets is the "revisit variable," a unique code applied to a patient that allows him or her to be followed throughout one year of data. Importantly, revisit variables reset each year, so the same patient may have different revisit variables in different years of the data, thereby preventing tracking of patients between years of the dataset. The revisit variable also allows for analysis of a patient's healthcare use across datasets (i.e. a patient's use of emergency departments and inpatient stays over the course of a year).

There are 11 states with State Inpatient and State Emergency Department datasets for the years of interest (2016, 2014, 2011, and 2008): Arizona, Florida, Iowa, Kentucky, Maryland, Nebraska, New York, New Jersey, North Carolina, Vermont, and Utah (Figure 1). Four of these states carry the revisit variable that allows for linkage across datasets and the tracking of a single patient's health care use: Florida, Nebraska, New York, and Utah. These states have data available since 2006.

Table 1. Census Geographic Region and Medicaid Expansion Status for States Considered

State	cate Census Geographic Region Medicaid Expa	
	.	Status .
Kentucky	South	Full Expansion

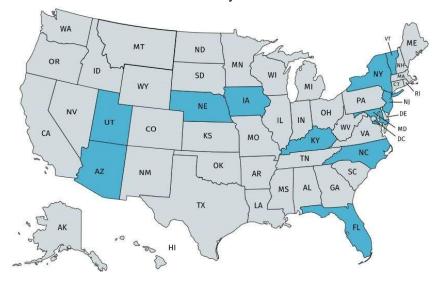




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Arizona	South	Full Expansion
lowa	Midwest	Full Expansion
Maryland	South	Full Expansion
New Jersey	Northeast	Full Expansion
New York	Northeast	Full Expansion
Vermont	Northeast	Full Expansion
Nebraska	Midwest	Full Expansion
Utah	West	Partial Expansion
Florida	South	No Expansion
North Carolina	South	No Expansion

Figure 1. State distribution to be used in analysis



Patients with diabetes will be identified by the presence of a diabetes-specific ICD-9 or ICD-10 code. Variables for age, race/ethnicity, geographic region, urban/rural location, and insurance type are each included in the SID, SED, NIS, and NEDD.

MEPS: Large scale survey of families and individuals, their medical providers (doctors, hospitals pharmacies, etc.) and employers across the United States.

In addition, annually, the AHRQ recruits a nationally-representative sample of households and collects data regarding their health expenditures, payment sources, and healthcare use in the Medical Expenditure Panel Survey (MEPS). The data include use of health services, cost of health services, frequency of service use, sociodemographic characteristics, and insurance coverage. The MEPS also has a restricted access component that involves data collection from physicians and health systems about prescriptions, as well as a component from pharmacies. The work conducted with the MEPS data will be exploratory in nature, but will develop the platform for a variety of other questions of importance regarding disparities in diabetes care nationally.

3.2 Study Population





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Aims 1 and 2: U.S. non-institutionalized population aged 18+, diagnosed with diabetes as indicated by presence of a diabetes-specific ICD-9 or ICD-10 codes which visited hospital inpatient and emergency department settings from years 2005-2016.

Aim 3: U.S. non-institutionalized population aged 18+, diagnosed with diabetes as indicated by presence of a diabetes-specific ICD-9 or ICD-10 codes, presence of self-reported diabetes, or prescription of 1+ diabetes medication in past 2 years.

3.3 Inclusion Criteria

Aim 1:

• Observation has presence of ICD-9 codes indicative of diabetes disease state (Appendix 1)

Or

• Observation has presence of ICD-10 indicative of diabetes disease state (Appendix 1) ☐ Patient is age 18+

Aim 2:

Observation has presence of ICD-9 codes indicative of diabetes disease state (Appendix 1)

Or

- Observation has presence of ICD-10 codes indicative of diabetes disease state (Appendix 1)
- Patient is age 18+
- Observation has presence of ICD-9 codes indicative of a potentially preventable hospitalization (Appendix 2)

Aim 3:

• Patient has indicated presence of self-reported diabetes

Or

• Patient has been diagnosed 1+ diabetes medication in past two years

Or

• Patient inpatient, outpatient, or emergency department visit has presence of ICD-9 codes indicative of diabetes disease state (Appendix 1)

Or

- Patient inpatient, outpatient, or emergency department visit has presence of ICD-10 codes indicative of diabetes disease state (Appendix 1)
- Patient is age 18+

3.4 Exclusion Criteria

Patient is <18 years old.

3.5 Stratification

Stratified according to the following factors:

- 1) Age
- 2) Race/ethnic group
- 3) Sex
- 4) Health Insurance Coverage
- 5) Geographic Region
- 6) Urban/Rural designation
- 7) Presence of comorbidities





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4 Variables and Epidemiological Measurements

4.1 Variables

All variables are gathered from cross-sectional snapshots from 2008-2016. No follow up or pre-index period is defined as there is no longitudinal aspect of this study. Variables for analysis are listed below, with relevant information supplied by the AHRQ's documentation for data elements. Each variable will be used for the purpose of quantitative descriptive analyses. We will start by taking the sum total of all-cause health care use and outcomes. From there, we will have to try to disaggregate the health care use that was "diabetes-related" based on the billing claim.

Variable	Definition	Unit
Age	NIS/NEDD/SID/SEDD	Mean years
	AGE	(SD),
	Age in years (AGE) is calculated from the birth date	Range
	(DOB) and the admission date (ADATE) in the HCUP	
	State databases with the few exceptions listed	
	below. Ages over 89 are aggregated into a single	
	category of 90 years or older in the HCUP	
	nationwide databases starting in data year 2012.	
	Age will be grouped into 18-44, 45-64, and 65+ for	
	purpose of analysis	
	MEPS	
	AGELAST	
	Person's Age Last Time Eligible	
	When date of birth was not provided but age was	
	provided (either from the MEPS interviews or the	
	2008-2009 NHIS data), the month and year of birth	
	were assigned randomly from among the possible	
	valid options. For any cases still not accounted for, age was imputed using:	
	(1) the mean age difference between MEPS	
	participants with certain family relationships	
	(where available) or	
	(2) the mean age value for MEPS participants.	
	Age will be grouped into 18-44, 45-64, and 65+ for purpose of analysis	
Sex	NIS/NEDD/SID/SEDD	





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	FEMALE	Number and
	Indicator of sex	%
	Categories: Male, Female, Missing, Invalid,	female/male
	Inconsistent	
	MEPS	
	SEX	
	Data on the sex of each RU member (SEX) were	
	initially determined from the 2008 NHIS for Panel	
	14 and from the 2009 NHIS for Panel 15. The SEX	
	variable was verified and, if necessary, corrected	
	during each MEPS interview.	

NIS/NEDS/SID/SEDD	Number
RACE Categories: White, Black, Hispanic, Asian or Pacific Islander, Native American, Other	and % of the cohort
MEPS	
FY PUFS 2002–2011	
Categories: White, Black, American Indian/Alaska	
Native Hawaiian/Pacific Islander, Multiple Races RACETHNX	
Categories: Hispanic, Black – No other race reported, Asian – No other race reported, Other race/Not	
Пізрапіс	
	RACE Categories: White, Black, Hispanic, Asian or Pacific Islander, Native American, Other MEPS FY PUFS 2002–2011 RACEX Categories: White, Black, American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, Multiple Races RACETHNX Categories: Hispanic, Black – No other race reported,

NIS/NEDS/SID/SEDD	
INIS/ NEDS/SID/ SEDD	



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Diabetes	DXn	Number
Disease State	In the HCUP databases, ICD-9-CM diagnoses are	in the
(Generated	represented as 3- to 5-character alphanumeric codes	cohort
Variable)	with implicit decimals (i.e., decimals not included).	
	l10_DXn	
	In the HCUP databases, ICD-10-CM diagnoses are	
	represented by alphanumeric codes with a maximum	
	length of 7 characters and implicit decimals (i.e.,	
	decimals not included). The HCUP data elements for	
	ICD-10-CM diagnoses are length 7.	
	NDX	
	NDX indicates the total number of ICD-9-CM diagnoses	
	(valid and invalid) coded on the discharge record. In	
	assigning NDX, the first listed diagnosis is included in	
	the count, even if it is blank, so long as there is a	
	secondary diagnosis present.	
	I10_NDX	
	For data beginning in the fourth quarter of 2015, the	
	count of the number of diagnoses is stored in the data	
	element I10_NDX to indicate the implementation of	
	the ICD-10-CM/PCS coding system.	
	MEPS	



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	DIABDX	Diabetes Diagnosis (>17)	
	OSDIA53	DCS: Diabetes Diagnosis by Health Prof	
F	RXNAME	Medicine name	
F	RXDRGNAM	Multum medicine name	
	CD9CODX	ICD-9-CM Code for Condition – Edited	
Į.	CD10CODX	ICD-10-CM Code for Condition – Edited	
	Aims 1&2:		
		ges with presence of ICD-9 or ICD-10	
	•	of diabetes in first 5 discharge	
		endix 1). Gestational diabetes is not	
	ncluded.	maix 17. destational diabetes is not	
S	Statistical measu	ures of validation: ²⁹	
S	Sensitivity: 95.6%	%,	
S	Specificity: 92.8%	%,	
F	PPV: 54.0%		
	NPV: 99.6%		
	Aim 3:		
		reported diabetes	
		ures of validation: ³⁰	
	Sensitivity: (58.5	•	
	Specificity: (95.6		
	PPV: (92.7%-95.4	•	
	NPV: (85.4% - 90	·	
		een prescribed 1+ diabetes medication in past	
[t	wo years or		

Physical Claims or Hospital Discharges with presence	
of any of ICD-	
9 or ICD-10 codes indicative of diabetes (Appendix 1)	
Statistical measures of validation: ²⁹	
Sensitivity: 95.6%,	
Specificity: 92.8%,	
PPV: 54.0%	
NPV: 99.6%	
The combined algorithm has not been validated.	





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Indicator for non-	Aims 1 and 2:	Number
diabetes	Lack of presence of any ICD-9 or ICD-10 codes indicative of	
(Generated Variable)	diabetes (Appendix 1) in any available discharge diagnoses.	cohort
,	Aim 3:	
	Lack of any positive indicator of diabetes:	
	No self-report of diabetes,	
	No diabetes medication script filled over two years,	
	No Physical Claims or Hospital Discharges with	
	presence of any of ICD- 9 or ICD-10 codes indicative of diabetes (Appendix 1)	
Geographic	NIS, NEDS, SID, SEDD	Number
location/Region	1413, 14203, 310, 3200	and %
		of the
	HOSP_REGION: Region of Hospital	cohort
	Categories: Northeast, Midwest, South, West	
	MEPS.	
	REGION	
	Categories: Northeast, Midwest, South, and West	
1		

Rural/ Urban	NIS, NEDS, SID, SEDD	Number
	PL_NCHS: Patient Location Categories: "Central" counties of metro areas, "Fringe" counties of metro areas", Counties in metro areas of 250,000-999,999, Counties in metro areas of 50,000- 249,999, Micropolitan counties, and Not metropolitan or micropolitan counties.	and % of the cohort





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The analyses will use Urban/Rural definitions based on the National

Center for Health Statistics 2013 Urban-Rural Classification Scheme.³¹

Urban:

Large central metro counties in metropolitan statistical area (MSA) of 1 million population that: (1) contain the entire population of the largest principal city of the MSA, or (2) are completely contained within the largest principal city of the MSA, or (3) contain at least 250,000 residents of any principal city in the MSA.

Large fringe metro counties in MSA of 1 million or more population that do not qualify as large central.

Medium metro counties in MSA of 250,000-999,999 population. Small metro counties in MSAs of less than 250,000 population.

Rural:

Micropolitan: Urban cluster population 10,000-49,999. Noncore: Nonmetropolitan counties that did not qualify as micropolitan.

Insurance	NIS/NEDS/SID/	SEDD	Number
Coverage	Medicaid, priva uniformity of co combines detai groups. Categories: Me	expected primary payer (Medicare, ate insurance, etc.). To ensure oding across data sources, PAY1 iled categories in the more general dicare, Medicaid, Private Insurance, arge, Other, Missing, Invalid	and % of the cohort
	PRVEVXX TRIEVXX MCREVXX MCDEVXX OPAEVXX OPBEVXX UNINSXX INSCOVXX	it An insurance coverage variable using responses for t the following binary variables (XX indicates year) Ever Have Private Insurance during XX Ever Have TRICARE/CHAMPVA during XX Ever Have Medicare during XX Ever Have Medicaid/SCHIP during XX	



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	Ever Have Other Public A Ins during XX Ever Have Other Public B Ins during XX Uninsured All of XX	
	Health Insurance Coverage Indicator XX Full Year Insurance Coverage Status XX	
Co-morbidities		

Micro-vascular	NIS, NEDS, SID, SEDD	Number
Complications	DXn	and % of
	In the HCUP databases, ICD-9-CM diagnoses are	the cohort
Macro-vascular	represented as 3- to 5-character alphanumeric codes	
Complications	with implicit decimals (i.e., decimals not included).	
	l10_DXn	
Depression/Anxiety	In the HCUP databases, ICD-10-CM diagnoses are	
	represented by alphanumeric codes with a maximum	
	length of 7 characters and implicit decimals (i.e., decimals	
	not included). The HCUP data elements for ICD-10-CM	
	diagnoses are length 7.	
	MEPS	
	ICD9CODX ICD-9-CM Code for Condition – Edited	
	Micro-Vascular Complications	
	Diabetic Retinopathy	
	Nephropathy	
	• Neuropathy	
	Macro-vascular Complications	



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- Acute Coronary Syndrome
- Acute Myocardial Infarction
- Angina
- Arrhythmia
- CABG Revascularization/Carotid Revascularization/ Claudication /
- Surgical Revascularization
- Heart Failure
- Peripheral Arterial Disease or Vascular Disease
- Stroke/TIA

Depression/Anxiety

Inclusion criteria includes ICD-09 and ICD-10 codes that indicate presence of suicidal behavior, anxiety disorders, and depression disorders. All individuals with psychoses or other bipolar disorders will be excluded.

ICD-9 and ICD-10 codes for above comorbidities/complications are listed in Appendix 4. The codes for retinopathy, nephropathy, neuropathy, and peripheral arterial disease or vascular disease were adapted from the criteria used for the Adjusted Diabetes Complication Severity Index. 32 and adapted to ICD-10 by Glasheen et.al. 33. The codes for the remaining complications were identified in the literature, or published by the AHRQ for health services research purposes and adapted to ICD-10 using the online resources cited by Glasheen et. al., ICD9Data.com and ICD10Data.com. 34-40

Existence of comorbidities will be identified using ICD-9 and ICD-10 codes with flagged variables to allow for analyses by comorbidity status.





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Potentially	NIS/NEDS/SID/SEDD	Number
preventable		and % of
hospitalizations		the cohort

DX_Visit_Reasonn and DXn

In the HCUP databases, ICD-9-CM diagnoses are represented as 3- to 5-character alphanumeric codes with implicit decimals (i.e., decimals not included).

I10_DXn

In the HCUP databases, ICD-10-CM diagnoses are represented by alphanumeric codes with a maximum length of 7 characters and implicit decimals (i.e., decimals not included). The HCUP data elements for ICD-10-CM diagnoses are length 7.

The original value of the first listed diagnosis (DX1), whether blank or coded, is retained in the first position of the diagnosis vector. Starting at the first secondary diagnosis (DX2), the diagnoses are shifted during HCUP processing to eliminate blank secondary diagnoses. For example, if DX2 and DX4 contain non-missing diagnoses and DX3 is blank, then the value of DX4 is shifted into DX3. Secondary diagnoses are never shifted into the first listed position (DX1).

DXPOAn

Indicates whether each diagnosis (DXn) was present at admission. This provides an indicator of complications arising during a hospitalization

The Prevention Quality Indicators are surveillance tools which can be used with hospital inpatient discharge data to identify potentially preventable hospitalizations.²⁴





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Criteria for a potentially preventable hospitalization are any hospitalization events that include a diagnosis included in the AHRQ's Prevention Quality Indicators for Diabetes. ICD-9 and ICD10 codes for Lower Extremity Ulcers and Hypoglycemia, to be used for sensitivity analysis, are also included in Appendix 2. The coding algorithms for the Prevention Quality Indicators are not available.

These codes were selected by the AHRQ's Evidence-Based Practice Center at the University of California at San Francisco and Stanford University, using comprehensive literature reviews and empirical evaluations. 41

Hypoglycemia ⁴²
Sensitivity: 97%,
Specificity: 99%,
PPV: 93%%
NPV: 88%

Hospital	NIS//SID/SEDD	Number and % of discharges
inpatient		
&		
emergency		
department		
services		

HCUP ED

Indicates records that have evidence of emergency department (ED) services reported on the HCUP record. A value of 1 or more indicates that there is evidence of ED services, per HCUP criteria. A value of 0 marks records that do not include evidence of ED services.

HCUP_OS

Indicates records that have evidence of observation stay (OS) services reported on the HCUP record. A value of 1 or greater indicates that there is evidence of OS. A value of 0 marks records that do not include evidence of OS. It is possible that records with HCUP_OS=0 did in fact have OS services, but that information was not captured on the HCUP record.

LOS

Length of stay (LOS) is calculated by subtracting the admission date (ADATE) from the discharge date (DDATE). Same-day stays are therefore coded as 0. Leave days are not subtracted.

NEDS



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NCPT indicates the total number of CPT or HCPCS procedures (valid and invalid) coded on the discharge record.

Identifying diabetes-related inpatient stays and emergency department visits will be through filtering the datasets for diabetes disease state indicators. Each independent observation in the NIS and NEDS are an inpatient stay or emergency visit. For state datasets with revisit variables, multiple utilization events over the course of a year are linked, allowing for a per-patient analysis. Use of the Emergency Department Services and Observation stay variables are for the purpose of characterizing inpatient stays only.

MEPS

XX indicates year

Full Year Consolidated

File

OPTOTVXX
OPDRVXX

ERTOTXX

Hospital Outpatient Visits
Physician Outpatient Visits
Total Emergency Room Visits

Total Inpatient Stays

IPDISXX Total Inpatient Stays Including Zero

IPNGTDXX Night Stays Zero Night Stays

IPZEROXX

ER Visits File Event date – year
ERDATEYR Event date – month

ERDATEMM Was surg proc performed on p this

SURGPROC visit

MEDPRESC Any medicine prescribed for p this

visit

Medical Conditions File IPNUM	# Inpatient Events Assoc. w/ Condition	
OPNUM	# Outpatient Events Assoc. w/ Condition	
OBNUM	# Office-Based Events Assoc. w/ Condition	
ERNUM	# ER Events Assoc. w/ Condition	





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Medication MEPS Number (% Antihyperglycemic of DRUGIDX Drug ID agents cohort) RXNAME Medicine • Antihyperlipedemic name RXDRGNAM agents RXQUANTY Multum No. • Antihypertensive agents RXFORM medicine reporting Antiplatelet agents name RXFRMUNT of actual Antidepressant/anxiolytic Quantity of drug or **RXSTRENG** agents Rx/prescribed drug **RXSTRUNT** medicine class will RXDAYSUP be in Dosage form RXNAME: scope Quantity unit TC1: for this of medication TC1S1: study Quantity unit TC1S1 1: of medication TC1S1 2: Unit of TC1S2: medication TC1S2_1: Days supplied TC1S3: of prescribed TC1S3_1: med TC2: Medicine TC2S1: name TC2S1 1: Multum TC2S1 2: therapeutic TC2S2: class #1 TC3: Multum TC3S1: therapeutic TCS3S1_1: sub-sub-class for TC1S1 Multum Antihyperglycemic atherapeutic sub-sub-class for TC1S1 Multum therapeutic sub-sub-class for TC1S1 Multum therapeutic sub-class #2 for TC1 Multum therapeutic sub-sub-class for TC1S2



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Multum therapeutic sub-class #3 for TC1 Multum therapeutic sub-sub-class for TC1S3 Multum therapeutic class #2 Multum therapeutic sub-class #1 for TC2 Multum therapeutic sub-sub-class for TC2S1 Multum therapeutic sub-sub-class for TC2S1 Multum therapeutic sub-class #2 for TC2 Multum therapeutic class #3 Multum therapeutic sub-class #1 for TC3 Multum therapeutic sub-sub-class for TC3S1

- Meglitinides
- Biguanides
- Sulphonylureas
- Alpha-glucosidase inhibitors
- Glitazones
- Thiazolidinediones
- DPP-4 inhibitors
- GLP-1 receptor agonists
- SGLT-2 inhibitors
- Long-acting insulin
- Intermediate acting insulin
- Rapid-Acting insulin



Epidemiology No.(PE Studies only): EP0xxxx.xx Antihypertensive agents Anti-hypertensive Diuretics Calcium channel blocking agents Angiotensin converting enzyme inhibitors Angiotensin II receptor antagonists Alpha-1 adrenergic receptor agonists Alpha-2 adrenergic receptor agonists Beta-adrenergic blocking agents Vasodilators **Renin Inhibitors** Aldosterone receptor antagonists Endothelium receptor antagonistsAntihypertensive combinations Antiplatelet agents Glycoprotein platelet inhibitors Platelet aggregation inhibitors Protease-activated receptor-1 antagonists Antihyperlipidemic agents Statins **Fibrates** Antidepressant/anxiolytic agents



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	SSRI antidepressants		
	Tricyclic antidepressants		
	Monoamine oxidase inhibitors		
	Phenylpiperazine antidepressants		
	Tetracyclic antidepressants		
	SSNR antidepressants		
	Barbiturates		
	Benzodiazepines		

4.2 Outcomes

Objective 1: To describe trends in ED visit rates and inpatient use rates among adults with diabetes in the United States from 2005-2016 by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage.

- Number of Hospital Inpatient Stays for years 2008, 2011, 2014, and 2016.
- Absolute and percentage change in number of Hospital Inpatient Stays from 2008 to 2016.
- Number of Hospital Inpatient Stays for years 2008, 2011, 2014, and 2016.
- Absolute and percentage change in number of Hospital Inpatient Stays from 2008 to 2016.
- Rate of Hospital Inpatient Stays per 1000 people with diabetes for years 2008, 2011, 2014, and 2016.
- Absolute and percentage change in rate of Hospital Inpatient Stays from 2008 to 2016.
- Rate of Emergency Department Visits per 1000 people for years 2008, 2011, 2014, and 2016.
- Absolute and percentage change in rate of Emergency Department Visits from 2008 to 2016.
- Stratification of findings by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage, and diabetes status.

Objective 2: To describe trends in the rates of potentially preventable hospitalizations among adults with diabetes in the United States from 2005-2016 by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage.

- Number of Potentially Preventable Hospitalizations among people with diabetes for years 2008, 2011, 2014, and 2016.
- Rates of Potentially Preventable Hospitalizations per 1000 persons with diabetes for years 2008, 2011, 2014, and 2016.
- Absolute and percent change in number of Potentially Preventable Hospitalizations from 2008 to 2016.
- Absolute and percent change in rates of Potentially Preventable Hospitalizations from 2008 to 2016.
- Stratification of percent change in rates of Potentially Preventable Hospitalizations by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage, and diabetes status.

Objective 3: To describe trends of prescription drug (specifically, antihyperglycemic agents, antihyperlipidemic agents, antihypertensive agents, antiplatelet agents, and antidepressant/anxiolytic





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agents) usage among adults with diabetes in the United States from 2005-2016 by age, sex, race/ethnicity, , presence of comorbidities, geographic region, and health insurance coverage.

- Number of people with diabetes prescribed medications in drug classes listed above in the years 2008, 2011, 2014, and 2016.
- Absolute and percent change in number of people receiving prescriptions in drug classes listed above from 2008-2016.
- Percent change in number of people with diabetes prescribed in drug classes listed above from 2008-2016.
- Stratification of findings by age, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and health insurance coverage.





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5 STUDY PROCEDURES

5.1 General Informed Consent

The State Inpatient Database, State Emergency Department Database, National Inpatient Sample, and National Emergency Department Databases each collect data on hospital-level claims and discharges from state governments and private data agencies with statewide inpatient data systems. Dissemination of the State Inpatient Database is controlled by the original data source, with measures taken to protect the identity of individual patients and physicians.⁴³

Individuals that participate in the Medical Expenditure Panel Survey are sampled from the National Health Interview Survey (NHIS). When the interviewer arrives at the household address, he/she provides a copy of an advance letter which contains information about the purpose of the NHIS and amount of time the interview will require, as well as verbal consent for survey participation. ⁴⁴ The Medical Expenditure Panel Survey keeps the identity of each individual household member who participates confidential. No information that may identify an individual is released to the public without prior consent. All personal identifying information is removed before data publication. ⁴⁵

Individuals that participated in the Behavioral Risk Factor Surveillance System were asked to provide informed consent during the phone interview. No personal information was collected, and individual data is kept confidential.⁵² The Behavioral Risk Factor Surveillance System interview is not being conducted for the purposes of this study.

This research is not considered to meet the definition of human subject research. As such, Emory does not require IRB review.

6 Safety and Product Quality Complaint Reporting and Related Procedures

Adverse Event (AE) and Product Quality Complaint (PQC) Reporting Language for Non-Interventional Study Protocols

Adverse Event and Product Quality Complaint Reporting

This is a non-interventional database study based on secondary use of data collected for other purposes. No administration of any therapeutic or prophylactic agent is required in this protocol. No reporting of individual adverse events or product quality complaints to regulatory agencies is planned for this database study because there is no access to individual patient/subject records and it is not possible to assess the causality of individual cases. Study-specific health outcomes of interest, including any that qualify as adverse events, will be summarized as part of any interim analysis (including safety analysis, if required) and in the final study report, which will be provided to regulatory agencies by the sponsor as required.





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Any relevant safety information will be summarized in the appropriate Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER) and/or Development Safety Update Reports (DSUR) if required.

If an investigator elects to spontaneously report any suspected adverse reactions or product quality complaints, they should be reported via fax to Local DPOC [fax number: 215-616-5677], in English using an AE and PQC report form (see section 12 for form) for reporting to worldwide regulatory agencies as appropriate.





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7 Statistical Analysis Plan

7.1 Statistical Methods

Descriptive analyses will be conducted pertaining to each aim in order to describe the trends in 1) Inpatient and ED care utilization rates, 2) Potentially preventable Hospitalization rates, and 3) Cardiovascular-modifying medication usage. Data from 4 different years will be used to conduct these analyses: 2008, 2011, 2014, and 2016.

Validation of the data will be run alongside the descriptive analysis, and data that are missing or incorrect will be corrected if possible and otherwise excluded. If analysis indicates that the missing data are missing completely at random, case deletion will be used to progress the analysis. Otherwise, multiple imputation methods will be used to impute values. The specific imputation model used will depend on the type of data element in the analysis that require imputation.

During 1988 to 2011, the NIS was constructed annually by including 100% of the discharges from 20% of US hospitals. Starting in 2012, the AHRQ redesigned the NIS as a 20% national patient-level sample in 2012, with nonrepresentative sampling across hospitals. ⁴⁶ This change will be addressed through the use of trend weights which allow for trend analysis prior to and post sampling change. ⁴⁷

These trend weights will be used for NIS data from 2008 and 2011 in order to make estimates comparable to the data from 2014 and 2016. For data from 2012 on, discharge weights will be used which will allow extrapolation of NIS sample discharges to produce nationwide estimates. The discharge weights are constant for all discharges within a stratum as defined by hospital characteristics. As Discharge weights will also be applied to the NEDS dataset in order to allow for the generation of nationwide estimates. These weights will address the complex survey design of the NIS and NEDS and account for clustering, stratification, and sampling bias.

The MEPS sample design includes stratification, clustering, multiple stages of selection, and disproportionate sampling. In order to obtain accurate descriptive statistics, the analysis will account for survey design complexities by applying MEPS survey weights to produce estimates. The sampling weights also reflect adjustments for survey nonresponse and adjustments to population control totals.⁴⁹

The analysis will use the Taylor-series linearization and/or the jack-knife methods to estimate the standard errors associated with weighted estimates.

Rate estimates will be calculated as follows:

Total Healthcare Service Use* in XX year \times 1000

Number of People with Diabetes in XX year

*Where Healthcare Service Use is defined as number of Hospital Inpatient Stays, ED visits, Potentially Preventable Hospitalizations, and Drugs Prescribed





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In order to create a denominator for use in estimating rates per 1000 persons with diabetes Behavioral Risk Factor Surveillance Survey (BRFSS) data will be used to determine the population of people with diabetes. The population estimates generated will use self-reported diabetes diagnosis to indicate presence of diabetes disease state. BRFSS data will be also be used to estimate the population of people with diabetes by sex, race/ethnicity, rural/urban designation, geographic region, and health insurance coverage status. These estimates will be used to generate rates per stratification of interest. Rates will be standardized using available demographic data to allow for comparison over years.

Overall rates of service use will be calculated by diabetes and non-diabetes status and compared using rate ratios for both within-group and between-group comparisons for each year of data available. Within-group rate ratios will be calculated using 2008 as the reference year. Approximate confidence intervals for standardized rate ratios will be calculated using the log-normal distribution.

Absolute change estimates will be calculated as follows:

Estimate for Healthcare Service use in 2016 - Estimate for Healthcare Service use in 2008

Percent change estimates will be calculated as follows:

$$\frac{Absolute\ Change\ from\ 2008-2016}{Estimate\ for\ Healthcare\ Service\ use\ in\ 2008}\times 100$$

Self-reported diabetes diagnosis will be used to indicate presence of diabetes disease state. In order to account for the complex survey design of the Behavioral Risk Factor Surveillance Survey, a sample weight will be applied to generate these estimates.

Each analytic procedure/code will first be conducted and validated with one year of data, and then applied and adjusted for use with prior years after confirmation of validity.

For Objectives 1 and 2, we will conduct revisit analyses. For states with revisit variables available (Florida, New York, Utah, and Nebraska), we will create variables to indicate the number of potentially preventable hospitalization each individual patient had. The analysis will be repeated among these states in order to generate patient-level health care use estimates, rather than encounterlevel use estimates. No revisit analyses will be completed with NIS data, as the revisit variable is unavailable.

We will repeat the analyses for Objectives 1 and 2 using nationally-representative NIS and NEDS data. These estimates will be used for the purposes of a sensitivity analysis and determine whether the estimates generated using SID and SEDD data are nationally representative. We will use MEPS to





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generate additional estimates for comparison when possible, specifically for total number of inpatient stays and ED visits.

Continuous variables will be expressed as the mean \pm standard deviation. Categorical variables will be presented in terms of expected count and frequency in the dataset. Rates will be expressed per 1000 persons with diabetes.

No statistical testing of differences will be performed as the analysis was designed as a descriptive study.

All statistical analysis will be performed using R (R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. www.R-project.org/).51

Shell tables are provided in the Appendix, as items 5, 6, 7. Variables to be reported in the course of the analysis are provided in the appendices.

Objective 1:

First, the total number of claims in the SID and SEDD will be estimated. The datasets will then be filtered to select for observations consistent with a diabetes disease state, using variables that indicate ICD-9 and ICD-10 codes (Appendix 1). The mean age will be calculated and reported along with range for each year. A frequency distribution will then be generated in terms of sex, rural/urban designation, race, and insurance coverage, which will be reported as the estimated count and percent of observations represented (Appendix 5, Table 2).

After describing the dataset, both unweighted and weighted estimates for the count of hospital inpatient stays and ED visits for each year will be calculated. A variable for age group will be created, with categories as follows: 18-44, 45-64, and 65+. The estimates will be reported by age group, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and insurance coverage, alongside the percentage of observations represented. Absolute change and percent change from 2008 to 2016 will then be estimated and reported (Appendix 5, Tables 3 and 4).

The estimates generated by the previous analyses will be divided by the estimates generated in the Behavioral Risk Factor Surveillance Survey, specific to the stratifications of interest to generate rates of health care use per 1000 persons with diabetes (Appendix 5, Tables 5 and 6).

Objective 2

Of the filtered dataset generated for our first objective, we will then filter observations for presence of ICD-9 or ICD-10 codes indicative of a potentially preventable hospitalization (Appendix 2).

Two variables will be created:

1) a binary variable that flags whether or not an inpatient stay was potentially preventable





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2) a variable to indicate what type of potentially preventable hospitalization is present (Short-Term Diabetes Complications, Long-Term Diabetes

> Complications, Uncontrolled Diabetes without Complications, Diabetes-related Lower-Extremity Amputations, Lower Extremity Ulcers/inflammation/infections, or Hypoglycemia).

The dataset will then be filtered for observations flagged for potentially preventable hospitalizations. The counts of potentially preventable hospitalizations by age group, sex, race/ethnicity, rural/urban designation, presence of comorbidities, geographic region, and insurance coverage, alongside the percentage of observations represented will then be estimated. Rates of potentially preventable hospitalizations per 1000 persons with diabetes will be estimated using BRFSS estimates as the denominator (Appendix 6, Table 7). Absolute change and percent change in potentially preventable hospitalizations from 2008 to 2016 will then be estimated and reported (Appendix 6, Table 8).

This analysis will be conducted again using the conditions suggested by Tseng et al., hypoglycemia and lower extremity ulcers.²⁸ The results of this analysis will be compared to the initial estimates and will serve as a sensitivity analysis.

Objective 3

For the MEPS analysis, survey weights will be applied to the dataset to account for stratification, clustering, multiple stages of selection, and disproportionate sampling. First, the total database population will be estimated. The datasets will then be filtered to select for observations consistent with a diabetes disease state, using variables that indicate ICD-9 and ICD-10 codes, presence of selfreported diabetes, or the prescription of a diabetes medication in the past year (Appendix 1).

The mean age will be calculated and reported along with range for each year. A frequency distribution will then be generated in terms of age group, sex, race/ethnicity, , presence of comorbidities, geographic region, and insurance coverage, which will be reported as the estimated count and percent of observations represented (Appendix 7, Table 9).

After describing the dataset, variables will be created which indicate whether an individual was prescribed antihyperglycemic agents, antihyperlipidemic agents, antihypertensive agents, antiplatelet agents, and/or antidepressant/anxiolytic agents. Drugs will be described and reported and analyzed by category of drug and not by class or name.

We will then estimate and report the weighted count and % of people with diabetes prescribed antihyperglycemic agents, antihyperlipidemic agents, antihypertensive agents, antiplatelet agents, and antidepressant/anxiolytic agents each year, as well as the absolute and percent change from 2008 to 2016 (Appendix 7. Table 10).

Weighted estimates will then be calculated by age group, sex, race/ethnicity, presence of comorbidities, geographic region, and insurance coverage. Absolute change and percent change in





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prescriptions for medications from 2008 to 2016 will then be estimated and reported (Appendix 7. Table 11).

7.2 Bias

Selection of state inpatient databases to be used in the analysis was limited by budget and data availability issues. Each state provides different variables, and data availability varies by state. This may result in a bias towards the health service utilization characteristics present in higher-resource states which have greater data availability. Although the analysis uses data from geographically distributed states, it may not be a representative national sample. However, no national datasets contain the patient-level and health care use details that HCUP's state databases do.

7.2.1 Methods to Minimize Bias

The analysis will use weights as necessary in order to eliminate possible sampling bias. For the NIS, the analysis will use trend weights prior to 2011 and discharge weights after 2011 to allow for comparison of estimates. For the NEDS, the analysis will use discharge weights to generate nationally representative estimates. As the NEDS does not have a variable indicating state, we will compare NEDS estimates with SEDD estimates by region.

To address possible bias stemming from variations in state characteristics, the analysis will use 11 states which are widely distributed terms of geographic location and political leaning. In order to test whether our sample is providing nationally representative findings, we will use NIS data, which contains a 20% sample of all discharges across the US (46 states and D.C.). We will then perform sensitivity analyses for objectives 1 and 2 to determine if the results using the 11 states are generally similar (provide a good reflection of national sample results) or dissimilar (suggesting presence of bias).

However, because not all states provide data to the National Inpatient Sample there may be some bias in national estimates that occur if omitted states have substantially different hospitalization patterns than states that do provide data.⁵⁰

The analysis will also validate findings, when possible, with MEPS data. For example, MEPS includes a variable which provides the total number of inpatients stays a patient had over the course of the past two years – this variable could be used to compare estimates of health service utilization generated with NIS or SID data.

The MEPS sample design includes stratification, clustering, multiple stages of selection, and disproportionate sampling. In order to obtain accurate statistics, the analysis will account for survey design complexities by applying MEPS survey weights to produce estimates. The sampling weights also reflect adjustments for survey non-response and adjustments to population control totals.⁴⁹





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7.2.2 Limitations

- 1) As it pertains to Aims 1 and 2, the use of state databases leads to generalizability issues. Although we have selected states that vary in terms of geographic and political distribution, the results from analyses that use state databases will not be nationally representative.
- 2) The NIS, NEDS, SID, and SEDD all provide hospital-level health care claims data. We will disaggregate the health care use that was "diabetes-related" but this might be subject to clinician billing. Relying on ICD-9 and ICD-10 codes may result in misclassifications, as claims data is originally intended for administrative purposes, and not health services research. Additionally, using claims data to identify diagnoses may result in inaccurate estimates for certain conditions, as algorithms may vary in validity.^{34,35}
- 3) For analyses conducted using National Inpatient Sample data, there is no method to identify individual patients, so recurrent hospitalizations are all considered as distinct observations. To address this limitation, we will conduct analyses using pooled state inpatient data and apply an adjustment factor to the results found in the National Inpatient Sample to produce Nationwide estimates. These estimates will be presented with the acknowledgement that the pooled states used to produce the adjustment factor may not be nationally representative. Further, outpatient encounters observation-only stays are not included within the sample. Conditions and procedures that occur across multiple healthcare settings may be underrepresented.⁴⁶
- 4) Relying on the Prevention Quality Indicators to define potentially preventable hospitalizations may result in some necessary hospitalizations being categorized as potentially preventable. One could only determine whether or not a hospitalization was potentially preventable by examining each individual case.⁴¹
- 5) Both the NIS and MEPS are designed so as to not support state-level analysis. This limits the use of the NIS and MEPS in generating health care utilization estimates at the state level. Although we may be able to calculate the effect of the revisit variable on health care use estimates, we will not be able to apply the effect as an adjustment factor to estimate nationwide rates of service use.
- 6) Relying on ICD-codes to identify non-diabetes status in individual events or patients may result in mis-identifying some patients, i.e., a patient may have diabetes, but the condition was not relevant to the patient encounter, and was excluded from the coding of the event. To address this limitation, we will use all discharges diagnoses (up to 30 diagnoses) available on each record to exclude records with diabetes diagnoses present





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ADMINISTRATIVE AND REGULATORY DETAILS

8.1 Confidentiality

8.1.1 Confidentiality of Data

By signing this protocol, the investigator affirms to the Sponsor that information furnished to the investigator by the Sponsor will be maintained in confidence, and such information will be divulged to the Institutional Review Board, Ethics Review Committee or similar or expert committee; affiliated institution and employees, only under an appropriate understanding of confidentiality with such board or committee, affiliated institution and employees. Data generated by this study will be considered confidential by the investigator, except to the extent that it is included in a publication as provided in the Publications section of this protocol.

8.1.2 Confidentiality of Subject Records

By signing this protocol, the investigator agrees that the Sponsor (or Sponsor representative), Institutional Review Board/Independent Ethics Committee (IRB/IEC), or Regulatory Agency representatives may consult and/or copy study documents in order to verify worksheet/case report form data. By signing the consent form, the subject agrees to this process. If study documents will be photocopied during the process of verifying worksheet/case report form information, the subject will be identified by unique code only; full names/initials will be masked prior to transmission to the Sponsor.

By signing this protocol, the investigator agrees to treat all subject data used and disclosed in connection with this study in accordance with all applicable privacy laws, rules and regulations.

8.1.3 Confidentiality of Investigator Information

By signing this protocol, the investigator recognizes that certain personal identifying information with respect to the investigator, and all subinvestigators and study site personnel, may be used and disclosed for study management purposes, as part of a regulatory submissions, and as required by law. This information may include:

- name, address, telephone number and e-mail address;
- hospital or clinic address and telephone number;
- curriculum vitae or other summary of qualifications and credentials; and
- other professional documentation.

Consistent with the purposes described above, this information may be transmitted to the Sponsor, and subsidiaries, affiliates and agents of the Sponsor, in your country and other countries, including countries that do not have laws protecting such information. Additionally, the investigator's name and business contact information may be included when reporting certain serious adverse events to regulatory agencies or to other investigators. By signing this protocol, the investigator expressly consents to these uses and disclosures.

If this is a multicenter study, in order to facilitate contact between investigators, the Sponsor may share an investigator's name and contact information with other participating investigators upon request.





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8.2 Compliance with Financial Disclosure Requirements

Financial Disclosure requirements are outlined in the US Food and Drug Administration Regulations, Financial Disclosure by Clinical Investigators (21 CFR Part 54). It is the Sponsor's responsibility to determine, based on these regulations, whether a request for Financial Disclosure information is required. It is the investigator's/subinvestigator's responsibility to comply with any such request.

The investigator/subinvestigator(s) agree, if requested by the Sponsor in accordance with 21 CFR Part 54, to provide his/her financial interests in and/or arrangements with the Sponsor to allow for the submission of complete and accurate certification and disclosure statements. The investigator/subinvestigator(s) further agree to provide this information on a Certification/Disclosure Form, commonly known as a financial disclosure form, provided by the Sponsor or through a secure password-protected electronic portal provided by the Sponsor. The investigator/subinvestigator(s) also consent to the transmission of this information to the Sponsor in the United States for these purposes. This may involve the transmission of information to countries that do not have laws protecting personal data.

8.3 Compliance with Law, Audit and Debarment

By signing this protocol, the investigator agrees to conduct the study in an efficient and diligent manner and in conformance with this protocol; generally accepted standards of Good Pharmacoepidemiology Practice and all applicable federal, state and local laws, rules and regulations relating to the conduct of the study.

The investigator also agrees to allow monitoring, audits, Institutional Review Board/Independent Ethics Committee review and regulatory agency inspection of study-related documents and procedures and provide for direct access to all study-related source data and documents.

The investigator agrees not to seek reimbursement from subjects, their insurance providers or from government programs for procedures included as part of the study reimbursed to the investigator by the Sponsor.

The Investigator shall prepare and maintain complete and accurate study documentation in compliance with Good Pharmacoepidemiology Practice, standards and applicable federal, state and local laws, rules and regulations; and, for each subject participating in the study, provide all data, and, upon completion or termination of the study, submit any other reports to the Sponsor as required by this protocol or as otherwise required pursuant to any agreement with the Sponsor.

Study documentation will be promptly and fully disclosed to the Sponsor by the investigator upon request and also shall be made available at the investigator's site upon request for inspection, copying, review and audit at reasonable times by representatives of the Sponsor or any regulatory agencies. The investigator agrees to promptly take any reasonable steps that are requested by the Sponsor as a result of an audit to cure deficiencies in the study documentation and worksheets/case report forms.

The investigator must maintain copies of all documentation and records relating to the conduct of the study in accordance with their institution's records retention schedule which is compliant with all applicable regional and national laws and regulatory requirements. If an institution does not have a records retention schedule to manage its records long-term, the investigator must maintain all documentation and records relating to the conduct of the study for 5 years after final report or first publication of study results, whichever comes later, per GPP guidelines. This documentation includes, but is not limited to, the protocol, worksheets/case report forms, advertising for subject participation, adverse event reports, subject source data, correspondence with regulatory authorities and IRBs/ERCs, consent forms, investigator's curricula vitae, monitor visit logs, laboratory reference





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ranges, laboratory certification or quality control procedures and laboratory director curriculum vitae. All study documents shall be made available if required by relevant regulatory authorities. The investigator must consult with the Sponsor prior to discarding study and/or subject files.

The investigator will promptly inform the Sponsor of any regulatory agency inspection conducted for this study.

Persons debarred from conducting or working on studies by any court or regulatory agency will not be allowed to conduct or work on this Sponsor's studies. The investigator will immediately disclose in writing to the Sponsor if any person who is involved in conducting the study is debarred or if any proceeding for debarment is pending or, to the best of the investigator's knowledge, threatened.

In the event the Sponsor prematurely terminates a particular study site, the Sponsor will promptly notify that site's IRB/IEC.

According to European legislation, a Sponsor must designate an overall coordinating investigator for a multicenter study (including multinational). When more than one study site is open in an EU country, Merck, as the Sponsor, will designate, per country, a national principal coordinator (Protocol CI), responsible for coordinating the work of the principal investigators at the different sites in that Member State, according to national regulations. For a single-center study, the Protocol CI is the principal investigator. In addition, the Sponsor must designate a principal or coordinating investigator to review the study report that summarizes the study results and confirm that, to the best of his/her knowledge, the report accurately describes the conduct and results of the study in the study's final report. The Sponsor may consider one or more factors in the selection of the individual to serve as the Protocol CI and or CSR CI (e.g., availability of the CI during the anticipated review process, thorough understanding of study methods, appropriate enrollment of subject cohort, timely achievement of study milestones). The Protocol CI must be a participating study investigator.

8.5 Quality Management System

By signing this protocol, all parties agree to following applicable standard operating procedures (SOPs). All parties also agree to ensuring all existing and new study personnel are appropriately trained to ensure the study is conducted and data are generated, documented, and reported in compliance with the protocol, Good Pharmacoepidemiology Practice (GPP), and all applicable federal, state, and local laws, rules and regulations. All parties should maintain transparency and open communication in order to effectively manage the study and proactively mitigate any risks.

The Sponsor may conduct routine or for-cause audits to ensure oversight and conduct of the study are completed in accordance with the protocol, quality standards (e.g. GPP), and applicable laws and regulations. If a significant quality issue (SQI) is identified at any time during the conduct of the study, it must be escalated to the Sponsor immediately. A SQI is any issue with the potential to negatively impact, either directly or indirectly, the rights, safety and well-being of patients or study participants and/or the integrity of the data. In the event an audit or SQI results in corrective or preventive actions, all parties are expected to appropriately implement the action plan in a timely manner.

8.6 Data Management

The investigator or qualified designee is responsible for recording and verifying the accuracy of subject data. By signing this protocol, the investigator acknowledges that his/her electronic signature is the





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legally binding equivalent of a written signature. By entering his/her electronic signature, the investigator confirms that all recorded data have been verified as accurate.

For an outsourced study the institutional policies of the vendor should be followed for development of data management plans. However, the vendor should ensure compliance with Good Pharmacoepidemiology Practice, and all applicable federal, state, and local laws, rules and regulations relating to the conduct of the study.





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9 **Publications**

The Risk Management Subteam (RMST) Lead /Clinical Safety Risk Manager (CSRM) Physician will be notified if any safety data are generated in the final study report or any interim report. The safety and conclusion sections of the final study report or interim report must be reviewed by the RMST Lead/CSRM Physician prior to finalization of the report. The review by the CSRM Physician must occur prior to any release of results to the public domain in the form of abstracts, posters, presentations or manuscripts.





10 References

- 1. Gregg EW, Li Y, Wang J, Rios Burrows N, Ali MK, Rolka D, et al. Changes in Diabetes-Related Complications in the United States, 1990–2010. N Engl J Med. 2014 Apr 17;370(16):1514–23.
- 2. CDC Press Releases [Internet]. CDC. 2016 [cited 2019 Sep 13]. Available from: https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html
- 3. Riddle MC, Herman WH. The Cost of Diabetes Care—An Elephant in the Room. Diabetes Care. 2018 May 1;41(5):929-32.
- 4. Beckles GL. Disparities in the Prevalence of Diagnosed Diabetes United States, 1999–2002 and 2011–2014. MMWR Morb Mortal Wkly Rep [Internet]. 2016 [cited 2019 Sep 13];65. Available from: https://www.cdc.gov/mmwr/volumes/65/wr/mm6545a4.htm
- 5. Voeks Jenifer H., McClure Leslie A., Go Rodney C., Prineas Ronald J., Cushman Mary, Kissela Brett M., et al. Regional Differences in Diabetes as a Possible Contributor to the Geographic Disparity in Stroke Mortality. Stroke. 2008 Jun 1;39(6):1675–80.
- 6. Nwasuruba C, Osuagwu C, Bae S, Singh KP, Egede LE. Racial differences in diabetes selfmanagement and quality of care in Texas. J Diabetes Complications. 2009 Apr;23(2):112-8.
- 7. Heisler M, Smith DM, Hayward RA, Krein SL, Kerr EA. Racial disparities in diabetes care processes, outcomes, and treatment intensity. Med Care. 2003 Nov;41(11):1221–32.
- 8. Young BA, Maynard C, Boyko EJ. Racial differences in diabetic nephropathy, cardiovascular disease, and mortality in a national population of veterans. Diabetes Care. 2003 Aug;26(8):2392– 9.
- 9. O'Connell J, Yi R, Wilson C, Manson SM, Acton KJ. Racial disparities in health status: a comparison of the morbidity among American Indian and U.S. adults with diabetes. Diabetes Care. 2010 Jul;33(7):1463-70.
- 10. Benjamin SM, Wang J, Geiss LS, Thompson TJ, Gregg EW. The Impact of Repeat Hospitalizations on Hospitalization Rates for Selected Conditions Among Adults With and Without Diabetes, 12 US States, 2011. Prev Chronic Dis. 2015 Nov 19:12:E200.
- 11. Ali MK, Bullard KM, Saaddine JB, Cowie CC, Imperatore G, Gregg EW. Achievement of Goals in U.S. Diabetes Care, 1999–2010. N Engl J Med. 2013 Apr 25;368(17):1613–24.
- 12. Ali MK, Bullard KM, Gregg EW, Del Rio C. A cascade of care for diabetes in the United States: visualizing the gaps. Ann Intern Med. 2014 Nov 18;161(10):681–9.
- 13. Cefalu WT, Golden SH. Innovative Approaches to Understanding and Addressing Health Disparities in Diabetes Care and Research. Diabetes Care. 2015 Feb;38(2):186–8.





Protocol/Amendment No.: xxx

VEAP ID NO: XXXXX

Epidemiology No.(PE Studies only): EP0xxxx.xx

- 14. Rosenstock S, Whitman S, West JF, Balkin M. Racial disparities in diabetes mortality in the 50 most populous US cities. J Urban Health Bull N Y Acad Med. 2014 Oct;91(5):873–85.
- 15. Wharam JF, Zhang F, Eggleston EM, Lu CY, Soumerai SB, Ross-Degnan D. Effect of High-Deductible Insurance on High-Acuity Outcomes in Diabetes: A Natural Experiment for Translation in Diabetes (NEXT-D) Study. Diabetes Care. 2018 May 1;41(5):940–8.
- 16. Ali MK, Bullard KM, Saaddine JB, Cowie CC, Imperatore G, Gregg EW. Achievement of Goals in U.S. Diabetes Care, 1999–2010 [Internet]. http://dx.doi.org/10.1056/NEJMsa1213829. 2013 [cited 2019 Sep 13]. Available from: https://www.nejm.org/doi/10.1056/NEJMsa1213829
- 17. Kazemian P, Shebl FM, McCann N, Walensky RP, Wexler DJ. Evaluation of the Cascade of Diabetes Care in the United States, 2005-2016. JAMA Intern Med [Internet]. 2019 Aug 12 [cited 2019 Sep 13]; Available from: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2740801
- 18. Strain W, Bluher M, Pladanius P. Clinical Inertia in Individualising Care for Diabetes: Is There Time to do More in Type 2 Diabetes? [Internet]. [cited 2019 Sep 16]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4269638/
- 19. Fernandes G, Sawhney B, Hannachi H, Wang T, McNeill A, Iglay K, et al. Clinical Inertia in Relation to Sociodemographic Factors among Patients with Type 2 Diabetes (T2D) in the United States. In San Francisco, CA, USA: Merck Sharp & Dohme Corp; 2019.
- 20. PAWASKAR M, NGUYEN J, HUYNH S, HASKELL T, LEE L, RAJPATHAK S. Socioeconomic Disparities in the Management of Glycemic Control among Adults with Type 2 Diabetes in the United States. In.
- 21. Ziemer DC, Doyle JP, Barnes CS, Branch WT, Cook CB, El-Kebbi IM, et al. An Intervention to Overcome Clinical Inertia and Improve Diabetes Mellitus Control in a Primary Care Setting: Improving Primary Care of African Americans With Diabetes (IPCAAD) 8. Arch Intern Med. 2006 Mar 13;166(5):507-13.
- 22. McEwen L, Herman W. HEALTH CARE UTILIZATION AND COSTS OF DIABETES. Ch. 40. In: Diabetes in America, 3rd ed [Internet]. 3rd ed. Bethesda, MD: NAtional Institutes of Health; [cited 2019 Jul 18]. p. 40.1-40.78. Available

from: https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/diabetes-inamerica-3rdedition

- 23. Wang J, Geiss LS, Williams DE, Gregg EW. Trends in Emergency Department Visit Rates for Hypoglycemia and Hyperglycemic Crisis among Adults with Diabetes, United States, 2006-2011. Rodríguez-Mañas L, editor. PLOS ONE. 2015 Aug 7;10(8):e0134917.
- 24. AHRQ Quality Indicators [Internet]. [cited 2019 Sep 11]. Available from: https://www.qualityindicators.ahrq.gov/modules/pqi overview.aspx





- 25. Rubens M, Saxena A, Ramamoorthy V, Khera R, Hong J, Veledar E, et al. Trends in Diabetes-Related Preventable Hospitalizations in the U.S., 2005–2014. Diabetes Care. 2018 May;41(5):e72-3.
- 26. Desai D, Mehta D, Mathias P, Menon G, Schubart UK. Health Care Utilization and Burden of Diabetic Ketoacidosis in the U.S. Over the Past Decade: A Nationwide Analysis. Diabetes Care. 2018 Aug 1;41(8):1631-8.
- 27. Harris CM, Albaeni A, Thorpe RJ, Norris KC, Abougergi MS. Racial factors and inpatient outcomes among patients with diabetes hospitalized with foot ulcers and foot infections, 2003-2014. PLoS ONE [Internet]. 2019 May 29 [cited 2019 Aug 21:14(5). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6541346/
- 28. Tseng C-L, Soroka O, Pogach LM. An expanded prevention quality diabetes composite: Quantifying the burden of preventable hospitalizations for older adults with diabetes. J Diabetes Complications. 2018 May;32(5):458-64.
- 29. Chen G, Khan N, Walker R, Quan H. Validating ICD coding algorithms for diabetes mellitus from administrative data. Diabetes Res Clin Pract. 2010 Aug 1;89(2):189–95.
- 30. Schneider ALC, Pankow JS, Heiss G, Selvin E. Validity and Reliability of Selfreported Diabetes in the Atherosclerosis Risk in Communities Study. Am J Epidemiol. 2012 Oct 15;176(8):738–43.
- 31. Rothwell CJ, Madans JH, Arispe IE. National Center for Health Statistics. :81.
- 32. Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721–6.
- 33. Glasheen WP, Renda A, Dong Y. Diabetes Complications Severity Index (DCSI)-Update and ICD-10 translation. J Diabetes Complications. 2017 Jun;31(6):1007–13.
- 34. Varas-Lorenzo C, Castellsague J, Stang MR, Tomas L, Aguado J, Perez-Gutthann S. Positive predictive value of ICD-9 codes 410 and 411 in the identification of cases of acute coronary syndromes in the Saskatchewan Hospital automated database. Pharmacoepidemiol Drug Saf. 2008 Aug;17(8):842-52.
- 35. Positive Predictive Values of ICD-9 Codes to Identify Patients With Stroke or TIA [Internet]. AJMC. [cited 2019 Sep 25]. Available from: https://www.ajmc.com/journals/issue/2014/2014vol20-n2/positive-predictivevalues-of-icd-9-codes-to-identify-patients-with-stroke-or-tia
- 36. Columbo JA, Kang R, Trooboff SW, Jahn KS, Martinez CJ, Moore KO, et al. Validating Publicly Available Crosswalks for Translating ICD-9 to ICD-10 Diagnosis Codes for Cardiovascular Outcomes Research. Circ Cardiovasc Qual Outcomes. 2018;11(10):e004782.
- 37. Inpatient Quality Indicators: Coronary Artery Bypass Graft (CABG) Volume [Internet]. AHRQ Quality Indicators. 2009. Available from:





Protocol/Amendment No.: xxx

VEAP ID NO: XXXXX

Epidemiology No.(PE Studies only): EP0xxxx.xx

https://www.qualityindicators.ahrq.gov/Downloads/Modules/IQI/V41/TechSpecs/I OI%2005%20CABG%20Volume.pdf

- 38. ICD-10: Clinical Concepts for Cardiology. 2015 Oct 1;29.
- 39. Weiss A, Barrett M, Heslin K, Stocks C. Trends in Emergency Department Visits Involving Mental and Substance Use Disorders, 2006–2013 [Internet]. HEALTH CARE COST AND UTILIZATION PROJECT: STATISTICAL BRIEF #216. 2016 [cited 2019 Sep 24]. Available from: https://www.hcupus.ahrq.gov/reports/statbriefs/sb216-Mental-Substance-Use-Disorder-ED-VisitTrends.pdf
- 40. Parisi R, Rutter MK, Lunt M, Young HS, Symmons DPM, Griffiths CEM, et al. Psoriasis and the Risk of Major Cardiovascular Events: Cohort Study Using the Clinical Practice Research Datalink. J Invest Dermatol. 2015 Sep 1;135(9):2189–97.
- 41. Wang J, Imai K, Engelgau MM, Geiss LS, Wen C, Zhang P. Secular trends in diabetes-related preventable hospitalizations in the United States, 1998-2006. Diabetes Care. 2009 Jul;32(7):1213–7.
- 42. Ginde AA, Blanc PG, Lieberman RM, Camargo CA. Validation of ICD-9-CM coding algorithm for improved identification of hypoglycemia visits. BMC Endocr Disord. 2008 Apr 1;8:4.
- 43. HCUP-US SID Overview [Internet]. [cited 2019 Sep 9]. Available from: https://www.hcupus.ahrq.gov/sidoverview.jsp
- 44. 2017 National Health Interview Survey (NHIS) Survey Description [Internet]. National Center for Health Statistics; 2018. Available from: ftp://ftp.cdc.gov/pub/Health Statistics/NCHS/Dataset Documentation/NHIS/2017/s rvydesc.pdf
- 45. MEPS [Internet]. "YOUR ROLE IN SHAPING THE NATION'S HEALTH." [cited 2019 Sep 9]. Available from: https://meps.ahrq.gov/communication/mpc_video/en/mpc_presentation.shtml
- 46. Khera R, Angraal S, Couch T, Welsh JW, Nallamothu BK, Girotra S, et al. Adherence to Methodological Standards in Research using the National Inpatient Sample. JAMA. 2017 Nov 28;318(20):2011–8.
- 47. NIS Trend Weights [Internet]. [cited 2019 Sep 5]. Available from: https://www.hcup-us.ahrq.gov/db/nation/nis/trendwghts.jsp
- 48. INTRODUCTION TO THE HCUP NATIONAL INPATIENT SAMPLE (NIS), 2016 [Internet]. [cited 2019 Sep 9]. Available from: https://www.hcupus.ahrq.gov/db/nation/nis/NIS_Introduction_2016.jsp#weights
- 49. Medical Expenditure Panel Survey Computing Standard Errors for MEPS Estimates [Internet]. [cited 2019 Sep 5]. Available from: https://meps.ahrq.gov/survey_comp/standard_errors.jsp





Protocol/Amendment No.: xxx

VEAP ID NO: XXXXX

Epidemiology No.(PE Studies only): EP0xxxx.xx

- 50. Healthcare Cost and Utilization Project-Nationwide Inpatient Sample | Healthy People 2020 [Internet]. [cited 2019 Sep 9]. Available from: https://www.healthypeople.gov/2020/datasource/healthcare-cost-and-utilizationproject-nationwide-inpatient-sample
- 51. R Core Team (2014). R: A language and environment for statistical computing. R Foundation for StatisticalComputing, Vienna, Austria. URL http://www.Rproject.org/

11 Appendices

Appendix 1.

ICD-9-CM and ICD-10-CM Codes indicating Diabetes Disease State

ICD-9-CM		ICD-10-CM	ICD-10-CM	
25000	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	E119	Type 2 diabetes mellitus without complications	
25001	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	E109	Type 1 diabetes mellitus without complications	
25002	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	E1165	Type 2 diabetes mellitus with hyperglycemia	
25003	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	E1065	Type 1 diabetes mellitus with hyperglycemia	
	Diabetes with	E1169	Type 2 diabetes mellitus with other specified complication	
25010	ketoacidosis, type II or unspecified type, not states as uncontrolled	E1310	Other specified diabetes mellitus with ketoacidosis without coma	
25011	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	E1010	Type 1 diabetes mellitus with ketoacidosis without coma	
		E1165	Type 2 diabetes mellitus with hyperglycemia	
	Diabetes with	E1169	Type 2 diabetes mellitus with other specified complication	
25012	ketoacidosis, type II or unspecified type, uncontrolled	E1310	Other specified diabetes mellitus with ketoacidosis without coma	



	Diabetes with ketoacidosis, type I	E1010	Type 1 diabetes mellitus with ketoacidosis without coma
25013	[juvenile type], uncontrolled	E1065	Type 1 diabetes mellitus with hyperglycemia
	Diabetes with hyperosmolarity, type II	E1100	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
25020	or unspecified type, not stated as uncontrolled	E1101	Type 2 diabetes mellitus with hyperosmolarity with coma
25021	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	E1069	Type 1 diabetes mellitus with other specified complication
	Diabetes with hyperosmolarity, type II	E1100	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperclycemic-hyperosmolar coma (NKHHC)
25022	or unspecified type, uncontrolled	E1165	Type 2 diabetes mellitus with hyperglycemia
	Diabetes with hyperosmolarity, type I	E1065	Type 1 diabetes mellitus with hyperglycemia
25023	[juvenile type], uncontrolled	E1069	Type 1 diabetes mellitus with other specified complication
25030	Diabetes with other coma, type II or unspecified type, not states as uncontrolled	E11641	Type 2 diabetes mellitus with hypoglycemia with coma
	Diabetes with other coma, type I [juvenile	E1011	Type 1 diabetes mellitus with ketoacidosis with coma
25031	type], not stated as uncontrolled	E10641	Type 1 diabetes mellitus with hypoglycemia with coma
	2.1		Type 2 diabetes mellitus with
	Diabetes with other	E1101	hyperosmolarity with coma

25032	Diabetes with other coma, type II or unspecified type, uncontrolled	E1101 E1165	Type 2 diabetes mellitus with hyperosmolarity with coma Type 2 diabetes mellitus with hyperglycemia
	Diabetes with other	E1011	Type 1 diabetes mellitus with ketoacidosis with coma
25033	coma, type I [juvenile type], uncontrolled	E1065	Type 1 diabeters mellitus with hyperglycemia





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25040	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	E1129	Typer 2 diabetes mellitus with other diabetic kidney complication
25041	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	E1029	Type 1 diabetes mellitus with other diabetic kidney complication
	Diabetes with renal manifestations, type II or	E1121	Type 2 diabetes mellitus with diabetic nephropathy
25042	unspecified type, uncontrolled	E1165	Type 2 diabetes mellitus with hyperglycemia
	Diabetes with renal manifestations, type I	E1021	Type 1 diabetes mellitus with diabetic neuropathy
25043	[juvenile type], uncontrolled	E1065	Type 1 diabetes mellitus with hyperglycemia
		E11311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema.
		E11319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
	Diabetes with ophthalmic	E1136	Type 2 diabetes mellitus with diabetic cataract
25050	manifestations, type II or unspecified type, not stated as uncontrolled	E1139	Type 2 diabetes mellitus with other diabetic ophthalmic complication
		E10311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema.
		E10319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
	Diabetes with ophthalmic	E1036	Type 1 diabetes mellitus with diabetic cataract
25051	manifestations, type I [juvenile type], not states as uncontrolled	E1039	Type 1 diabetes mellitus with other diabetic ophthalmic complication
25052	Diabetes with ophthalmic manifestations, type II or	E11311	Type 2 diabetes mellitus with unspecified diabetic



	unspecified type, uncontrolled		retinopathy with macular edema.
		E11319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
		E1136	Type 2 diabetes mellitus with diabetic cataract
		E1139	Type 2 diabetes mellitus with other diabetic ophthalmic complication
		E1165	Type 2 diabetes mellitus with hyperglycemia
		E10311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema.
		E10319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
		E1036	Type 1 diabetes mellitus with diabetic cataract
	Diabetes with ophthalmic manifestations, type I	E1039	Type 1 diabetes mellitus with other diabetic ophthalmic complication
25053	[juvenile type], uncontrolled)	E1065	Type 1 diabetes mellitus with hyperglycemia
25060	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	E1140	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
25061	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	E1040	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	E1140	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
25062		E1165	Type 2 diabetes mellitus with hyperglycemia

	Diabetes with		Type 1 diabetes mellitus with
	neurological		diabetic neuropathy,
25063		E1040	unspecified





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Epidemiology N	No.(PE Studies only): EP0xxxx.xx	F106F	Time 1 dishertes mellitus with
	manifestations, type I [juvenile type], uncontrolled	E1065	Type 1 diabetes mellitus with hyperglycemia
25070	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	E1151	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
25071	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	E1051	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
23071	Diabetes with peripheral circulatory disorders, type II or unspecified type,	E1151	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
25072	uncontrolled	E1165	Type 2 diabetes mellitus with hyperglycemia
	Diabetes with peripheral circulatory disorders, type	E1051	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
25073	I [juvenile type], uncontrolled	E1065	Type 1 diabetes mellitus with hyperglycemia
		E11618	Type 2 diabetes mellitus with other diabetic arthropathy
		E11620	Type 2 diabetes mellitus with diabetic dermatitis
		E11621	Type 2 diabetes mellitus with foot ulcer
		E11622	Type 2 diabetes mellitus with other skin ulcer
	Diabetes with other specified manifestations, type II or	E11628	Type 2 diabetes mellitus with other skin complications
35000	unspecified type, not stated as uncontrolled	F44630	Type 2 diabetes mellitus with periodontal disease
25080		E11630	



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Epidemiology No	o.(PE Studies only): EP0xxxx.xx		
			Type 2 diabetes mellitus with
			other oral complications
		E11638	
			Type 2 diabetes mellitus with
			hypoglycemia without coma
		E11649	
			Type 2 diabetes mellitus with
			hyperglycemia
		E1165	
			Type 2 diabetes mellitus with
			other specified complication
		E1169	
		LIIOS	Torre de distante a manifesta contain
			Type 1 diabetes mellitus with other diabetic arthropathy
		510510	other diabetic artifiopatily
		E10618	
			Type 1 diabetes mellitus with
			diabetic dermatitis
		E10620	
			Type 1 diabetes mellitus with
			foot ulcer
		E10621	
	Diabetes with other		Type 1 diabetes mellitus with
	specified		other skin ulcer
	manifestations, type I	F10C22	other skin dicer
	[juvenile type], not stated	E10622	
	as uncontrolled		Type 1 diabetes mellitus with
25081		E10628	other skin complications
			Type 1 diabetes mellitus with
			periodontal disease
		E10630	
			Type 1 diabetes mellitus with
			other oral complications
		E10638	other oral complications
		110036	
			Type 1 diabetes mellitus with
			hypoglycemia without coma
		E10649	
			Type 1 diabetes mellitus with
			hyperglycemia
		E1065	
•	•		





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		E1069	Type 1 diabetes mellitus with other specified complication
		E1165	Type 2 diabetes mellitus with hyperglycemia
25082	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	E1169	Type 2 diabetes mellitus with other specified complication
	Diabetes with other	E1065	Type 1 diabetes mellitus with hyperglycemia
25083	specified manifestations, type I [juvenile type], uncontrolled	E1069	Type 1 diabetes mellitus with other specified complication
	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled		Type 2 diabetes mellitus with unspecified complications
25090	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	E118	Type 1 diabetes mellitus with unspecified complications
25091		E108	
	Diabetes with unspecified complication, type II or	E1165	Type 2 diabetes mellitus with hyperglycemia
25092	unspecified type, uncontrolled	E118	Type 2 diabetes mellitus with unspecified complications
	Diabetes with unspecified complication, type I	E1065	Type 1 diabetes mellitus with hyperglycemia
25093	[juvenile type], uncontrolled	E108	Type 1 diabetes mellitus with unspecified complications
	1	E1100	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)



E1101	Type 2 diabetes mellitus with hyperosmolarity with coma			
E1121	Type 2 diabetes mellitus with diabetic nephropathy			
E1122	Type 2 diabetes mellitus with diabetic chronic kidney disease			
E1129	Type 2 diabetes mellitus with other diabetic kidney complication			

E11311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11321	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E11331	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E11341	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11349	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E11351	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema



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E11	36	Type 2 diabetes mellitus with diabetic cataract
E11	39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11	40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11	41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11	42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11	43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11	44	Type 2 diabetes mellitus with diabetic amyotrophy
E11	49	Type 2 diabetes mellitus with other diabetic neurological complication
E11	51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11	52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11	59	Type 2 diabetes mellitus with other circulatory complications
E11	610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11	618	Type 2 diabetes mellitus with other diabetic arthropathy

E11620	Type 2 diabetes mellitus with diabetic dermatitis
E11621	Other specified diabetes mellitus with foot ulcer
E11622	Other specified diabetes mellitus with other skin ulcer
E11628	Other specified diabetes mellitus with other skin complications
E11630	Other specified diabetes mellitus with periodontal disease
E11638	Other specified diabetes mellitus with other oral complications
E11641	Other specified diabetes mellitus with hypoglycemia with coma





XX.XX	
E11649	Other specified diabetes mellitus with hypoglycemia without coma
E1165	Other specified diabetes mellitus with hyperglycemia
E1169	Type 2 diabetes mellitus with other specified complication
E118	Type 2 diabetes mellitus with unspecified complications
E119	Type 2 diabetes mellitus without complications
E1300	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E1301	Other specified diabetes mellitus with hyperosmolarity with coma
E1310	Other specified diabetes mellitus with ketoacidosis without coma
E1311	Other specified diabetes mellitus with ketoacidosis with coma
E1321	Other specified diabetes mellitus with diabetic nephropathy
E1322	Other specified diabetes mellitus with diabetic chronic kidney disease
E1329	Other specified diabetes mellitus with other diabetic kidney complication
E13311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13319	Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema
E13321	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13329	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E13331	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13339	Other specified diabetes mellitus with moderate



	nonproliferative diabetic retinopathy without macular edema
E13341	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13349	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
	Other specified diabetes mellitus with severe nonproliferative diabetic
E13351	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema
E1336	Other specified diabetes mellitus with diabetic cataract
E1339	Other specified diabetes mellitus with other diabetic ophthalmic complication
E1340	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E1341	Other specified diabetes mellitus with diabetic mononeuropathy
E1342	Other specified diabetes mellitus with diabetic polyneuropathy
E1343	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E1344	Other specified diabetes mellitus with diabetic amyotrophy
E1349	Other specified diabetes mellitus with other diabetic neurological complication
E1351	Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene
E1352	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
E1359	Other specified diabetes mellitus with other circulatory complications
E13610	Other specified diabetes mellitus with diabetic neuropathic arthropathy





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	E13618	Other specified diabetes mellitus with other diabetic arthropathy
	E13620	Other specified diabetes mellitus with other diabetic arthropathy
	E13621	Other specified diabetes mellitus with other diabetic
	E13622	Other specified diabetes mellitus with other skin ulcer
	E13628	Other specified diabetes mellitus with other skin complications
	E13630	Other specified diabetes mellitus with periodontal disease
	E13638	Other specified diabetes mellitus with other oral complications
	E13641	Other specified diabetes mellitus with hypoglycemia with coma
	E13649	Other specified diabetes mellitus with hypoglycemia without coma
	E1365	Other specified diabetes mellitus with hyperglycemia
	E1369	Other specified diabetes mellitus with other specified complication
	E138	Other specified diabetes mellitus with unspecified complications
	E139	Other specified diabetes mellitus without complications

Appendix 2. ICD-9 and ICD-10 codes used for Diabetes Prevention Quality Indicators, as described by the Agency for Healthcare Research and Quality $^{22-25}$

	ICD-9-CM:		ICD-10-CM:	
1) short-term diabetes complications (e.g., diabetic	25010	DM KETO T2, DM CONT	E1010	Type 1 diabetes mellitus with ketoacidosis without coma
ketoacidosis, hypersomolarity, or coma)*	25011	DM KETO T1, DM CONT	E1011	Type 1 diabetes mellitus with ketoacidosis with coma
	25012	DM KETO T2, DM UNCONT	E10641	Type 1 diabetes mellitus with hypoglycemia with coma





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	25013	DM KETO T1, DM UNCONT	E1065	Type 1 diabetes mellitus with hyperglycemia
	25020	DM W/ HYPROSM T2, DM CONT	E1100	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic- hyperosmolar coma (NKHHC)
	25021	DM W/ HYPROSM T1, DM CONT	E1101	Type 2 diabetes mellitus with hyperosmolarity with coma
	25022	DM W/ HYPROSM T2, DM UNCNT	E11641	Type 2 diabetes mellitus with hypoglycemia with coma
	25023	DM W/ HYPROSM T1, DM UNCNT	E1165	Type 2 diabetes mellitus with hyperglycemia
	25030	DM COMA NEC TYP II, DM CNT		
	25031	DM COMA NEC T1, DM CONT		
	25032	DM COMA NEC T2, DM UNCONT		
	25033	DM COMA NEC T1, DM UNCONT		
2) long-term	ICD-9-CM		ICD-10-CM	
diabetes complications (e.g., renal, ophthalmic, or neurological manifestations and peripheral	25040	DM RENAL COMP T2 CONT	E1021	Type 1 diabetes mellitus with diabetic nephropathy
	25041	DM RENAL COMP T1 CONT	E1022	Type 1 diabetes mellitus with diabetic chronic kidney disease



circulatory disorders)	25042	DM RENAL COMP T2 UNCNT	E1029	Type 1 diabetes mellitus with other diabetic kidney
	25043	DM RENAL COMP T1 UNCNT	E10311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
	25050	DM EYE COMP T2 CONT	E10319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
	25051	DM EYE COMP T1 CONT	E10321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema

25052	DM EYE COMP T2 UNCNT	E10329	Type 1 diabetes mellitus with mild nonproliferative
25053	DM EYE COMP T1 UNCNT	E10331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
25060	DM NEURO COMP T2 CONT	E10339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
25061	DM NEURO COMP T1 CONT	E10341	Type 1 diabetes mellitus with severe nonproliferative
25062	DM NEURO COMP T2 UNCNT	E10349	Type 1 diabetes mellitus with severe nonproliferative
25063	DM NEURO COMP T1 UNCNT	E10351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
25070	DM CIRCU DIS T2 CONT	E10359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema





25071	DM CIRCU DIS T1 CONT	E1036	Type 1 diabetes mellitus with diabetic cataract
25072	DM CIRCU DIS T2 UNCNT	E1039	Type 1 diabetes mellitus with other diabetic ophthalmic complication
25073	DM CIRCU DIS T1 UNCNT	E1040	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
25080	DM W COMP NEC T2 CONT	E1041	Type 1 diabetes mellitus with diabetic mononeuropathy
25081	DM W COMP NEC T1 CONT	E1042	Type 1 diabetes mellitus with diabetic polyneuropathy
25082	DM W COMP NEC T2 UNCNT	E1043	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
25083	DM W COMP NEC T1 UNCNT	E1044	Type 1 diabetes mellitus with diabetic amyotrophy
25090	DM W COMPL NOS T2 CONT	E1049	Type 1 diabetes mellitus with other diabetic neurological complication
25091	DM W COMPL NOS T1 CONT	E1051	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
25092	DM W COMPL NOS T2 UNCNT	E1052	Type 1 diabetes mellitus with diabetic peripheral with gangrene
25093	DM W COMPL NOS T1 UNCNT	E1059	Type 1 diabetes mellitus with other circulatory complications
		E10610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
		E10618	Type 1 diabetes mellitus with other diabetic arthropathy
		E10620	Type 1 diabetes mellitus with diabetic dermatitis
		E10621	Type 1 diabetes mellitus with foot ulcer
		E10622	Type 1 diabetes mellitus with other skin ulcer





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E10628	Type 1 diabetes mellitus with other skin complications
E10630	Type 1 diabetes mellitus with periodontal disease
E10638	Type 1 diabetes mellitus with other oral complications

E1069	Type 1 diabetes mellitus with other specified complication
E108	Type 1 diabetes mellitus with unspecified complications
E1121	Type 2 diabetes mellitus with diabetic nephropathy
E1122	Type 2 diabetes mellitus with diabetic chronic kidney
E1129	Type 2 diabetes mellitus with other diabetic kidney complication
E11311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11321	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E11331	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E11341	Type 2 diabetes mellitus with severe nonproliferative diabetic



		retinopathy with edema	macular
	E11349	Type 2 diabetes severe nonprolif retinopathy with edema	erative diabetic
	E11351	Type 2 diabetes proliferative dial retinopathy with edema	petic
	E11359	Type 2 diabetes proliferative dial retinopathy with edema	petic
	E1136	Type 2 diabetes diabetic cataract	
	E1139	Type 2 diabetes other diabetic opcomplication	
	E1140	Type 2 diabetes diabetic neuropa	
	E1141	Type 2 diabetes diabetic monone	
	E1142	Type 2 diabetes diabetic polyneu	
	E1143	Type 2 diabetes diabetic autonor (poly)neuropath	mic
	E1144	Type 2 diabetes diabetic amyotro	
	E1149	Type 2 diabetes other diabetic no complication	
	E1151	Type 2 diabetes diabetic periphe without gangren	ral angiopathy
		E1152	Type 2 diabetes mellitus with diabetic peripheral



		angiopathy with gangrene
	E1159	Type 2 diabetes mellitus with other circulatory complications
	E11610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
	E11618	Type 2 diabetes mellitus with other diabetic arthropathy
	E11620	Type 2 diabetes mellitus with diabetic dermatitis
	E11622	Type 2 diabetes mellitus with other skin ulcer E11628
	E11628	Type 2 diabetes mellitus with other skin complications
	E11630	Type 2 diabetes mellitus with periodontal disease
	E11638	Type 2 diabetes mellitus with other oral complications
	E1169	Type 2 diabetes mellitus with other specified



<u>Epidemiology No.(PE S</u> I	tudies only): EPU	XXXX.XX			
			E118	Type 2 diabetes mellitus with unspecified complications	
3) uncontrolled	ICD-9-CM	ICD-9-CM		ICD-10-CM	
diabetes without complications	25002	DMII WO CMP UNCTRLD	E1065	Type 1 diabetes mellitus with hyperglycemia	
(e.g., high glucose concentrations)	25003	DMI WO CMP UNCNTRLD	E1165	Type 2 diabetes mellitus with hyperglycemia	
Concentrations			E10649	Type 1 diabetes mellitus with hypoglycemia without coma	
			E11649	Type 2 diabetes mellitus with hypoglycemia without coma	
4) diabetes-	ICD-9-PC		ICD-10-PC		
related lower- extremity amputations	8410	LOWER LIMB AMPUTATIONOS	0Y620Z Z	Detachment at Right Hindquarter, Open Approach	
	8412	AMPUTATION THROUGH FOOT	0Y630Z Z	Detachment at Left Hindquarter, Open Approach	
	8413	DISARTICULATION OF ANKLE	0Y640Z Z	Detachment at Bilateral Hindquarter, Open Approach	
	8414	AMPUTAT THROUGH MALLEOLI	0Y670Z Z	Detachment at Right Femoral Region, Open Approach	
	8415	BELOW KNEE AMPUTAT NEC	0Y680Z Z	Detachment at Left Femoral Region, Open Approach	



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	8416	DISARTICULATION OF KNEE	0Y6C0 Z1	Detachment at Right Upper Leg, High, Open Approach
	8417	ABOVE KNEE AMPUTATION	0Y6C0 Z2	Detachment at Right Upper Leg, Mid, Open Approach
	8418	DISARTICULATION OF HIP	0Y6C0 Z3	Detachment at Right Upper Leg, Low, Open Approach
	8419	HINDQUARTER AMPUTATION	0Y6D0 Z1	Detachment at Left Upper Leg, High, Open Approach
			0Y6D0 Z2	Detachment at Left Upper Leg, Mid, Open Approach
			0Y6D0 Z3	Detachment at Left Upper Leg, Low, Open Approach

OY6F0Z Z	Detachment at Right Knee Region, Open Approach
0Y6G0 ZZ	Detachment at Left Knee Region, Open Approach
0Y6H0 Z1	Detachment at Right Lower Leg, High, Open Approach
0Y6H0 Z2	Detachment at Right Lower Leg, Mid, Open Approach
0Y6H0 Z3	Detachment at Right Lower Leg, Low, Open Approach
0Y6J0Z 1	Detachment at Left Lower Leg, High, Open





	Approach
0Y6J0Z 2	Detachment at Left Lower Leg, Mid, Open Approach
0Y6J0Z 3	Detachment at Left Lower Leg, Low, Open Approach
0Y6M0 Z0	Detachment at Right Foot, Complete, Open Approach
0Y6M0 Z4	Detachment at Right Foot, Complete, Open Approach
0Y6M0 Z5	Detachment at Right Foot, Complete 1st Ray, Open
0Y6M0 Z6	Detachment at Right Foot, Complete 2nd Ray, Open
0Y6M0 Z7	Detachment at Right Foot, Complete 3rd Ray, Open
0Y6M0 Z8	Detachment at Right Foot, Complete 4th Ray, Open
0Y6M0 Z9	Detachment at Right Foot, Complete 5th Ray, Open
OY6M0 ZB	Detachment at Right Foot, Partial 1st Ray, Open
OY6M0 ZC	Detachment at Right Foot, Partial 2nd Ray, Open
0Y6M0 ZD	Detachment at Right Foot, Partial 3rd Ray, Open
0Y6M0 ZF	Detachment at Right Foot, Partial 4th Ray, Open
0Y6N0 Z0	Detachment at Right Foot, Partial 5th Ray, Open





0Y6N0 Z4	Detachment at Left Foot, Complete, Open Approach
0Y6N0 Z5	Detachment at Left Foot, Complete 1st Ray, Open
0Y6N0 Z6	Detachment at Left Foot, Complete 2nd Ray, Open
0Y6N0 Z7	Detachment at Left Foot, Complete 3rd Ray, Open
0Y6N0 Z8	Detachment at Left Foot, Complete 4th Ray, Open
0Y6N0 Z9	Detachment at Left Foot, Complete 5th Ray, Open
0Y6N0 ZB	Detachment at Left Foot, Partial 1st Ray, Open

0Y6N0 ZC	Detachment at Left Foot, Partial 2nd Ray, Open
0Y6N0 ZD	Detachment at Left Foot, Partial 3rd Ray, Open
0Y6N0 ZF	Detachment at Left Foot, Partial 4th Ray, Open
0Y6P0Z 0	Detachment at Left Foot, Partial 5th Ray, Open
0Y6P0Z 1	Detachment at Right 1st Toe, Complete, Open
0Y6P0Z 2	Detachment at Right 1st Toe, High, Open Approach
0Y6P0Z 3	Detachment at Right 1st Toe, Mid, Open Approach
0Y6Q0 Z0	Detachment at Right 1st Toe, Low, Open Approach





0Y6Q0 Z1	Detachment at Left 1st Toe, Complete, Open Approach
0Y6Q0 Z2	Detachment at Left 1st Toe, High, Open Approach
0Y6Q0 Z3	Detachment at Left 1st Toe, Mid, Open Approach
0Y6R0 Z0	Detachment at Left 1st Toe, Low, Open Approach
0Y6R0 Z1	Detachment at Right 2nd Toe, Complete, Open
0Y6R0 Z2	Detachment at Right 2nd Toe, High, Open Approach
0Y6R0 Z3	Detachment at Right 2nd Toe, Mid, Open Approach
0Y6S0Z 0	Detachment at Right 2nd Toe, Low, Open Approach
0Y6S0Z 1	Detachment at Left 2nd Toe, Complete, Open
0Y6S0Z 2	Detachment at Left 2nd Toe, High, Open Approach
0Y6S0Z 3	Detachment at Left 2nd Toe, Mid, Open Approach
0Y6T0 Z0	Detachment at Left 2nd Toe, Low, Open Approach
0Y6T0 Z1	Detachment at Right 3rd Toe, Complete, Open
0Y6T0 Z2	Detachment at Right 3rd Toe, High, Open Approach
0Y6T0 Z3	Detachment at Right 3rd Toe, Mid, Open Approach
0Y6U0 Z0	Detachment at Right 3rd Toe, Low, Open



	Approach
0Y6U0 Z1	Detachment at Left 3rd Toe, Complete, Open
0Y6U0 Z2	Detachment at Left 3rd Toe, High, Open Approach
0Y6U0 Z3	Detachment at Left 3rd Toe, Mid, Open Approach

23	Mid, Open Approach
0Y6V0 Z0	Detachment at Left 3rd Toe, Low, Open Approach
0Y6V0 Z1	Detachment at Right 4th Toe, Complete, Open
0Y6V0 Z2	Detachment at Right 4th Toe, High, Open Approach
0Y6V0 Z3	Detachment at Right 4th Toe, Mid, Open Approach
0Y6W0 Z0	Detachment at Right 4th Toe, Low, Open Approach
0Y6W0 Z1	Detachment at Left 4th Toe, Complete, Open Approach
0Y6W0 Z2	Detachment at Left 4th Toe, High, Open Approach
0Y6W0 Z3	Detachment at Left 4th Toe, Mid, Open Approach
0Y6X0 Z0	Detachment at Left 4th Toe, Low, Open Approach
0Y6X0 Z1	Detachment at Right 5th Toe, Complete, Open
0Y6X0 Z2	Detachment at Right 5th Toe, High, Open Approach
0Y6X0 Z3	Detachment at Right 5th Toe, Mid, Open



	Approach
0Y6Y0 Z0	Detachment at Right 5th Toe, Low, Open Approach
0Y6Y0 Z1	Detachment at Left 5th Toe, Complete, Open Approach
0Y6Y0 Z2	Detachment at Left 5th Toe, High, Open Approach
0Y6Y0 Z3	Detachment at Left 5th Toe, Mid, Open Approach
0Y6T0 Z0	Detachment at Left 5th Toe, Low, Open Approach
0Y6T0 Z1	Detachment at Right Hindquarter, Open Approach
0Y6T0 Z2	Detachment at Left Hindquarter, Open Approach
0Y6T0 Z3	Detachment at Bilateral Hindquarter, Open Approach
0Y6U0 Z0	Detachment at Right Femoral Region, Open Approach
0Y6U0 Z1	Detachment at Left Femoral Region, Open Approach
0Y6Y0 Z2	Detachment at Right Upper Leg, High, Open Approach
0Y6Y0 Z3	Detachment at Right Upper Leg, Mid, Open Approach
0Y6C0 Z1	Detachment at Right Upper Leg, Low, Open Approach
0Y6C0 Z2	Detachment at Right Upper Leg, High, Open Approach
0Y6C0 Z3	Detachment at Right Upper Leg, Mid, Open Approach



			0Y620Z Z 0Y6J0Z 1	Detachment at Right Upper Leg, Low, Open Approach Detachment at Right Hindquarter,
			0Y6J0Z 2	Open Approach Detachment at Left Lower Leg, High, Open
			OY6J0Z 3	Approach Detachment at Left Lower Leg, Mid, Open Approach
Proposed PQI: Lower Extremity Ulcers/inflammation/ infections ²⁸	ICD-9-CM 4540	Varicose Veins of lower extremities with ulcer	ICD-10-CM I83.009	Varicose veins of unspecified lower extremity with ulcer of unspecified site
			I83.019	Varicose veins of right lower extremity with ulcer of unspecified site
			183.029	Varicose veins of left lower extremity with ulcer of unspecified site



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	707.1	Ulcer of lower limb, unspecified	L97.909	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with unspecified severity
	680.6	Carbuncle and furuncle of leg, except foot	L02.429	Furuncle of limb, unspecified
			L02.439	Carbuncle of limb, unspecifie
	680.7	Carbuncle and furuncle of foot	L02.629	Furuncle of unspecified foot
			L02.639	Carbuncle of unspecified foot
	681.1	Cellulitis and abscess of toe, unspecified	L03.039	Cellulitis of unspecified toe
			L03.049	Acute lymphangitis of unspecified toe
	682.6	Cellulitis and abscess of leg, except foot	L03.129	Acute lymphangitis of unspecified part of limb
			L03.119	Cellulitis of unspecified part of limb



Epidennology No.(FE Studies only). LI UAAAA.AA			
	682.7	Cellulitis and abscess of foot, except toes	L03.119	Cellulitis of unspecified part of limb
			L03.129	Acute lymphangitis of unspecified part of limb
	711.05	Pyogenic arthritis, pelvic region and	M00.05 9	Staphylococcal arthritis, unspecified ankle and foot
		thigh	M00.15 9	Pneumococcal arthritis, unspecified hip
			M00.25 9	Other streptococcal arthritis, unspecified hip
			M00.85 9	Arthritis due to other bacteria, unspecified hip

	711.06	Pyogenic arthritis, lower leg	M00.06 9	Pneumococcal arthritis, unspecified hip
			M00.16 9	Pneumococcal arthritis, unspecified knee
			M00.26 9	Other streptococcal arthritis, unspecified knee
		M00.86 9	Arthritis due to other bacteria, unspecified knee	



711.07	Pyogenic arthritis,	M00.07	Staphylococcal arthritis,
	ankle and foot	09	unspecified ankle and foot
		M00.17	Pneumococcal arthritis,
		9	unspecified ankle and foot
		M00.27	Other streptococcal
		9	arthritis, unspecified ankle and foot
		M00.87	Arthritis due to other
		9	bacteria, unspecified ankle and foot
730.05	Acute osteomyelitis,	M86.15	Other acute osteomyelitis,
	pelvic region and thigh	9	unspecified femur
		M86.25	Subacute osteomyelitis,
		9	unspecified femur
730.06	Acute osteomyelitis,	M86.16	Other acute osteomyelitis,
	lower leg	9	unspecified tibia and fibula
		M86.26	Subacute osteomyelitis,
		9	unspecified tibia and fibula
730.07	Acute osteomyelitis,	M86.17	Other acute osteomyelitis,
	ankle and foot	9	unspecified ankle and foot
		M86.27	Subacute osteomyelitis,
		9	unspecified ankle and foot
730.15	Chronic	M86.65	Other chronic
	osteomyelitis, pelvic region and thigh	9	osteomyelitis, unspecified thigh
730.16	Chronic	M86.66	Other chronic
	osteomyelitis, lower leg	9	osteomyelitis, unspecified tibia and fibula
730.17	Chronic	M86.67	Other chronic
	osteomyelitis, ankle and foot	9	osteomyelitis, unspecified ankle and foot



VEAP ID NO: XXXXX Epidemiology No.(PE Studies only): EP0xxxx.xx

Epiaciinoio	gy No.(FE Studies	only): EPUXXXX.XX		
	730.25	Unspecified osteomyelitis, pelvic region and thigh	M86.9	Osteomyelitis, unspecified
	730.26	Unspecified osteomyelitis, lower leg	M86.9	Osteomyelitis, unspecified
	730.27	Unspecified osteomyelitis, ankle and foot	M86.9	Osteomyelitis, unspecified

730.35 730.36	Periostitis, without mention of osteomyelitis, pelvic region and thigh Periostitis, without mention of osteomyelitis, lower leg	M86.9 M86.9	Osteomyelitis, unspecified Osteomyelitis, unspecified
730.37	Periostitis, without mention of osteomyelitis, ankle and foot	M86.9	Osteomyelitis, unspecified
730.85	Other infections involving bone in diseases classified elsewhere, pelvic region and thigh	M90.85 9	Osteopathy in diseases classified elsewhere, unspecified thigh
730.86	Other infections involving bone in diseases classified elsewhere, lower leg	M90.86 9	Osteopathy in diseases classified elsewhere, unspecified lower leg
730.87	Other infections involving bone in diseases classified elsewhere, ankle and foot	M90.87 9	Osteopathy in diseases classified elsewhere,



Epidemiology No.(PE Studi	CS Offry). LI OAAAA	X.AA		<u> </u>
				unspecified ankle and foot
	730.95	Unspecified infection of bone, pelvic region and thigh	M86.9	Osteomyelitis, unspecified
	730.96	Unspecified infection of bone, lower leg	M86.9	Osteomyelitis, unspecified
	730.97	Unspecified infection of bone, ankle and foot	M86.9	Osteomyelitis, unspecified
	785.4	Gangrene	196	Gangrene, not elsewhere classified
Proposed PQI:	ICD-9-CM		ICD-10-CM	
Hypoglycemia ²⁸ Algorithm described by	251.0	Hypoglycemic coma	E15	Nondiabetic hypoglycemic coma
Ginde et al. (Appendix 3)	251.1	Other specified hypoglycemia	E16.0	Drug-induced hypoglycemia without coma
			E16.1	Other hypoglycemia
	251.2	Hypoglycemia, unspecified	E16.2	Hypoglycemia, unspecified
	270.3	Leucine- induced hypoglycemia	E71.0	Maple-syrup- urine disease
			E71.120	Methylmalonic acidemia
			E71.19	Other disorders of branched- chain aminoacid metabolism



Epidemiology No.(PE Studie	S OHLY). EFUXXXX	.XX		
			E71.2	Disorder of branched-chain amino-acid metabolism, unspecified
	775.0	Hypoglycemia in an infant born to a diabetic mother	P70.0	Syndrome of infant of mother with gestational diabetes
			P70.1	Syndrome of infant of a diabetic mother
	775.6	Neonatal hypoglycemia	P70.4	Other neonatal hypoglycemia
	962.3	Poisoning by insulins and antidiabetic agents	T38.3X 1A	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, accidental (unintentional), initial encounter
			T38.3X 2A	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, intentional self- harm, initial encounter

		T38.3X 3A	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, assault, initial encounter
		T38.3X 4A	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, undetermined, initial encounter
250.80	Diabetes with other specified manifestations, type II or unspecified	E11.618	Type 2 diabetes mellitus with other diabetic arthropathy



Epidemiology No.(PE	Studies only): EP0xxxx.xx		
	type, not stated as uncontrolled	E11.620	Type 2 diabetes mellitus with diabetic dermatitis
		E11.621	Type 2 diabetes mellitus with foot ulcer
		E11.622	Type 2 diabetes mellitus with other skin ulcer
		E11.628	Type 2 diabetes mellitus with other skin complications
		E11.630	Type 2 diabetes mellitus with periodontal disease
		E11.638	Type 2 diabetes mellitus with other oral complications
		E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
		E11.65	Type 2 diabetes mellitus with hyperglycemia
		E11.69	Type 2 diabetes mellitus with other specified complication
259.8	Secondary diabetic glycogenosis	E34.8	Other specified endocrine disorders
272.7	Lipidoses	E75.21	Fabry (-Anderson) disease
		E75.22	Gaucher disease
		E75.249	Niemann-Pick disease, unspecified
		E77.0	Defects in post- translational modification of



logy 140.(1 L btu	dies only): EPUXXXX.XX		
			lysosomal enzymes
		E77.1	Defects in glycoprotein degradation
681.00	Cellulitis and abscess of finger, unspecified	L03.019	Cellulitis of unspecified finger
		L03.029	Acute lymphangitis of unspecified finger
707.1	Ulcers of lower extremity	E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
707.2	Ulcers of lower extremity	E11.620	Type 2 diabetes mellitus with diabetic dermatitis
707.3	Ulcers of lower extremity	E11.621	Type 2 diabetes mellitus with foot ulcer
707.4	Ulcers of lower extremity	E11.622	Type 2 diabetes mellitus with other skin ulcer
707.5	Ulcers of lower extremity	E11.628	Type 2 diabetes mellitus with other skin complications
707.6	Ulcers of lower extremity	E11.630	Type 2 diabetes mellitus with periodontal disease
707.7	Ulcers of lower extremity	E11.638	Type 2 diabetes mellitus with other oral complications
707.8	Ulcers of lower extremity	E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
707.9	Ulcers of lower extremity	E11.65	Type 2 diabetes mellitus with hyperglycemia
709.3	Degenerative skin disorders	L92.1	Necrobiosis lipoidica, not elsewhere classified
		L94.2	Calcinosis cutis
		L98.8	Other specified disorders of the skin and subcutaneous tissue
730.00	Acute osteomyelitis, site unspecified	M86.10	Other acute osteomyelitis, unspecified site



Epidemiology No.(PE Studies only): EP0xxxx.xx

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			M86.20	Subacute osteomyelitis, unspecified site
	730.1	Chronic osteomyelitis, site unspecified	M86.60	Other chronic osteomyelitis, unspecified site
	730.2	Unspecified osteomyelitis, site unspecified	M86.9	Osteomyelitis, unspecified
	731.8	Other bone involvement in diseases classified elsewhere	M90.80	Osteopathy in diseases classified elsewhere, unspecified site
	250.3	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
			E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
			E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
			E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
			E11.65	Type 2 diabetes mellitus with hyperglycemia
			E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
			E10.65	Type 1 diabetes mellitus with hyperglycemia

Appendix 3. Figure describing coding algorithm for hypoglycemic events, published by Ginde et al.⁴²





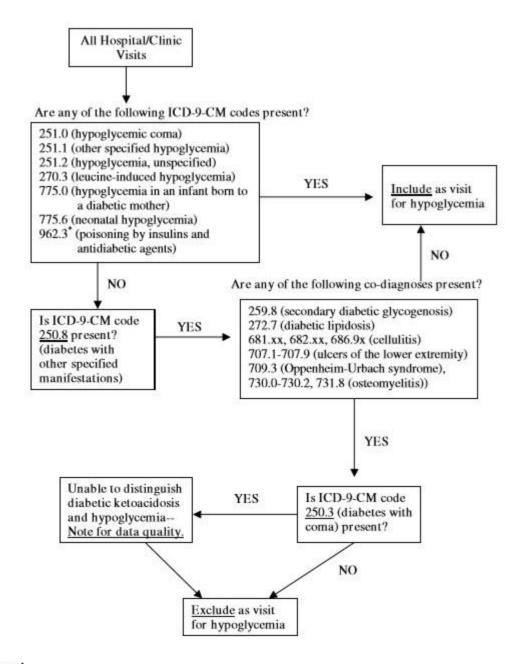


Figure 1
ICD-9-CM coding algorithm to identify emergency department visits for hypoglycemia. ICD-9-CM — International Classification of Diseases, Ninth Revision. * Consider exclusion of this code from algorithm, since positive predictive value was 54% in this analysis, and exclusion improved the accuracy of the algorithm.



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Appendix 4. ICD-9 and ICD-10 codes to describe comorbidities, as described by the Updated Diabetes Severity Index and previously published Literature

Microvascular comp	olications				
Retinopathy ³²	ICD-9-CM:	ICD-9-CM:		ICD-10-CM:	
,33	249.5x	Secondary diabetes with ophthalmic manifestations	Main Codes		
	250.5x	Diabetic ophthalmologic disease	E08	Diabetes Mellitus due to underlying conditions	
	362.01	Background diabetic retinopathy	E09	Drug or chemical induced diabetes mellitus	
	362.1x	Other background retinopathy and retinal vascular changes	E10	Type 1 diabetes mellitus	
	362.0x, excluding 362.02	Diabetic retinopathy, excluding proliferative diabetic retinopathy	E11	Type 2 diabetes mellitus	
	362.81- 362.83	Retinal hemorrhage, retinal exudates and deposits, retinal edema	E13	Other specified diabetes mellitus	
	361.x	Retinal detachment		de above, with vant subcodes:	
	362.02	Proliferative retinopathy	E**.34x	Severe nonproliferative diabetic retinopathy	
	369.x	Blindness and low vision	E**.35x	Proliferative diabetic retinopathy	
			Regular codes	::	



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			H33.x	Retinal detachments and breaks
			H35.0x	Background retinopathy and retinal vascular changes
			H35.35x	Cystoid macular degeneration
			H35.6x	Retinal hemorrhage
			H35.8x	Other specified retinal disorders
			H35.9	Unspecified retinal disorder
			H43.1x	Vitreous hemorrhage
			H54.x	Blindness and low vision
Nephropathy ³	ICD-9	ICD-9		·
2,33	250.4x	Diabetes with renal manifestations	Main Codes	
	249.4x	Secondary diabetes with renal manifestations	E08	Diabetes mellitus due to underlying condition
	580.x	Acute glomerulonephritis	E09	Drug or chemical induced diabetes mellitus
	581.x	Nephrotic syndrome	E10	Type 1 diabetes mellitus
	581.81	Hypertension, nephrosis1	E11	Type 2 diabetes mellitus
	582.x	Chronic glomerulonephritis	E13	Other specified diabetes mellitus
	583.x	Nephritis and nephropathy not specified as acute or chronic		de above, with vant subcodes:



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	585.1	CKD, Stage 1	E**.21	With diabetic nephropathy
	585.2	CKD, Stage 2 (mild)	E**.22	With diabetic chronic kidney disease
	585.3	CKD, Stage 3 (moderate)	E**.29	With other diabetic kidney complication
	585.9	CKD, unspecified	Regular codes:	

	585.4	CKD Stage 4 (severe)	N00.x	Acute nephritic syndrome
	585.5	CKD Stage 5	N04.x	Nephrotic syndrome
	585.6	End stage renal disease	N03.x	Chronic nephritic syndrome
	586	Renal failure, unspecified	N05.x	Unspecified nephritic syndrome
	593.9	Unspecified disorder of kidney and ureter	N18.1	CKD, Stage 1
			N18.2	CKD, Stage 2 (mild)
			N18.3	CKD, Stage 3 (moderate)
			N18.9	CKD, unspecified
			N18.4	CKD, Stage 4 (severe)
			N18.5	CKD, Stage 5
			N18.6	End stage renal disease
			N19	Unspecified kidney failure
Neuropathy ³² ,	ICD-9-		ICD-10-CM	
	249.6x	Secondary diabetes with neurological manifestations	Main Codes	
	250.6x,	Diabetes with neurological manifestations,	E08	Diabetes mellitus due to underlying condition
	357.2	Polyneuropathy in diabetes	E09	Drug or chemical induced diabetes mellitus



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337.0x	Idiopathic peripheral autonomic neuropathy	E10	Type 1 diabetes mellitus	
337.1	Peripheral autonomic neuropathy in disorders classified elsewhere	E11	Type 2 diabetes mellitus	
354.x	Mononeuritis of upper limb and mononeuritis multiplex	E13	Other specified diabetes mellitus	
355.x	Mononeuritis of lower limb and unspecified site	Each main code above, with following relev subcodes:		
356.9	Unspecified hereditary and idiopathic peripheral neuropathy	E**.4x	With neurological complications	
358.1	Myasthenic syndromes in diseases classified elsewhere	Regular Codes	s:	
458.0	Orthostatic hypotension	G90.09	Other [than carotid sinus syncope] idiopathic peripheral autonomic neuropathy	
536.3	Gastroparesis	G90.8	Other disorders of autonomic nervous system	
564.5	Functional diarrhea	G90.9	Disorder of the autonomic nervous system, unspecified;	
596.54	Neurogenic bladder NOS	G99.0	Autonomic neuropathy in diseases classified elsewhere	
713.5	Arthropathy associated with neurological disorders	G56.x	Mononeuropathies of upper limb	
458.0	Orthostatic hypotension	G57.x	Mononeuropathies of lower limb	



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	536.3	Gastroparesis	G60.9	Hereditary and	
				idiopathic	
				neuropathy,	
				unspecified	
	564.5	Functional	G73.3	Myasthenic	
		diarrhea		syndromes in	
				other diseases	
				classified	
				elsewhere	
	713.5	Arthropathy	G90.01	Carotid sinus	
		associated with		syncope	
		neurological			
		disorders			
	951.0	Injury to	H49.x	Paralytic	
		oculomotor		strabismus	
		nerve			
	951.1	Injury to	195.1	Orthostatic	
		trochlear nerve		hypotension	

	951.3	Injury to abducens nerve	K31.84	Gastroparesis
			K59.1	Functional diarrhea
			N31.9	Neuromuscular dysfunction of bladder, unspecified
			M14.6x	Charcôt's joint
			S04.x	Injury to cranial nerve
Macrovascular compl	ications			
Acute	ICD-9-CM		ICD-10-CM	
Coronary Syndrome ³⁴	411.0	Postmyocardial infarction syndrome	124.0	Acute coronary thrombosis not resulting in myocardial infarction
	411.0	Intermediate coronary syndrome	124.8	Other forms of acute ischemic heart disease
	411.1	Intermediate coronary syndrome	124.9	Acute ischemic heart disease, unspecified



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		411.8	Other acute and subacute forms of ischemic heart disease		
		411.81	Acute coronary occlusion without myocardial infarction		
-		411.89	Other acute and subacute forms of ischemic heart disease, other		
	Acute	ICD-9-CM		ICD-10-CM	
	Myocardial Infarction ⁴⁰	410	Acute myocardial infarction of anterolateral wall, episode of care unspecified	121	Acute myocardial infarction
		410.01	Acute myocardial infarction of anterolateral wall, initial episode of care	121.0	Acute transmural myocardial infarction of anterior wall
		410.02	Acute myocardial infarction of anterolateral wall, subsequent episode of care	121.1	Acute transmural myocardial infarction of inferior wall
		410.1	Acute myocardial infarction of other anterior wall, episode of care unspecified	l21.2	Acute transmural myocardial infarction of other sites
		410.11	Acute myocardial infarction of other anterior	121.3	Acute transmural myocardial



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		wall, initial episode of care		infarction of unspecified site	
	410.12	Acute myocardial infarction of other anterior wall, subsequent episode of care	121.4	Acute subendocardial myocardial infarction	
	410.2	Acute myocardial infarction of inferolateral wall, episode of care unspecified	121.9	Acute myocardial infarction, unspecified	
	410.21	Acute myocardial infarction of inferolateral wall, initial episode of care	122	Subsequent myocardial infarction	
	410.22	Acute myocardial infarction of inferolateral wall, subsequent episode of care	122.0	Subsequent myocardial infarction of anterior wall	
	410.3	Acute myocardial infarction of inferoposterior wall, episode of care unspecified	122.1	Subsequent myocardial infarction of inferior wall	

410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care	122.8	Subsequent myocardial infarction of other sites
410.32	Acute myocardial infarction of inferoposterior wall, subsequent episode of care	122.9	Subsequent myocardial infarction of unspecified site



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410.4	Acute myocardial infarction of other inferior wall, episode of care unspecified	123	Certain current complications following acute myocardial infarction
410.41	Acute myocardial infarction of other inferior wall, initial episode of care	123.0	Haemopericardium as current complication following acute myocardial infarction
410.42	Acute myocardial infarction of other inferior wall, subsequent episode of care	123.1	Atrial septal defect as current complication following acute myocardial infarction
410.5	Acute myocardial infarction of other lateral wall, episode of care unspecified	123.2	Ventricular septal defect as current complication following acute myocardial infarction
410.51	Acute myocardial infarction of other lateral wall, initial episode of care	123.3	Rupture of cardiac wall without haemopericardium as current complication following acute myocardial
410.52	Acute myocardial infarction of other lateral wall, subsequent episode of care	123.4	Rupture of chordae tendineae as current complication following acute myocardial infarction
410.6	True posterior wall infarction, episode of care unspecified	123.5	Rupture of papillary muscle as current complication following acute myocardial infarction
410.61	True posterior wall infarction, initial episode of care	123.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute my
410.62	True posterior wall infarction, subsequent episode of care	123.8	Other current complications following acute myocardial infarction
410.7	Subendocardial infarction, episode of care unspecified		
410.71	Subendocardial infarction, initial episode of care		
410.72	Subendocardial infarction,		



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		subsequent episode
		of care
		Acute myocardial
		infarction of other
	410.8	specified sites,
		episode of care
		unspecified
		Acute myocardial
	410.81	infarction of other
	410.81	specified sites, initial
		episode of care
		Acute myocardial
		infarction of other
	410.82	specified sites,
		subsequent episode
		of care
		Acute myocardial
		infarction of
	410.9	unspecified site,
		episode of care
		unspecified
		Acute myocardial
	410.91	infarction of
	410.91	unspecified site,
		initial episode of care

	410.92	Acute myocardial infarction of unspecified site, subsequent episode of care		
	411.89	Other acute and subacute forms of ischemic heart disease, other		
Angina ³⁸	ICD-9-		ICD-10-CM	
	411.1	Intermediate coronary syndrome	120.0	Unstable angina
	413.1	Prinzmetal angina	120.1	Angina pectoris with



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				documented
		Other and		other forms of
		unspecified		angina pectoris
	413.9	angina		
		pectoris	120.0	
			120.8	
	706 5	Chest pain, unspecified		Angina pectoris, unspecified
	786.5	unspecified	120.9	unspecified
		Due soudiel main	120.9	Chast rain an
	786.51	Precordial pain	207.4	Chest pain on breathing
			R07.1	_
	786.52	Painful		Precordial pain
		respiration	R07.2	
	786.59	Other chest pain		Pleurodynia
			R07.81	
			R07.82	Intercostal pain
			R07.89	Other chest pain
			R07.9	Chest pain,
				unspecified
Arrythmia ³⁸	ICD-9- CM		ICD-10-CM	
	427.41	Ventricular fibrillation	149.01	Ventricular fibrillation
	427.42	Ventricular	149.02	Ventricular
		flutter		flutter
	427.60	Premature beats,		Atrial premature
		unspecified	149.1	depolarization
		Supraventricular		Junctional
	427.61	premature beats		premature
			149.2	depolarization
		Other premature		Ventricular
	427.69	beats		premature
			1	depolarization
			149.3	acpolarization
		Sinoatrial node	149.3	Unspecified
	427.81	Sinoatrial node dysfunction		Unspecified premature
	427.81	dysfunction	149.3	Unspecified premature depolarization
	427.81	dysfunction Other specified		Unspecified premature depolarization Other
	427.81	dysfunction Other specified cardiac		Unspecified premature depolarization Other premature
		dysfunction Other specified		Unspecified premature depolarization Other



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	427.9	Cardiac dysrhythmia, unspecified	149.5	Sick sinus syndrome
	785.0	Tachycardia, unspecified	149.8	Other specified cardiac arrhythmias
	785.1	Palpitations	149.9	Cardiac arrhythmia, unspecified
	785.3	Other abnormal heart sounds	R00.0	Tachycardia, unspecified
			R00.1	Bradycardia, unspecified
			R00.2	Palpitations
			R00.8	Other abnormalities of heart beat
			R00.9*	Unspecified abnormalities of heart beat
	ICD-9- CM		ICD-10-CM	

CABG Revasculariza tion/ Carotid Revasculariza tion/ Claudication/	433.1	Carotid artery occlusion and stenosis without mention of cerebral infarction	I63.139	Carotid artery occlusion and stenosis without mention of cerebral infarction
Surgical Revasculariza tion _{36,37}	433.11	Carotid artery occlusion and stenosis with cerebral infarction	163.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid artery
	433.3	Multiple and bilateral carotid artery occlusion and stenosis without mention of cerebral infarction	165.8	Occlusion and stenosis of other precerebral arteries



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433.31	Multiple and bilateral carotid artery occlusion and stenosis with cerebral infarction	163.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
435.9	Transient cerebral ischemia	G45.9	Transient cerebral ischemic attack, unspecified
362.34	Amaurosis fugax	167.848	Other cerebrovascular vasospasm and vasoconstriction
38.12	Carotid endarterectomy	H34.00	Transient retinal artery occlusion, unspecified eye
39.5	Angioplasty or atherectomy of noncoronary vessel	03CH0Z Z	Extirpation of Matter from Right Common Carotid Artery, Open Approach
39.7	Endovascular repair of vessel	03CH4Z Z	Extirpation of Matter from Right Common Carotid Artery, Percutaneous Endoscopic Approach
39.9	Insertion of noncoronary artery stent or stents	03CJ0ZZ	Extirpation of Matter from Left Common Carotid Artery, Open Approach
0.63	Percutaneous insertion of carotid artery stent	03CJ4ZZ	Extirpation of Matter from Left Common Carotid Artery, Percutaneous Endoscopic Approach
36.1	Bypass anastomosis for	03CK0Z Z	Extirpation of Matter from Right Internal



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	heart		Carotid Artery,
	revascularization		Open Approach
36.10	Aortocoronary bypass for heart revascularization, not otherwise specified	03CK4Z Z	Extirpation of Matter from Right Internal Carotid Artery, Percutaneous Endoscopic Approach
36.11	(Aorto)coronary bypass of one coronary artery	03CL0Z Z	Extirpation of Matter from Left Internal Carotid Artery, Open Approach
36.12	(Aorto)coronary bypass of two coronary arteries	03CL4Z Z	Extirpation of Matter from Left Internal Carotid Artery, Percutaneous Endoscopic Approach
36.13	(Aorto)coronary bypass of three coronary arteries	03CM0Z Z	Extirpation of Matter from Right External Carotid Artery, Open Approach
36.14	(Aorto)coronary bypass of four or more coronary arteries	03CM4Z Z	Extirpation of Matter from Right External Carotid Artery, Percutaneous Endoscopic Approach
36.15	Single internal mammarycoronary artery bypass	03CN0Z Z	Extirpation of Matter from Left External Carotid Artery, Open Approach
36.16	Double internal mammarycoronary artery bypass	03CN4Z Z	Extirpation of Matter from Left External Carotid Artery, Percutaneous Endoscopic Approach





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	36.17	Abdominal - coronary artery bypass	03CP0Z Z	Extirpation of Matter from Right Vertebral Artery, Open Approach			
	36.19	Other bypass anastomosis for heart revascularization	03CP4Z Z	Extirpation of Matter from Right Vertebral Artery, Percutaneous Endoscopic Approach			

36.2	Heart revascularization by arterial implant	03CQ0Z Z	Extirpation of Matter from Left Vertebral Artery, Open Approach
34.20	flaccid hemiplegia	03CQ4Z Z	Extirpation of Matter from Left Vertebral Artery, Percutaneous Endoscopic Approach
42.70	paroxysmal supraventricular tachycardia	03CR0Z Z	Extirpation of Matter from Face Artery, Open Approach
42.73	atrial fibrillation and flutter	03CR3Z Z	Extirpation of Matter from Face Artery, Percutaneous Approach
42.74	ventricular fibrillation and flutter	03CR4Z Z	Extirpation of Matter from Face Artery, Percutaneous Endoscopic Approach
42.75	cardiac arrest	03CS0Z Z	Extirpation of Matter from Right Temporal Artery, Open Approach
42.78	other specified cardiac dysrhythmias	03CS3Z Z	Extirpation of Matter from Right Temporal Artery, Percutaneous Approach
42.79	unspecified cardiac dysrhythmia	03CS4Z Z	Extirpation of Matter from Right Temporal Artery, Percutaneous Endoscopic Approach
42.80	congestive heart failure unspecified	03CT0Z Z	Extirpation of Matter from Left Temporal Artery, Open Approach



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42.81	left heart failure	03CT0Z Z	Extirpation of Matter from Left Temporal Artery, Open Approach
42.82	systolic heart failure	03CT3Z Z	Extirpation of Matter from Left Temporal Artery, Percutaneous Approach
40.00		03CT4Z Z	Extirpation of Matter from Left Temporal Artery, Percutaneous
42.83	diastolic heart failure combined systolic and diastolic heart failure	03CU0Z Z	Endoscopic Approach Extirpation of Matter from Right Thyroid Artery, Open Approach
42.89	unspecified heart failure	03CU3Z Z	Extirpation of Matter from Right Thyroid Artery, Percutaneous Approach
43.40	cerebral thrombosis	03CU4Z Z	Extirpation of Matter from Right Thyroid Artery, Percutaneous Endoscopic Approach
43.50	basilar artery syndrome	03CV0Z Z	Extirpation of Matter from Left Thyroid Artery, Open Approach
51.84	unspecified acute edema of lung	03CV3Z Z	Extirpation of Matter from Left Thyroid Artery, Percutaneous Approach
51.85	pulmonary insufficiency following trauma&surgery	03CV4Z Z	Extirpation of Matter from Left Thyroid Artery, Percutaneous Endoscopic Approach
55.70	acute vascular insufficiency of intestine	027x- 037x	Dilation of multiple arteries and veins using various devices
55.79	unspecified vascular insufficiency of intestine	<u>021008</u> <u>W</u>	Bypass Coronary Artery, One Artery from Aorta with Zooplastic Tissue, Open Approach
56.09	unspecified intestinal obstruction	<u>021009</u> <u>W</u>	Bypass Coronary Artery, One Artery from Aorta with Autologous Venous Tissue,



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			Open Approach
59.33	stricture or kinking of ureter	02100A W	Bypass Coronary Artery, One Artery from Aorta with Autologous Arterial Tissue, Open Approach
59.39	unspecified disorder of kidney and ureter	<u>02100JW</u>	Bypass Coronary Artery, One Artery from Aorta with Synthetic Substitute, Open Approach
7810	abnormal involuntary movements	021048 W	Bypass Coronary Artery, One Artery from Aorta with Zooplastic Tissue, Percutaneous Endoscopic Approach

9970	nervous system	021049 W	Bypass Coronary Artery, One
	complications nec		Artery from
			Aorta with Autologous
			Venous Tissue,
			Percutaneous Endoscopic
			Approach
9971	cardiac complications	02104A W	Bypass Coronary Artery, One
	nec		Artery from
			Aorta with Autologous
			Arterial Tissue,
			Percutaneous Endoscopic
			Approach
9973	respiratory	02104JW	Bypass Coronary Artery, One
	complications nec		Artery from
			Aorta with Synthetic
			Substitute,
			Percutaneous Endoscopic
			Approach
9974	digestive system	02104K W	Bypass Coronary Artery, One
	complication nec		Artery from
			Aorta with Nonautologous
			Tissue
			Substitute, Percutaneous
			Endoscopic
			Approach



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9975	surg complication urinary tract	021108 W	Bypass Coronary Artery, Two Arteries from Aorta with Zooplastic Tissue, Open Approach
9985	postoperative infection not elsewhere classified	021109 W	Bypass Coronary Artery, Two Arteries from Aorta with Autologous Venous Tissue, Open Approach
59.33	stricture or kinking of ureter	02110A W	Bypass Coronary Artery, Two Arteries from Aorta with Autologous Arterial Tissue, Open Approach
59.39	unspecified disorder of kidney and ureter	02110JW	Bypass Coronary Artery, Two Arteries from Aorta with Synthetic Substitute, Open Approach
78.10	abnormal involuntary movements	02110K W	Bypass Coronary Artery, Two Arteries from Aorta with Nonautologous Tissue Substitute, Open Approach
99.70	nervous system complications nec	021148 W	Bypass Coronary Artery, Two Arteries from Aorta with Zooplastic Tissue, Percutaneous Endoscopic Approach
99.71	cardiac complications nec	021149 W	Bypass Coronary Artery, Two Arteries from Aorta with Autologous Venous Tissue, Percutaneous Endoscopic Approach
99.73	respiratory complications nec	02114A W	Bypass Coronary Artery, Two Arteries from Aorta with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
99.74	digestive system complication nec	02114JW	Bypass Coronary Artery, Two Arteries from Aorta with Synthetic Substitute, Percutaneous Endoscopic Approach



99.75	surg complication	02114K W	Bypass Coronary Artery,
	urinary tract		Two Arteries from
			Aorta with Nonautologous
			Tissue
			Substitute, Percutaneous
			Endoscopic
			Approach
99.85	postoperative	021208	Bypass Coronary Artery, Three
	infection not	W	Arteries from Aorta with Zooplastic
	elsewhere classified		Tissue, Open Approach
342.00	flacid hemiplegia	021209	Bypass Coronary Artery, Three
	affecting unspecified	W	Arteries from Aorta with Autologous
	side		Venous Tissue, Open Approach
342.01	flacid hemiplegia	02120A	Bypass Coronary Artery, Three
	affecting dominant	w	Arteries from Aorta with Autologous
	side		Arterial Tissue, Open Approach

342.02	flacid hemiplegia affecting nondominant side	02120JW	Bypass Coronary Artery, Three Arteries from Aorta with Synthetic Substitute, Open Approach
342.10	spastic hemiplegia affecting unspecified side	02120K W	Bypass Coronary Artery, Three Arteries from Aorta with Nonautologous Tissue Substitute, Open Approach
342.11	spastic hemiplegia affecting dominant side	02120K W	Bypass Coronary Artery, Three Arteries from Aorta with Nonautologous Tissue Substitute, Open Approach
342.12	spastic hemiplegia affecting nondominant side	002120K W	Bypass Coronary Artery, Three Arteries from Aorta with Nonautologous Tissue Substitute, Open Approach
342.80	other spec hemiplegia affecting unspec side	02124A W	Bypass Coronary Artery, Three Arteries from Aorta with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
342.81	other spec hemiplegia affecting dominant side	02124JW	Bypass Coronary Artery, Three Arteries from Aorta with Synthetic Substitute, Percutaneous Endoscopic Approach
342.82	other spec hemiplegia affecting nondominant side	02124K W	Bypass Coronary Artery, Three Arteries from Aorta with Nonautologous Tissue



			Substitute, Percutaneous Endoscopic Approach
342.90	unspec hemiplegia affecting unspec side	021308 W	Bypass Coronary Artery, Four or More Arteries from Aorta with Zooplastic Tissue, Open Approach
342.91	unspecified hemiplegia affecting dominant side	021309 W	Bypass Coronary Artery, Four or More Arteries from Aorta with Autologous Venous Tissue, Open Approach
342.92	unspec hemiplegia affecting nondominant side	02130A W	Bypass Coronary Artery, Four or More Arteries from Aorta with Autologous Arterial Tissue, Open Approach
362.34	transient arterial occlusion of retina	02130JW	Bypass Coronary Artery, Four or More Arteries from Aorta with Synthetic Substitute, Open Approach
368.12	transient visual loss	02130K W	Bypass Coronary Artery, Four or More Arteries from Aorta with Nonautologous Tissue Substitute, Open Approach
427.31	atrial fibrillation	021348 W	Bypass Coronary Artery, Four or More Arteries from Aorta with Zooplastic Tissue, Percutaneous Endoscopic Approach
427.32	atrial flutter	021349 W	Bypass Coronary Artery, Four or More Arteries from Aorta with Autologous Venous Tissue, Percutaneous Endoscopic Approach





427.41	ventricular fibrillation	02134A W	Bypass Coronary Artery, Four or More Arteries from Aorta with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
427.42	ventricular flutter	02134JW	Bypass Coronary Artery, Four or More Arteries from Aorta with Synthetic Substitute, Percutaneous Endoscopic Approach
427.81	sinoatrial node dysfunction	02134K W	Bypass Coronary Artery, Four or More Arteries from Aorta with Nonautologous

			Tissue Substitute, Percutaneous Endoscopic Approach
427.89	other specified cardiac dysrhythmias	0210088	Bypass Coronary Artery, One Artery from Right Internal Mammary with Zooplastic Tissue, Open Approach
428.20	unspecified systolic heart failure	0210089	Bypass Coronary Artery, One Artery from Left Internal Mammary with Zooplastic Tissue, Open Approach
428.21	acute systolic heart failure	021008C	Bypass Coronary Artery, One Artery from Thoracic Artery with Zooplastic Tissue, Open Approach
428.22	chronic systolic heart failure	0210098	Bypass Coronary Artery, One Artery from Right Internal Mammary with Autologous Venous Tissue, Open Approach
428.23	acute on chronic systolic heart failure	0210099	Bypass Coronary Artery, One Artery from Left Internal Mammary with Autologous



iiology No.(Fi	E Studies only): EP0xxxx.xx		
			Venous Tissue, Open Approach
428.30	unspecified diastolic heart failure	021009C	Bypass Coronary Artery, One Artery from Thoracic Artery with Autologous Venous Tissue, Open Approach
428.31	acute diastolic heart failure	02100A8	Bypass Coronary Artery, One Artery from Right Internal Mammary with Autologous Arterial Tissue, Open Approach
428.32	chronic diastolic heart failure	02100A9	Bypass Coronary Artery, One Artery from Left Internal Mammary with Autologous Arterial Tissue, Open Approach
428.33	acute on chronic diastolic heart failure	02100A C	Bypass Coronary Artery, One Artery from Thoracic Artery with Autologous Arterial Tissue, Open Approach
428.40	unspec combined systolic&diastolic heart failure	02100J8	Bypass Coronary Artery, One Artery from Right Internal Mammary with Synthetic Substitute, Open Approach
428.41	acute combined systolic&diastolic heart failure	02100J9	Bypass Coronary Artery, One Artery from Left Internal Mammary with Synthetic Substitute, Open Approach
428.42	chronic comb systolic&diastolic heart failure	02100JC	Bypass Coronary Artery, One Artery from Thoracic Artery with Synthetic Substitute, Open Approach
428.43	acute chronic comb systolic&diastolic heart fail	02100K8	Bypass Coronary Artery, One Artery from Right Internal Mammary with



			Nonautologous Tissue Substitute, Open Approach
433.00	occlusion&stenos basilar art w/o mention infarct	02100K9	Bypass Coronary Artery, One Artery from Left Internal Mammary with Nonautologous Tissue Substitute, Open Approach
433.01	occlusion&stenosis basilar artery w/infarct	02100K C	Bypass Coronary Artery, One Artery from Thoracic Artery with Nonautologous Tissue Substitute, Open Approach
433.10	occlusion&stenos carotid art w/o mention infarct	02100Z8	Bypass Coronary Artery, One Artery from Right Internal Mammary, Open Approach
433.11	occlusion&stenosis carotid artery w/infarct	02100Z9	Bypass Coronary Artery, One Artery from Left Internal Mammary, Open Approach
433.20	occlusion&stenos vert art w/o mention infarct	02100ZC	Bypass Coronary Artery, One Artery from Thoracic Artery, Open Approach
433.21	occlusion&stenosis vertebral artery w/infarct	210488	Bypass Coronary Artery, One Artery from Right Internal Mammary with Zooplastic Tissue, Percutaneous Endoscopic Approach
433.30	occl&stenos mx&bilat precerbrl art w/o infarct	210489	Bypass Coronary Artery, One Artery from Left Internal Mammary with Zooplastic Tissue, Percutaneous Endoscopic Approach
433.31	occl&stenos mx&bilat precerbrl art w/infarct	021048C	Bypass Coronary Artery, One Artery from Thoracic Artery with Zooplastic Tissue,



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			Percutaneous Endoscopic Approach
433.80	occl&stenos oth spec precerbrl art w/o infarct	210498	Bypass Coronary Artery, One Artery from Right Internal Mammary with Autologous Venous Tissue, Percutaneous Endoscopic Approach
433.81	occl&stenos oth spec precerbrl art w/infarct	210499	Bypass Coronary Artery, One Artery from Left Internal Mammary with Autologous Venous Tissue, Percutaneous Endoscopic Approach
433.90	occl&stenos uns precerbrl art w/o infarct	021049C	Bypass Coronary Artery, One Artery from Thoracic Artery with Autologous Venous Tissue, Percutaneous Endoscopic Approach
433.91	occlusion&stenos unspec precerbrl art w/infarct	02104A8	Bypass Coronary Artery, One Artery from Right Internal Mammary with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
434.00	cerebral thrombosis without mention infarct	02104A9	Bypass Coronary Artery, One Artery from Left Internal Mammary with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
434.01	cerebral thrombosis with cerebral infarction	02104A C	Bypass Coronary Artery, One Artery from Thoracic Artery with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
434.10	cerebral embolism without mention infarct	02104J8	Bypass Coronary Artery, One Artery from



434.11	cerebral embolism with cerebral infarction	02104J9	Right Internal Mammary with Synthetic Substitute, Percutaneous Endoscopic Approach Bypass Coronary Artery, One Artery from Left Internal Mammary with Synthetic Substitute, Percutaneous Endoscopic
434.90	unspec cerbrl art occlusion w/o mention infarct	02104JC	Approach Bypass Coronary Artery, One Artery from Thoracic Artery with Synthetic Substitute, Percutaneous Endoscopic Approach
434.91	unspecified cerebral artery occlusion w/infarct	02104K8	Bypass Coronary Artery, One Artery from Right Internal Mammary with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
438.10	unspec spch&lange deficit due cerebrvasc disease	02104K9	Bypass Coronary Artery, One Artery from Left Internal Mammary with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
438.11	aphasia due to cerebrovascular disease	02104K C	Bypass Coronary Artery, One Artery from Thoracic Artery with Nonautologous Tissue

			Substitute, Percutaneous Endoscopic Approach
438.12	dysphasia due to cerebrovascular	02104Z8	Bypass Coronary Artery, One Artery from
	disease		Right Internal Mammary, Percutaneous



			Endoscopic Approach
438.13	dysarthria	02104Z9	Bypass Coronary Artery, One Artery from Left Internal Mammary, Percutaneous Endoscopic Approach
438.14	fluency disorder	02104ZC	Bypass Coronary Artery, One Artery from Thoracic Artery, Percutaneous Endoscopic Approach
438.19	oth spch&lange deficits due cerebrvasc disease	211088	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Zooplastic Tissue, Open Approach
438.20	hemipl affect unspec side due cerebrvasc disease	211089	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Zooplastic Tissue, Open Approach
438.21	hemipl affct dominant side due cerebrvasc dz	021108C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Zooplastic Tissue, Open Approach
438.22	hemipl affct nondominant side due cerebrvasc dz	211098	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Autologous Venous Tissue, Open Approach
438.30	monopleg upper limb uns side due cerebrvasc dz	211099	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Autologous Venous Tissue, Open Approach
438.31	monopleg upper limb dom side due cerebrvasc dz	021109C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Autologous Venous Tissue, Open Approach
438.32	monopleg up limb nondom side due cerebrvasc dz	02110A8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Autologous Arterial Tissue, Open Approach



438.40	monopleg low limb unspec side due cerebrvasc dz	02110A9	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Autologous Arterial Tissue, Open Approach
438.41	monopleg low limb dom side due cerebrvasc dz	02110A C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Autologous Arterial Tissue, Open Approach
438.42	monopleg low limb nondom side due cerebrvasc dz	02110J8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Synthetic Substitute, Open Approach
438.50	oth paralyt synd affct uns sidecerebrvasc dz	02110J9	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Synthetic Substitute, Open Approach
438.51	oth paralyt synd affct dom sidecerebrvasc dz	02110JC	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Synthetic Substitute, Open Approach
438.52	oth paralyt synd affct nondom side- cerebrvasc dz	02110K8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Nonautologous Tissue Substitute, Open Approach
438.53	other paralytic syndrome, bilateral	02110K9	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with
			Nonautologous Tissue Substitute, Open Approach
438.81	apraxia due to cerebrovascular disease	02110K C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Nonautologous Tissue Substitute, Open Approach



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438.82	dysphagia due to cerebrovascular disease	02110Z8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary, Open Approach
438.83	facial weakness late effect cerebrovascular dz	0211079	Bypass Coronary Artery, Two Arteries from Left Internal Mammary, Open Approach
438.84	ataxia as late effect of cerebrovascular disease	02110ZC	Bypass Coronary Artery, Two Arteries from Thoracic Artery, Open Approach
438.85	vertigo as late effect cerebrovascular disease	211488	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Zooplastic Tissue, Percutaneous Endoscopic Approach
438.89	other late effects of cerebrovascular disease	211489	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Zooplastic Tissue, Percutaneous Endoscopic Approach
997.00	unspecified nervous system complication nec	021148C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Zooplastic Tissue, Percutaneous Endoscopic Approach
997.01	central nervous system complication nec	211498	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Autologous Venous Tissue, Percutaneous Endoscopic Approach
997.02	iatrogenic cerebrovascular infarct/hemorrhage ne	211499	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Autologous Venous Tissue, Percutaneous Endoscopic Approach
997.09	other nervous system complications nec	021149C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Autologous



			Venous Tissue, Percutaneous Endoscopic Approach
443.9	Peripheral vascular disease, unspecified - intermittent claudication	02114A8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
39.25	Aorto-iliac femoral bypass	02114A9	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
39.29	Peripheral bypass	02114A C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
38.08	Incision of lower limb arteries	02114J8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Synthetic Substitute, Percutaneous Endoscopic Approach
38.16	Endarterectomy of abdominal arteries	02114J9	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Synthetic

				Substitute, Percutaneous Endoscopic Approach
38	8.18	Endarterectomy of lower limb arteries	02114JC	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Synthetic Substitute, Percutaneous Endoscopic Approach



02114K8	Bypass Coronary Artery, Two Arteries from Right Internal Mammary with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
02114K9	Bypass Coronary Artery, Two Arteries from Left Internal Mammary with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
02114K C	Bypass Coronary Artery, Two Arteries from Thoracic Artery with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
170.51	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities intermittent claudication
PCS 0410x- 041Jx	Bypass Abdominal Aorta - Bypass Left External Iliac Artery
PCS 0312x061V4x	Bypass Innominate Artery – Bypass Bypass Left Foot Vein
04Bx- 04W4YZ	Excision of Right Femoral Artery - Revision of Other Device in Lower Artery
PCS 045Kx- 045Yx	Destruction of Right Femoral Artery - Destruction of Lower Artery
04LK0C Z - 04LW4Z Z	Occlusion of Right Femoral Artery - Occlusion of Left Foot Artery



170.511	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, right leg
170.512	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, left leg
170.518	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, other extremity
170.519	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.61A	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, unspecified extremity

170.71	therosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication
170.41	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication
170.31	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication
170.21	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication



187.8	Atherosclerosis of native arteries of extremities with intermittent claudication
173.9	Claudicatio venosa intermittens
02114Z8	Claudication (intermittent)
02114Z9	Bypass Coronary Artery, Two Arteries from Right Internal Mammary, Percutaneous Endoscopic Approach
02114ZC	Bypass Coronary Artery, Two Arteries from Left Internal Mammary, Percutaneous Endoscopic Approach
021208C	Bypass Coronary Artery, Two Arteries from Thoracic Artery, Percutaneous Endoscopic Approach
021209C	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Zooplastic Tissue, Open Approach
02120A C	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Autologous Venous Tissue, Open Approach
02120JC	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Autologous Arterial Tissue, Open Approach
02120K C	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Synthetic Substitute, Open Approach
02120ZC	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Nonautologous Tissue Substitute, Open Approach
021248C	Bypass Coronary Artery, Three Arteries from Thoracic Artery, Open Approach
021249C	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Zooplastic Tissue,



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		Percutaneous Endoscopic Approach
	02124A C	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Autologous Venous Tissue, Percutaneous Endoscopic Approach
	02124JC	Bypass Coronary Artery, Three Arteries from Thoracic Artery with Autologous Arterial Tissue, Percutaneous Endoscopic Approach

02124K	Bypass Coronary Artery, Three
С	Arteries from Thoracic Artery
	with Synthetic Substitute, Percutaneous
	Endoscopic
	Approach
02124ZC	Bypass Coronary Artery, Three
	Arteries from Thoracic Artery
	with Nonautologous
	Tissue Substitute, Percutaneous
	Endoscopic Approach
021308C	Bypass Coronary Artery, Three
	Arteries from Thoracic Artery,
	Percutaneous Endoscopic Approach
021309C	Bypass Coronary Artery, Four or
0213030	More
	Arteries from Thoracic Artery
	with
	Zooplastic Tissue, Open
	Approach
02130A	Bypass Coronary Artery, Four or
С	More
	Arteries from Thoracic Artery
	with
	Autologous Venous Tissue,
	Open Approach
02130JC	Bypass Coronary Artery, Four or
	More
	Arteries from Thoracic Artery
	with
	Autologous Arterial Tissue,
	Open Approach



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02130K	Bypass Coronary Artery, Four or
С	More
	Arteries from Thoracic Artery
	with
	Synthetic Substitute, Open
	Approach
02130ZC	Bypass Coronary Artery, Four or
	More
	Arteries from Thoracic Artery
	with
	Nonautologous Tissue
	Substitute, Open Approach
021348C	Bypass Coronary Artery, Four or
0220.00	More
	Arteries from Thoracic Artery,
	Open
	Approach
021349C	Bypass Coronary Artery, Four or
0215450	More
	Arteries from Thoracic Artery
	with
	Zooplastic Tissue, Percutaneous
	Endoscopic Approach
02134A	Bypass Coronary Artery, Four or
C	More
	Arteries from Thoracic Artery
	with
	Autologous Venous Tissue,
	Percutaneous
	Endoscopic Approach
02134JC	Bypass Coronary Artery, Four or
0213410	More
	Arteries from Thoracic Artery
	with
	Autologous Arterial Tissue,
	Percutaneous
	Endoscopic Approach
021244	
02134K	Bypass Coronary Artery, Four or More
	Arteries from Thoracic Artery
	with
	Synthetic Substitute,
	Percutaneous
	Endoscopic Approach
	Endoscopic Approach



02134ZC	Bypass Coronary Artery, Four or
	More
	Arteries from Thoracic Artery
	with
	Nonautologous Tissue
	Substitute,
	Percutaneous Endoscopic
	Approach
021008F	Bypass Coronary Artery, Four or
	More
	Arteries from Thoracic Artery,
	Percutaneous Endoscopic
	Approach

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02100	Bypass Coronary Artery, One Artery from Abdominal Artery with Zooplastic Tissue, Open Approach
02100	OAF Bypass Coronary Artery, One Artery from Abdominal Artery with Autologous Venous Tissue, Open Approach
02100	OJF Bypass Coronary Artery, One Artery from Abdominal Artery with Autologous Arterial Tissue, Open Approach
02100	OKF Bypass Coronary Artery, One Artery from Abdominal Artery with Synthetic Substitute, Open Approach
02100	DZF Bypass Coronary Artery, One Artery from Abdominal Artery with Nonautologous Tissue Substitute, Open Approach
02104	Bypass Coronary Artery, One Artery from Abdominal Artery, Open Approach
02104	Bypass Coronary Artery, One Artery from Abdominal Artery with Zooplastic Tissue,



	Percutaneous Endoscopic Approach
02104AF	Bypass Coronary Artery, One Artery from Abdominal Artery with Autologous Venous Tissue, Percutaneous Endoscopic Approach
02104JF	Bypass Coronary Artery, One Artery from Abdominal Artery with Autologous Arterial Tissue, Percutaneous Endoscopic Approach
02104KF	Bypass Coronary Artery, One Artery from Abdominal Artery with Synthetic Substitute, Percutaneous Endoscopic Approach
02104ZF	Bypass Coronary Artery, One Artery from Abdominal Artery with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0210083	Bypass Coronary Artery, One Artery from Abdominal Artery, Percutaneous Endoscopic Approach
0210093	Bypass Coronary Artery, One Artery from Coronary Artery with Zooplastic Tissue, Open Approach
02100A3	Bypass Coronary Artery, One Artery from Coronary Artery with Autologous Venous Tissue, Open Approach
02100J3	Bypass Coronary Artery, One Artery from Coronary Artery with Autologous Arterial



Judiniology 140.(1 L Studies only). Et oxxxx.xx		Tissue, Open Approach
	02100K3	Bypass Coronary Artery, One Artery from Coronary Artery with Synthetic Substitute, Open Approach
	02100Z3	Bypass Coronary Artery, One Artery from Coronary Artery with Nonautologous Tissue Substitute, Open Approach
	0210483	Bypass Coronary Artery, One Artery from Coronary Artery, Open Approach

0210493	Bypass Coronary Artery, One
0210493	Artery from
	Coronary Artery with Zooplastic
	Tissue,
	,
	Percutaneous Endoscopic
	Approach
02104A3	Bypass Coronary Artery, One
	Artery from
	Coronary Artery with
	Autologous Venous
	Tissue, Percutaneous
	Endoscopic Approach
02104J3	Bypass Coronary Artery, One
	Artery from
	Coronary Artery with
	Autologous Arterial
	Tissue, Percutaneous
	Endoscopic Approach
02104K3	Bypass Coronary Artery, One
	Artery from Coronary Artery
	with Synthetic Substitute,
	Percutaneous Endoscopic
	Approach
02104Z3	Bypass Coronary Artery, One
	Artery from
	Coronary Artery with
	Nonautologous
	Tissue Substitute, Percutaneous
	Endoscopic Approach



021K0Z8	Bypass Coronary Artery, One Artery from Coronary Artery, Percutaneous Endoscopic Approach
021K0Z9	Bypass Right Ventricle to Right Internal Mammary, Open Approach
021K0Z C	Bypass Right Ventricle to Left Internal Mammary, Open Approach
021K0Z W	Bypass Right Ventricle to Thoracic Artery, Open Approach
021K4Z8	Bypass Right Ventricle to Aorta, Open Approach
021K4Z9	Bypass Right Ventricle to Right Internal Mammary, Percutaneous Endoscopic Approach
021K4Z C	Bypass Right Ventricle to Left Internal Mammary, Percutaneous Endoscopic Approach
021K4Z W	Bypass Right Ventricle to Thoracic Artery, Percutaneous Endoscopic Approach
021L0Z8	Bypass Right Ventricle to Aorta, Percutaneous Endoscopic Approach
021L0Z9	Bypass Left Ventricle to Right Internal Mammary, Open Approach
021L0Z C	Bypass Left Ventricle to Left Internal Mammary, Open Approach
021L4Z8	Bypass Left Ventricle to Thoracic Artery, Open Approach
021L4Z9	Bypass Left Ventricle to Right Internal Mammary, Percutaneous Endoscopic Approach



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021L4Z C	Bypass Left Ventricle to Left Internal Mammary, Percutaneous Endoscopic
G8190	Approach Bypass Left Ventricle to Thoracic Artery, Percutaneous
G8191	Endoscopic Approach hemiplegia, unspecified affecting unspecified side

G8192	hemiplegia, unspecified affecting right dominant side
G8193	hemiplegia, unspecified affecting left dominant side
G8194	hemiplegia, unspecified affecting right nondominant side
G9781	hemiplegia, unspecified affecting left nondominant side
G9782	other intraoperative complications of nervous system
1509	other postprocedural complications and disorders of nervous system
16359	heart failure, unspecified
1658	cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
16609	occlusion and stenosis of other precerebral arteries
16619	occlusion and stenosis of unspecified middle cerebral artery
16629	occlusion and stenosis of unspecified anterior cerebral artery
1669	occlusion and stenosis of unspecified posterior cerebral artery
169928	occlusion and stenosis of unspecified cerebral artery
169998	other speech and language deficits following unspecified cerebrovascular disease



J9589	other sequelae following unspecified cerebrovascular disease
K550	other postprocedural complications and disorders of respiratory system, not elsewhere classified
R001	acute vascular disorders of intestine
G8100	vertebro-basilar artery syndrome
G8101	flaccid hemiplegia affecting unspecified side
G8102	flaccid hemiplegia affecting right dominant side
G8103	flaccid hemiplegia affecting left dominant side
G8104	flaccid hemiplegia affecting right nondominant side
G8110	flaccid hemiplegia affecting left nondominant side
G8111	spastic hemiplegia affecting unspecified side
G8112	spastic hemiplegia affecting right dominant side
G8113	spastic hemiplegia affecting left dominant side

G8114	spastic hemiplegia affecting right nondominant side
G970	spastic hemiplegia affecting left nondominant side
H3400	cerebrospinal fluid leak from spinal puncture
H53129	transient retinal artery occlusion, unspecified eye
1469	transient visual loss, unspecified eye
1471	cardiac arrest, cause unspecified
14891	supraventricular tachycardia
14892	unspecified atrial fibrillation
14901	unspecified atrial flutter



14902	ventricular fibrillation
1495	ventricular flutter
1498	sick sinus syndrome
1499	other specified cardiac arrhythmias
1501	cardiac arrhythmia, unspecified
15020	left ventricular failure
15021	unspecified systolic (congestive) heart failure
15022	acute systolic (congestive) heart failure
15023	chronic systolic (congestive) heart failure
15030	acute on chronic systolic (congestive) heart failure
I5031	unspecified diastolic (congestive) heart failure
15032	acute diastolic (congestive) heart failure
15033	chronic diastolic (congestive) heart failure
15040	acute on chronic diastolic (congestive) heart failure
15041	unspecified combined systolic (congestive) and diastolic (congestive) heart failure
15042	acute combined systolic (congestive) and diastolic (congestive) heart failure
15043	chronic combined systolic (congestive) and diastolic (congestive) heart failure
163019	acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
163119	cerebral infarction due to thrombosis of unspecified vertebral artery



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163139	cerebral infarction due to embolism of unspecified vertebral artery
16320	cerebral infarction due to embolism of unspecified carotid artery

163219	cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
16322	cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral arteries
163239	cerebral infarction due to unspecified occlusion or stenosis of basilar arteries
16330	cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries
16340	cerebral infarction due to thrombosis of unspecified cerebral artery
16350	cerebral infarction due to embolism of unspecified cerebral artery
16509	cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery
l651	occlusion and stenosis of unspecified vertebral artery
16529	occlusion and stenosis of basilar artery
1659	occlusion and stenosis of unspecific carotid artery
169898	occlusion and stenosis of unspecified precerebral artery
169920	other sequelae of other cerebrovascular disease
169921	aphasia following unspecified cerebrovascular disease
169922	dysphasia following unspecified cerebrovascular disease



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	169923	dysarthria following unspecified cerebrovascular disease
	169931	fluency disorder following unspecified cerebrovascular disease
	169932	monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
	169933	monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
	169934	monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side
	169939	monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side
	169941	monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side
	169942	monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side

169943	monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
169944	monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
169949	monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side



169951	monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side
169952	hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side
169953	hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
169954	hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side
169959	hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side
169961	hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side
169962	other paralytic syndrome following unspecified cerebrovascular disease affecting right dominant side
169963	other paralytic syndrome following unspecified cerebrovascular disease affecting left dominant side
169964	other paralytic syndrome following unspecified cerebrovascular disease affecting right non-dominant side
169965	other paralytic syndrome following unspecified cerebrovascular disease affecting left non-dominant side



169969	other paralytic syndrome following unspecified cerebrovascular disease, bilateral	
169990	other paralytic syndrome following unspecified cerebrovascular disease affecting unspecified side	
169991	apraxia following unspecified cerebrovascular disease	
169992	dysphagia following unspecified cerebrovascular disease	
169993	facial weakness following unspecified cerebrovascular disease	
197710	ataxia following unspecified cerebrovascular disease	

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197790	intraoperative cardiac arrest during cardiac surgery
197811	other intraoperative cardiac functional disturbances during cardiac surgery
197821	intraoperative cerebrovascular infarction during other surgery
19788	postprocedural cerebrovascular infarction following other surgery
19789	other intraoperative complications of the circulatory system, not elsewhere classified
J810	other postprocedural complications and disorders of the circulatory system, not elsewhere classified
J951	acute pulmonary edema
J952	acute pulmonary insufficiency following thoracic surgery
J953	acute pulmonary insufficiency following nonthoracic surgery
J95821	chronic pulmonary insufficiency following surgery



J95822	acute postprocedural respiratory failure		
J95851	acute and chronic postprocedural respiratory failure		
J95859	ventilator associated pneumonia		
J9588	other complication of respirator [ventilator]		
J9600	other intraoperative complications of respiratory system, not elsewhere classified		
J9620	acute respiratory failure, unspecified whether with hypoxia or hypercapnia		
K559	acute and chronic respiratory failure, unspecified whether with hypoxia or hypercapnia		
K5660	vascular disorder of intestine, unspecified		
K6811	unspecified intestinal obstruction		
K913	postprocedural retroperitoneal abscess		
K9181	postprocedural intestinal obstruction		
K9182	other intraoperative complications of digestive system		
K9183	postprocedural hepatic failure		
K9186	postprocedural hepatorenal syndrome		
К9189	retained cholelithiasis following cholecystectomy		
N135	other postprocedural complications and disorders of digestive system		
N289	crossing vessel and stricture of ureter without hydronephrosis		
N9989	disorder of kidney and ureter, unspecified		





R250	other postprocedural complications and disorders of genitourinary system
R253	cramp and spasm
R259	fasciculation
R29890	other symptoms and signs involving the nervous system
T81.710 A	complication of mesenteric artery following a procedure, not elsewhere classified, initial encounter
T81.711 A	complication of renal artery following a procedure, not elsewhere classified, initial encounter
T81.718 A	complication of other artery following a procedure, not elsewhere classified, initial encounter
T8172X A	complication of vein following a procedure, not elsewhere classified, initial encounter
T81.710 A	complication of mesenteric artery following a procedure, not elsewhere classified, initial encounter
T81.711 A	complication of renal artery following a procedure, not elsewhere classified, initial encounter
T81.718 A	complication of other artery following a procedure, not elsewhere classified, initial encounter
T81.72X A	complication of vein following a procedure, not elsewhere classified, initial encounter
34200	flacid hemiplegia affecting unspecified side
34201	flacid hemiplegia affecting dominant side
34200	flacid hemiplegia affecting unspecified side



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34201	flacid hemiplegia affecting dominant side
34202	flacid hemiplegia affecting nondominant side
34210	spastic hemiplegia affecting unspecified side
34211	spastic hemiplegia affecting dominant side
34212	spastic hemiplegia affecting nondominant side
34280	other spec hemiplegia affecting unspec side
34281	other spec hemiplegia affecting dominant side
34282	other spec hemiplegia affecting nondominant side
34290	unspec hemiplegia affecting unspec side
34291	unspecified hemiplegia affecting dominant side
34292	unspec hemiplegia affecting nondominant side

	36234	transient arterial occlusion of retina
	36812	transient visual loss
	42731	atrial fibrillation
	42732	atrial flutter
	42741	ventricular fibrillation
	42742	ventricular flutter
	42781	sinoatrial node dysfunction
	42789	other specified cardiac dysrhythmias
	42820	unspecified systolic heart failure
	42821	acute systolic heart failure
	42822	chronic systolic heart failure
	42823	acute on chronic systolic heart failure



unspecified diastolic heart failure	
acute diastolic heart failure	
chronic diastolic heart failure	
acute on chronic diastolic heart failure	
unspec combined systolic&diastolic heart failure	
acute combined systolic&diastolic heart failure	
chronic comb systolic&diastolic heart failure	
acute chronic comb systolic&diastolic heart fail	
occlusion&stenos basilar art w/o mention infarct	
occlusion&stenosis basilar artery w/infarct	
occlusion&stenos carotid art w/o mention infarct	
occlusion&stenosis carotid artery w/infarct	
occlusion&stenos vert art w/o mention infarct	
occlusion&stenosis vertebral artery w/infarct	
occl&stenos mx&bilat precerbrl art w/o infarct	
occl&stenos mx&bilat precerbrl art w/infarct	
occl&stenos oth spec precerbrl art w/o infarct	
occl&stenos oth spec precerbrl art w/infarct	
occl&stenos uns precerbrl art w/o infarct	

	43391	occlusion&stenos unspec precerbrl art w/infarct
	43400	cerebral thrombosis without mention infarct



cerebral thrombosis with cerebral infarction
cerebral embolism without mention infarct
cerebral embolism with cerebral infarction
unspec cerbrl art occlusion w/o mention infarct
unspecified cerebral artery occlusion w/infarct
unspec spch&lange deficit due cerebrvasc disease
aphasia due to cerebrovascular disease
dysphasia due to cerebrovascular disease
dysarthria
fluency disorder
oth spch&lange deficits due cerebrvasc disease
hemipl affect unspec side due cerebrvasc disease
hemipl affct dominant side due cerebrvasc dz
hemipl affct nondominant side due cerebrvasc dz
monopleg upper limb uns side due cerebrvasc dz
monopleg upper limb dom side due cerebrvasc dz
monopleg up limb nondom side due cerebrvasc dz
monopleg low limb unspec side due cerebrvasc dz
monopleg low limb dom side due cerebrvasc dz
monopleg low limb nondom side due cerebrvasc dz
oth paralyt synd affct uns side-cerebrvasc dz
oth paralyt synd affct dom side- cerebrvasc dz



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43852	oth paralyt synd affct nondom sidecerebrvasc dz
43853	other paralytic syndrome, bilateral
43881	apraxia due to cerebrovascular disease
43882	dysphagia due to cerebrovascular disease
43883	facial weakness late effect cerebrovascular dz

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	43884	ataxia as late effect of cerebrovascular disease		
		cerebrovascular disease		
	43885	vertigo as late effect		
		cerebrovascular disease		
	43889	other late effects of		
		cerebrovascular disease		
	51851	ac resp fail post		
		trauma/surgery		
	51852	ot pulm insuff post		
		trauma/surg		
	51853	ac/chr resp fail post		
		trauma/surg		
	78191	loss of height		
	78192	abnormal posture		
	78193	ocular torticollis		
	78194	facial weakness		
	78199	oth symptoms invlv		
		nerv&musculoskeletal		
		systems		
	99700	unspecified nervous system		
		complication nec		
	99701	central nervous system		
		complication nec		
	99702	iatrogenic		
		cerebrovascular		
		infarct/hemorrhage ne		
	99709	other nervous system		
		complications nec		
	99731	ventilator associated		
		pneumonia		



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			99732	postprocedural aspiration pneumonia
			99739	other respiratory complications
			99741	retained stone fol cholecystectomy
			99749	ot digestive system complications
			99771	vascular complications of mesenteric artery
			99772	vascular complications of renal artery
			99779	vascular complications of other vessels
			99851	infected postoperative seroma nec
			99859	other postoperative infection nec
Heart Failure	ICD-9- CM		ICD-10-CM	
40	428.0	Congestive heart failure, unspecified	150.1	Left ventricular failure
	428.1	Left heart failure	150.20	Unspecified systolic (congestive) heart failure
	428.20	Systolic heart failure	150.21	Acute systolic (congestive) heart failure
	428.21	Systolic heart failure	150.22	Chronic systolic (congestive) heart failure
	428.22	Chronic systolic heart failure	150.23	Acute on chronic systolic (congestive) heart failure
	428.23	Acute on chronic systolic heart failure	150.30	Unspecified diastolic (congestive) heart failure

428.30	Diastolic heart failure, unspecified	150.31	Acute diastolic (congestive) heart failure
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Epidemiology No.(PE	Studies only): EP	<u>UXXXX.XX</u>		
	428.31	Acute diastolic heart failure	150.32	Chronic diastolic (congestive) heart failure
	428.32	Chronic diastolic heart failure	150.33	Acute on chronic diastolic (congestive) heart failure
	428.33	Acute on chronic diastolic heart failure	150.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
	428.40	Combined systolic and diastolic heart failure, unspecified	150.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
	428.41	Acute combined systolic and diastolic heart failure	150.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
	428.42	Chronic combined systolic and diastolic heart failure	150.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
	428.43	Acute on chronic combined systolic and diastolic heart failure	150.9	Heart failure, unspecified
	428.9	Heart failure, unspecified		
Peripheral Arterial or	ICD-9- CM		ICD-10-CM	
Vascular Disease _{32,33}	250.7x	Diabetes with peripheral circulatory disorders	Main Codes	



249.7x	Secondary diabetes with peripheral circulatory disorders	E08	Diabetes mellitus due to underlying condition
440.21	Atherosclerosis of native arteries of the extremities with intermittent claudication	E09	Drug or chemical induced diabetes mellitus
442.3	Aneurysm of artery of lower extremity	E10	Type 1 diabetes mellitus
443.81	Peripheral angiopathy in diseases classified elsewhere (including claudication)	E11	Type 2 diabetes mellitus
443.9	Peripheral vascular disease, unspecified	E13	Other specified diabetes mellitus
892.1	Open wound of foot except toe(s) alone, complicated	Relevant Subco	des
040.0	Gas gangrene	E**.51	Diabetic peripheral angiopathy, no gangrene
444.22	Arterial embolism and thrombosis of lower extremity	E**.52	Diabetic peripheral angiopathy, with gangrene
707.1x	Ulcer of lower limbs, except decubitus ulcer	E**.59	Diabetes, other circulatory complications
785.4	Gangrene	E**.621	Diabetic foot ulcer
	1	Regular Codes:	1



Epidemiology No	(PE Studies only):	EP0xxxx.xx

<u>pidemiology No.(</u>	PE Studies only):	EPUXXXX.XX		
			172.4	Aneurysm of artery of lower extremity
			170 211	Atherosclerosis of native arteries of extremities with intermittent claudication
			I70.21x	
			173.89	Other specified peripheral vascular diseases
			173.9	Peripheral vascular disease, unspecified
			S91.3x	Open wound of foot
			A48.0	Gas gangrene
			174.3	Embolism and thrombosis of arteries of the lower extremities
			L97.x	Embolism and thrombosis of arteries of the lower extremities
				Non-pressure chronic ulcer of lower limb, not elsewhere
			L97.x	classified
			196	Gangrene, not elsewhere classified
Stroke _{35,32}	ICD-9- CM		ICD-10-CM	1 * * * * * * * * * * * * * * * * * * *
	430	Subarachnoid hemorrhage	16000	Nontraumatic subarachnoid hemorrhage from unspecified carotid siphon and bifurcation
		Intracerebral		Nontraumatic
	431	hemorrhage	16001	subarachnoid



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			hemorrhage from right carotid siphon and bifurcation
432.0	Nontraum extradural hem	16002	Nontraumatic subarachnoid hemorrhage from left carotid siphon and bifurcation
432.1	Subdural hemorrhage	16010	Nontraumatic subarachnoid hemorrhage from unspecified middle cerebral artery
432.9	Intracranial hemorr nos	16011	Nontraumatic subarachnoid hemorrhage from right middle cerebral artery
433.01	Basi art occl w/ infarct	16012	Nontraumatic subarachnoid hemorrhage from left middle cerebral artery
433.11	Carotd occl w/	16020	Nontraumatic subarachnoid hemorrhage from unspecified anterior communicating artery
433.21	Vertb art occl w/ infrct	16021	Nontraumatic subarachnoid hemorrhage from right anterior communicating artery
433.31	Mult precer occl w/ infrct	16022	Nontraumatic subarachnoid hemorrhage from left anterior communicating artery
433.81	Precer occl nec w/ infrct	16030	Nontraumatic subarachnoid hemorrhage from unspecified



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				posterior communicating artery	
	433.91	Precer occl nos w/ infrct	16031	Nontraumatic subarachnoid hemorrhage from right posterior communicating artery	
	434.01	Cere thrombosis w/ infrct	16032	Nontraumatic subarachnoid hemorrhage from left posterior communicating artery	
	434.11	Cere embolism w/ infrct	1604	Nontraumatic subarachnoid hemorrhage from basilar artery	

434.91	Cereb occl nos w/ infrct	16050	Nontraumatic subarachnoid hemorrhage from unspecified vertebral artery
433.91	Precer occl nos w/ infrct	16051	Nontraumatic subarachnoid hemorrhage from right vertebral artery
434.01	Cere thrombosis w/ infrct	16052	Nontraumatic subarachnoid hemorrhage from left vertebral artery
434.11	Cere embolism w/	1606	Nontraumatic subarachnoid hemorrhage from other intracranial arteries
434.91	Cereb occl nos w/	1607	Nontraumatic subarachnoid hemorrhage from unspecified intracranial artery
436.x	Acute, but ill- defined,	167.89	Other cerebrovascular disease



VEAP ID NO: XXXXX Epidemiology No.(PE Studies only): EP0xxxx.xx

	cerebrovascular disease		
V12.54	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits	1608	Other nontraumatic subarachnoid hemorrhage
	1	1609	Nontraumatic subarachnoid hemorrhage, unspecified
		1610	Nontraumatic intracerebral hemorrhage in hemisphere, subcortical
		1611	Nontraumatic intracerebral hemorrhage in hemisphere, cortical
		1612	Nontraumatic intracerebral hemorrhage in hemisphere, unspecified
		1613	Nontraumatic intracerebral hemorrhage in brain stem
		1614	Nontraumatic intracerebral hemorrhage in cerebellum
		1615	Nontraumatic intracerebral hemorrhage, intraventricular
		1616	Nontraumatic intracerebral hemorrhage, multiple localized
		1618	Other nontraumatic intracerebral hemorrhage



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1619	Nontraumatic intracerebral hemorrhage, unspecified
16200	Nontraumatic subdural hemorrhage, unspecified
16201	Nontraumatic acute subdural hemorrhage

16202	Nontraumatic subacute subdural
	hemorrhage
16203	Nontraumatic chronic subdural hemorrhage
1621	Nontraumatic extradural hemorrhage
1629	Nontraumatic intracranial hemorrhage, unspecified
16300	Cerebral infarction due to thrombosis of unspecified precerebral artery
l63011	Cerebral infarction due to thrombosis of right vertebral artery
I63012	Cerebral infarction due to thrombosis of left vertebral artery
163019	Cerebral infarction due to thrombosis of unspecified vertebral artery
16302	Cerebral infarction due to thrombosis of basilar artery
163031	Cerebral infarction due to thrombosis of right carotid artery
163032	Cerebral infarction due to thrombosis of left carotid artery
163039	Cerebral infarction due to thrombosis of unspecified carotid artery



16309	Cerebral infarction due to thrombosis of other precerebral artery
16310	Cerebral infarction due to embolism of unspecified precerebral artery
163111	Cerebral infarction due to embolism of right vertebral artery
163112	Cerebral infarction due to embolism of left vertebral artery
163119	Cerebral infarction due to embolism of unspecified vertebral artery
16312	Cerebral infarction due to embolism of basilar artery
163131	Cerebral infarction due to embolism of right carotid artery
163132	Cerebral infarction due to embolism of left carotid artery

163:	139	Cerebral infarction due to embolism of unspecified carotid artery
163	19	Cerebral infarction due to embolism of other precerebral artery
1633	20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
1633	211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral arteries
163:	212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral arteries
163	219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral arteries



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		16322	Cerebral infarction due to unspecified occlusion or stenosis of basilar arteries
		l63231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
		163232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
		163239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries
		16329	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
		16330	Cerebral infarction due to thrombosis of unspecified cerebral artery
		163311	Cerebral infarction due to thrombosis of right middle cerebral artery
	163312	Cerebral infarction due to thrombosis of left middle cerebral artery	
		163319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery
	163321	Cerebral infarction due to thrombosis of right anterior cerebral artery	
		163322	Cerebral infarction due to thrombosis of left anterior cerebral artery
		163329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery
		163331	Cerebral infarction due to thrombosis of right posterior cerebral artery



163332	Cerebral infarction due to thrombosis of left posterior cerebral artery
163339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery
163341	Cerebral infarction due to thrombosis of right cerebellar artery
163342	Cerebral infarction due to thrombosis of left cerebellar artery
163349	Cerebral infarction due to thrombosis of unspecified cerebellar artery
16339	Cerebral infarction due to thrombosis of other cerebral artery
16340	Cerebral infarction due to embolism of unspecified cerebral artery
163411	Cerebral infarction due to embolism of right middle cerebral artery
163412	Cerebral infarction due to embolism of left middle cerebral artery
163419	Cerebral infarction due to embolism of unspecified middle cerebral artery
163421	Cerebral infarction due to embolism of right anterior cerebral artery
163422	Cerebral infarction due to embolism of left anterior cerebral artery
163429	Cerebral infarction due to embolism of unspecified anterior cerebral artery
163431	Cerebral infarction due to embolism of right posterior cerebral artery
	I63339



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	163	Cerebral infarction due to embolism of left posterior cerebral artery
	163	Cerebral infarction due to embolism of unspecified posterior cerebral artery
	163	Cerebral infarction due to embolism of right cerebellar artery
	163	Cerebral infarction due to embolism of left cerebellar artery
	163	Cerebral infarction due to embolism of unspecified cerebellar artery
	163	Cerebral infarction due to embolism of other cerebral artery
	163	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery
	163	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
	163	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
		Cerebral infarction due to unspecified occlusion or stenosis of unspecified middle cerebral artery
		Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
	163	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
	163	Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery



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<u>Jideiiiioiogy</u>	No.(PE Studies only): EPUXXXX.XX		
		I63531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
		163532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
		163539	Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery
		163541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery
		163542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery
		163549	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery
		16359	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
		1636	Cerebral infarction due to cerebral venous thrombosis, nonpyogenic
		1638	Other cerebral infarction
		1639	Cerebral infarction, unspecified

Depression/A	ICD-9	ICD-10
nxiety ³⁹	Inclusion criteria: Depression, anxiety, stress reaction, and suicidal ideation attempt	





dies only): EP0xxx	X.XX		
296.20	Major depressive disorder, single episode – unspecified	F32.9	Major depressive disorder, single episode, unspecified
296.22	Major depressive disorder, single episode – moderate	F32.1	Major depressive disorder, single episode, moderate
296.23	Major depressive disorder, single episode – severe, without mention of psychotic behavior	F32.2	Major depressive disorder, single episode, severe without psychotic features
296.30	Major depressive disorder, recurrent episode – unspecified	F33.9	Major depressive disorder, recurrent, unspecified
296.32	Major depressive disorder, recurrent episode – moderate	F33.1	Major depressive disorder, recurrent, moderate
296.33	Major depressive disorder, recurrent episode – severe, without mention of psychotic behavior	F33.2	Major depressive disorder, recurrent severe without psychotic features
300.00	Anxiety state, unspecified	F41.9	Anxiety disorder, unspecified
300.01	Panic disorder without agoraphobia	F41.0	Panic disorder [episodic paroxysmal anxiety] without agoraphobia
300.02	Generalized anxiety disorder	F41.1	Generalized anxiety disorder



<u>pidemiology No.(PE Stud</u>	ies only): EPUXXX	X.XX		
	300.09	Other anxiety, dissociative, and somatoform disorders	F41.8	Other specified anxiety disorders
	300.21	Agoraphobia with panic disorder	F40.01	Agoraphobia with panic disorder
	300.22	Agoraphobia without mention of panic attacks	F40.02	Agoraphobia without panic disorder
	300.23	Social phobia	F40.10	Social phobia, unspecified
	300.29	Other isolated or specific phobias	F40.218	Other animal type phobia
			F40.240	Claustrophobia
			F40.241	Acrophobia
			F40.8	Other phobic anxiety disorders
	300.3	Obsessive- compulsive disorders	F42	Obsessive- compulsive disorder
	300.4	Dysthymic disorder	F34.1	Dysthymic disorder
	300.6	Depersonalization disorder	F48.1	Depersonalization- derealization syndrome
	300.7	Hypochondriasis	F45.21	Hypochondriasis

F45.22	Body dysmorphic disorder	





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300.81	Somatization disorder	F45.0	Somatization disorder
300.82	Undifferentiated somatoform disorder	F45.1	Undifferentiated somatoform disorder
		F45.9	Somatoform disorder, unspecified
300.89	Other somatoform disorders	F45.8	Other somatoform disorders
		F48.8	Other specified nonpsychotic mental disorders
300.9	Unspecified nonpsychotic mental disorder	F48.9	Nonpsychotic mental disorder, unspecified
		F99	Mental disorder, not otherwise specified
308.0	Predominant disturbance of emotions	F43.0	Acute stress reaction
308.1	Predominant disturbance of consciousness	F43.0	Acute stress reaction
308.2	Predominant psychomotor disturbance	F43.0	Acute stress reaction
308.3	Other acute reactions to stress	F43.0	Acute stress reaction
308.4	Mixed disorders as reaction to stress	F43.0	Acute stress reaction
308.9	Unspecified acute reaction to stress	F43.0	Acute stress reaction
		R45.7	State of emotional shock and stress, unspecified
309.0	Adjustment disorder with depressed mood	F43.21	Adjustment disorder with depressed mood



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309.1	Prolonged depressive	F43.21	Adjustment disorder with
	reaction		depressed mood
309.24	Adjustment disorder	F43.22	Adjustment disorder with
	with anxiety		anxiety
309.28	Adjustment disorder	F43.23	Adjustment disorder with
	with mixed anxiety and depressed mood		mixed
	and depressed mood		anxiety and depressed mood
309.29	Other adjustment	F43.29	Adjustment disorder with
	reactions with		other
predominant disturbance of other		symptoms	
	emotions	F94.8	Other childhood
			disorders of social functioning
			Turictioning
309.3	Adjustment disorder	F43.24	Adjustment disorder with
	with disturbance of conduct		disturbance of conduct
309.4	Adjustment disorder with mixed	F43.25	Adjustment disorder with mixed
	disturbance of		disturbance of emotions

309.4	Adjustment disorder with mixed disturbance of emotions and conduct	F43.25	Adjustment disorder with mixed disturbance of emotions and conduct
309.81	Posttraumatic stress disorder	F43.10	Post-traumatic stress disorder, unspecified
		F43.12	Post-traumatic stress disorder, chronic
309.82	Adjustment reaction with physical symptoms	F43.8	Other reactions to severe stress
309.83	Adjustment reaction with withdrawal	F43.8	Other reactions to severe stress



	E Studies only): EP0xxxx.xx	F42.0	Other resetions to severe
309.89	Other specified adjustment reactions	F43.8	Other reactions to severe stress
309.9	Unspecified adjustment reaction	F43.20	Adjustment disorder, unspecified
311	Depressive disorder, not elsewhere classified	F32.9	Major depressive disorder, single episode, unspecified
V6284	Suicidal Ideation	R45851	Suicidal Ideations
E950.0	Suicide and self- inflicted poisoning by analgesics, antipyretics, and antirheumatics		
E950.1	Suicide and self- inflicted poisoning by barbiturates		
E950.2	Suicide and self- inflicted poisoning by other sedatives and hypnotics		
E950.3	Suicide and self- inflicted poisoning by tranquilizers and other psychotropic agents		
E950.4	Suicide and self-inflicted poisoning by other specified drugs and medicinal substances		
E950.5	Suicide and self- inflicted poisoning by unspecified drug or medicinal substances		
E950.6	Suicide and self-inflicted poisoning by agricultural and horticultural chemical and pharmaceutical preparations other than plant foods and fertilizers		





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	E950.7	Suicide and self-inflicted poisoning by corrosive and caustic substances
	E950.8	Suicide and self- inflicted poisoning by arsenic and its compounds
	E950.9	Suicide and self- inflicted poisoning by other and unspecified solid and liquid substances

E951.0	Suicide and self-
2331.0	inflicted poisoning by
	gas disturbed by
	pipeline
E951.1	Suicide and self-
	inflicted poisoning by
	liquefied petroleum
	gas distributed in
	mobile containers
E951.8	Suicide and self-
	inflicted poisoning by
	other utility gas
E952.0	Suicide and self-
	inflicted poisoning by
	motor vehicle
	exhaust gas
E952.1	Suicide and self-
	inflicted poisoning by
	other carbon
	monoxide
E952.8	Suicide and self-inflicted
	poisoning by other specified
	gases and vapors
E952.9	Suicide and self-
	inflicted poisoning by
	unspecified gases
	and vapors
E953.0	Suicide and self-
	inflicted injury by
	hanging



E953.1	Studies only): EP0xxxx.xx Suicide and self- inflicted injury by suffocation by plastic bag		
E953.8	Suicide and self- inflicted injury by other specified means		
E953.9	Suicide and self- inflicted injury by hanging, strangulation, and suffocation — unspecified means		
E954	Suicide and self- inflicted injury by submersion [drowning]	X71.8X XA	Other intentional self- harm by drowning and submersion, initial encounter
		X71.9X XA	Intentional self-harm by drowning and submersion, unspecified, initial encounter
E955.0	Suicide and self- inflicted injury by handgun		
E955.1	Suicide and self- inflicted injury by shotgun	X73.0X XA	Intentional self-harm by shotgun discharge, initial encounter
E955.2	Suicide and self- inflicted injury by hunting rifle	X72.XX XA	Intentional self-harm by handgun discharge, initial encounter
E955.4	Suicide and self- inflicted injury by other and unspecified firearms	X73.9X XA	Intentional self-harm by unspecified larger firearm discharge, initial encounter
E955.5	Suicide and self- inflicted injury by explosives	X75.XX XA	Intentional self-harm by explosive material, initial encounter



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E955.6	Suicide and self- inflicted injury by air gun	X74.01 XA	Intentional self-harm by airgun, initial encounter
E955.9	Suicide and self- inflicted injury by unspecified firearms, air guns, and explosives	X74.9X XA	Intentional self-harm by unspecified firearm discharge, initial encounter
E956	Suicide and self- inflicted injury by cutting and piercing instruments	X78.9X XA	Intentional self-harm by unspecified sharp object, initial encounter
E957.0	Suicide and self-inflicted injuries by jumping from residential premises	X80.XX XA	Intentional self-harm by jumping from a high place, initial encounter
		Y92.00 9	Unspecified place in unspecified noninstitutional (private) residence as the place of occurrence of the external cause
E957.1	Suicide and self- inflicted injuries by jumping from other	X80.XX XA	Intentional self-harm by jumping from a high place, initial encount
	man-made structures	Y92.89	Other specified places as the place of occurrence of the external cause
E957.2	Suicide and self- inflicted injuries by jumping from natural sites	X80.XX XA	Intentional self-harm by jumping from a high place, initial encounter
		Y92.82 8	Other wilderness area as the place of occurrence of the external cause



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		Y92.83 8	Other recreation area as the place of occurrence of the external cause
E957.9	Suicide and self- inflicted injuries by jumping from unspecified high place	X80.XX XA	Intentional self-harm by jumping from a high place, initial encounter
		Y92.9	Unspecified place or not applicable
E958.0	Suicide and self- inflicted injury by jumping or lying before a moving object	X81.8X XA	Intentional self-harm by jumping or lying in front of other moving object, initial encounter
E958.1	Suicide and self- inflicted injury by burns, fire	X76.XX XA	Intentional self-harm by smoke, fire and flames, initial encounter
E958.2	Suicide and self- inflicted injury by scald	X77.2X XA	Intentional self-harm by other hot fluids, initial encounter
E958.3	Suicide and self- inflicted injury by extremes of cold	X83.2X XA	Intentional self-harm by exposure to extremes of cold, initial encounter
E958.4	Suicide and self- inflicted injury by electrocution	X83.1X XA	Intentional self-harm by electrocution, initial encounter

E958.5	Suicide and self- inflicted injury by crashing of motor vehicle	X82.8X XA	Other intentional self- harm by crashing of motor vehicle, initial encounter
E958.7	Suicide and self- inflicted injury by caustic substances, except poisoning	X83.8X XA	Intentional self-harm by other specified means, initial encounter



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E958.8	Suicide and self- inflicted injury by other and specified means	X83.8X XA	Intentional self-harm by other specified means, initial encounter
Exclusion Criteria	: Psychoses or bipolar disorders		
296.00	Bipolar I disorder, single manic episode – unspecified	F30.10	Manic episode without psychotic symptoms, unspecified
296.03	Bipolar I disorder, single manic episode – severe, without mention of psychotic behavior	F30.13	Manic episode, severe, without psychotic symptoms
296.04	Bipolar I disorder, single manic episode – severe, specified as with psychotic behavior	F30.2	Manic episode, severe with psychotic symptoms
296.10	Manic disorder, recurrent episode – unspecified	F30.10	Manic episode without psychotic symptoms, unspecified
296.13	Manic disorder, recurrent episode – severe, without mention of psychotic behavior	F30.13	Manic episode, severe, without psychotic symptoms
296.14	Manic disorder, recurrent episode – severe, specified as with psychotic behavior	F30.2	Manic episode, severe with psychotic symptoms
296.24	Major depressive disorder, single episode – severe, specified as with psychotic behavior	F32.3	Major depressive disorder, single episode, severe with psychotic features
296.34	Major depressive disorder, recurrent episode – severe, specified as with psychotic behavior	F33.3	Major depressive disorder, recurrent, severe with psychotic symptoms
296.40	Bipolar I disorder; most recent episode	F31.10	Bipolar disorder, current episode manic without



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nology No.(PE	(or current) manic – unspecified		psychotic features, unspecified
296.41	296.41 Bipolar I disorder; most recent episode (or current) manic – mild 296.42 Bipolar I disorder; most recent episode (or current) manic – moderate 296.43 Bipolar I disorder; most recent episode (or current) manic – severe, without mention of psychotic behavior 296.44 Bipolar I disorder; most recent episode (or current) manic – severe, specified as with psychotic disorder		Bipolar disorder, current episode manic without psychotic features, mild
296.42			Bipolar disorder, current episode manic without psychotic features, moderate
296.43			Bipolar disorder, current episode manic without psychotic features, severe
296.44			Bipolar disorder, current episode manic severe with psychotic features
296.50	Bipolar I disorder; most recent episode (or current) depressed – unspecified	F31.30	Bipolar disorder, current episode depressed, mild or moderate severity, unspecified
296.52	Bipolar I disorder; most recent episode (or current) depressed – moderate	F31.32	Bipolar disorder, current episode depressed, moderate
296.53	Bipolar I disorder; most recent episode (or current) depressed – severe, without mention of psychotic behavior	F31.4	Bipolar disorder, current episode depressed, severe, without psychotic features
296.54	Bipolar I disorder; most recent episode (or current) depressed – severe,	F31.5	Bipolar disorder, current episode depressed, severe, with psychotic features



specified as with psychotic disorder

Hology No.(PE Su	udies only): EP0xxxx.xx		
296.60	Bipolar I disorder; most recent episode (or current) mixed – unspecified	F31.60	Bipolar disorder, current episode mixed, unspecified
296.62	Bipolar I disorder; most recent episode (or current) mixed – moderate	F31.62	Bipolar disorder, current episode mixed, moderate
296.63	Bipolar I disorder; most recent episode (or current) mixed – severe, without mention of psychotic behavior	F31.63	Bipolar disorder, current episode mixed, severe, without psychotic features
296.64	Bipolar I disorder; most recent episode (or current) mixed – severe, specified as with psychotic disorder	F31.64	Bipolar disorder, current episode mixed, severe, with psychotic features
296.7	Bipolar I disorder; most recent episode (or current) unspecified	F31.9	Bipolar disorder, unspecified
296.80	Bipolar disorder, unspecified	F31.9	Bipolar disorder, unspecified
296.90	Unspecified episodic mood disorder	F39	Unspecified mood [affective] disorder
296.99	Other specified episodic mood disorder	F34.8	Other persistent mood [affective] disorders
295.00	Simple type schizophrenia – unspecified	F20.89	Other schizophrenia
295.01	Simple type schizophrenia – subchronic	F20.89	Other schizophrenia
295.02	Simple type schizophrenia – chronic	F20.89	Other schizophrenia
295.03	Simple type schizophrenia –	F20.89	Other schizophrenia



	subchronic with			
	acute			
295.04	exacerbation Simple type schizophrenia – chronic with acute	F20.89	Other schizophrenia	
295.05	exacerbation Simple type schizophrenia – in remission	F20.89	Other schizophrenia	
295.10	Disorganized type schizophrenia – unspecified	F20.1	Disorganized schizophrenia	
295.11	Disorganized type schizophrenia – subchronic	F20.1	Disorganized schizophrenia	
295.12	Disorganized type schizophrenia – chronic	F20.1	Disorganized schizophrenia	
295.13	Disorganized type F20.1 schizophrenia - subchronic with acute exacerbation	F20.1	Disorganized schizophrenia	
295.14	Disorganized type schizophrenia – chronic with acute exacerbation	F20.1	Disorganized schizophrenia	
295.15	Disorganized type schizophrenia – in remission	F20.1	Disorganized schizophrenia	
295.20	Catatonic type schizophrenia – unspecified	F20.2	Catatonic schizophrenia	
295.21	Catatonic type schizophrenia – subchronic	F20.2	Catatonic schizophrenia	
295.22	Catatonic type schizophrenia – chronic	F20.2	Catatonic schizophrenia	
295.23	Catatonic type	F20.2		



Catatonic schizophrenia

schizophrenia –

exacerbation

subchronic with acute

udies only): EP0xxxx.xx		
schizophrenia – chronic with acute exacerbation		Catatonic schizophrenia
Paranoid type schizophrenia – unspecified	F20.0	Paranoid schizophrenia
Paranoid type schizophrenia – subchronic	F20.0	Paranoid schizophrenia
Paranoid type schizophrenia – chronic	F20.0	Paranoid schizophrenia
Paranoid type schizophrenia – subchronic with acute exacerbation		Paranoid schizophrenia
Paranoid type schizophrenia – chronic with acute exacerbation		Paranoid schizophrenia
Paranoid type schizophrenia – in remission	F20.0	Paranoid schizophrenia
Schizophreniform disorder – unspecified	F20.81	Schizophreniform disorder
Schizophreniform disorder – subchronic	F20.81	Schizophreniform disorder
Schizophreniform disorder – chronic	F20.81	Schizophreniform disorder
295.43 Schizophreniform disorder – subchronic with acute		Schizophreniform disorder
5.44 Schizophreniform disorder – chronic with acute exacerbation		Schizophreniform disorder
Schizophreniform disorder – in remission	F20.81	Schizophreniform disorder
Latent schizophrenia – unspecified	F20.89	Other schizophrenia
	Catatonic type schizophrenia — chronic with acute exacerbation Paranoid type schizophrenia — unspecified Paranoid type schizophrenia — subchronic Paranoid type schizophrenia — chronic Paranoid type schizophrenia — subchronic with acute exacerbation Paranoid type schizophrenia — chronic with acute exacerbation Paranoid type schizophrenia — chronic with acute exacerbation Paranoid type schizophrenia — chronic with acute exacerbation Schizophreniform disorder — unspecified Schizophreniform disorder — subchronic Schizophreniform disorder — subchronic Schizophreniform disorder — subchronic Schizophreniform disorder — subchronic with acute exacerbation Schizophreniform disorder — chronic with acute exacerbation Schizophreniform disorder — chronic with acute exacerbation Schizophreniform disorder — in remission Latent schizophrenia —	Catatonic type schizophrenia — chronic with acute exacerbation Paranoid type schizophrenia — unspecified Paranoid type schizophrenia — subchronic Paranoid type schizophrenia — subchronic Paranoid type schizophrenia — subchronic Paranoid type schizophrenia — subchronic with acute exacerbation Paranoid type schizophrenia — chronic with acute exacerbation Paranoid type schizophrenia — chronic with acute exacerbation Paranoid type schizophrenia — chronic with acute exacerbation Paranoid type schizophreniform disorder — unspecified Schizophreniform disorder — subchronic Schizophreniform disorder — subchronic Schizophreniform disorder — subchronic Schizophreniform disorder — subchronic with acute exacerbation Schizophreniform disorder — chronic Schizophreniform disorder — chronic Schizophreniform fisorder — chronic with acute exacerbation Schizophreniform fisorder — in remission Latent schizophrenia — F20.89



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	295.53	Latent schizophrenia – subchronic with acute exacerbation	F20.89	Other schizophrenia				
	295.54	Latent schizophrenia – chronic with acute exacerbation	F20.89	Other schizophrenia				

295.60	Residual type schizophrenia – unspecified	F20.5	Residual schizophrenia	
295.62	Residual type schizophrenia – chronic	F20.5	Residual schizophrenia	
295.63	Residual type schizophrenia – subchronic with acute exacerbation	F20.5	Residual schizophrenia	
295.64	Residual type schizophrenia – chronic with acute exacerbation	F20.5	Residual schizophrenia	
295.65	Residual type schizophrenia – in remission	F20.5	Residual schizophrenia	
295.70	Schizoaffective disorder – unspecified	F25.9	Schizoaffective disorder, unspecified	
295.71	Schizoaffective disorder – subchronic	F25.9	Schizoaffective disorder, unspecified	
295.72	Schizoaffective disorder – chronic	F25.9	Schizoaffective disorder, unspecified	
295.73	Schizoaffective disorder – subchronic with acute exacerbation	F25.9	Schizoaffective disorder, unspecified	
295.74	Schizoaffective disorder – chronic with acute exacerbation	F25.9	Schizoaffective disorder, unspecified	



295.75	Schizoaffective disorder – in remission	F25.9	Schizoaffective disorder, unspecified
295.80	Other specified types of schizophrenia – unspecified	F20.89	Other schizophrenia
295.82	Other specified types of schizophrenia – chronic	F20.89	Other schizophrenia
295.83	Other specified types of schizophrenia – subchronic with acute exacerbation	F20.89	Other schizophrenia
295.84	Other specified types of schizophrenia – chronic with acute exacerbation	F20.89 Other schizophrenia	
295.85	Other specified types of schizophrenia – in remission	F20.89	Other schizophrenia
295.90	Unspecified schizophrenia – unspecified	F20.9	Schizophrenia, unspecified
295.91	Unspecified schizophrenia – subchronic	F20.9	Schizophrenia, unspecified
295.92	Unspecified schizophrenia – chronic	F20.9	Schizophrenia, unspecified
295.93	Unspecified schizophrenia – subchronic with acute exacerbation	F20.9	Schizophrenia, unspecified
295.95	Unspecified schizophrenia – in remission	F20.9	Schizophrenia, unspecified
297.0 Paranoid state, simple		F22	Delusional disorders
297.1	Delusional disorder	F22	Delusional disorders
297.2	Paraphrenia	F22	Delusional disorders



297.3	Shared psychotic disorder	F24	Shared psychotic disorder
297.8	Other specified paranoid states	F22	Delusional disorders
297.9	Unspecified paranoid state	F23	Brief psychotic disorder
298.0	Depressive type psychosis	F32.3	Major depressive disorder, single episode, severe with psychotic features
		F33.3	Major depressive disorder, recurrent, severe with psychotic symptoms
298.1	Excitative type psychosis	F28	Other psychotic disorder not due to a substance or known physiological condition
298.2	Reactive confusion	F44.89	Other dissociative and conversion disorders
298.3	Acute paranoid reaction	F23	Brief psychotic disorder
298.4	Psychogenic paranoid psychosis	F23	Brief psychotic disorder
298.8	Other and unspecified reactive psychosis	F23	Brief psychotic disorder
298.9	Unspecified psychosis	F29	Unspecified psychosis not due to a substance or known physiological condition

^{*} The character 'x' to the right of a decimal point indicates digits must be added to the preceding digits to create a billable code. The use of 'x' in ICD-10 codes indicates that all codes falling under the preceding head digits are to be included for the analysis.





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Appendix 5. Table shells for Aim 1

Table 2. Demographic characteristics of the diabetes population using Hospital Inpatient or Emergency

Department settings, years 2008, 2011, 2014, 2016

Variable			Year		Change 2008-2016		
	2008	2011	2014	2016	Absolute Change	% Change	
Age, years, n (%)							
18-29							
30-44							
45-64							
64-74							
75+							
Sex, n (%)							
Female							
Male							
Race, n (%)							
White							
Black							
Hispanic							
Asian or Pacific							
Islander							
Native American							
Region, n (%)							
Northeast							
Midwest							
South							
West							
Rural/Urban, n (%)							
Rural							
Urban							
Insurance, n (%)							
Medicare							
Medicaid							
Private Insurance							
Self-pay							
No Charge							
Other							
Comorbidities, n (%)							
Macrovascular							
Microvascular							
D							

Denominators for rates are from the Behavioral Risk Factor Surveillance Survey. Rates have been age-standardized to the U.S. population in the year 2010



Depression/Anxiety



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Table 3. Number of Hospital Inpatient Stays among diabetes mellitus population, years 2008, 2011, 2014, 2016

Variable Variable		<u> </u>	Year			e 2008-2016
	2008	2011	2014	2016	Absolute	% Change
					Change	
Age, years, n (%)						
18-29						
30-44						
45-64						
64-74						
75+						
Sex, n (%)						
Female						
Male						
Race, n (%)						
White						
Black						
Hispanic						
Asian or Pacific						
Islander						
Native American						
Region, n (%)						
Northeast						
Midwest						
South						
West						
Rural/Urban, n (%)						
Rural						
Urban						
Insurance, n (%)						
Medicare						
Medicaid						
Private Insurance						
Self-pay						
No Charge						
Other						
Comorbidities, n (%)						
Macrovascular						
Microvascular						
Depression/Anxiety						





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Table 4. Number of ED Visits among diabetes mellitus population, years 2008, 2011, 2014, 2016

Variable			Change 2008-2016			
	2008	2011	2014	2016	Absolute Change	% Change
Age, years, n (%)						
18-29						
30-44						
45-64						
64-74						
75+						
Sex, n (%)						
Female						
Male						
Race, n (%)						
White						
Black						
Hispanic						
Asian or Pacific						
Islander						
Native American						
Region, n (%)						
Northeast						
Midwest						
South						
West						
Rural/Urban, n (%)						
Rural						
Urban						
Insurance, n (%)						
Medicare						
Medicaid						
Private Insurance						
Self-pay						
No Charge						
Other						
Comorbidities, n (%)						
Macrovascular						
Microvascular						
Depression/Anxiety						





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Table 5. Rate of Hospital Inpatient Stays per 1000 people with diabetes mellitus, years 2008, 2011, 2014, 2016

Variable			Year		Change	e 2008-2016
	2008	2011	2014	2016	Absolute Change	% Change
Age, years						
18-29						
30-44						
45-64						
64-74						
75+						
Sex						
Female						
Male						
Race						
White						
Black						
Hispanic						
Asian or Pacific						
Islander						
Native American						
Region						
Northeast						
Midwest						
South						
West						
Rural/Urban						
Rural						
Urban						
Insurance						
Medicare						
Medicaid						
Private Insurance						
Self-pay						
No Charge						
Other						
Comorbidities						
Macrovascular						
Microvascular						
Depression/Anxiety						





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Table 6. Rate of ED Visits per 1000 people with diabetes mellitus, years 2008, 2011, 2014, 2016

Variable			Year			e 2008-2016
	2008	2011	2014	2016	Absolute Change	% Change
Age, years						
18-29						
30-44						
45-64						
64-74						
75+						
Sex						
Female						
Male						
Race						
White						
Black						
Hispanic						
Asian or Pacific						
Islander						
Native American						
Region						
Northeast						
Midwest						
South						
West						
Rural/Urban						
Rural						
Urban						
Insurance						
Medicare						
Medicaid						
Private Insurance						
Self-pay						
No Charge						
Other						
Comorbidities						
Macrovascular						
Microvascular						
Depression/Anxiety						





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Table 7. Age- and Sex- Adjusted Rates of Emergency Department Visits and Hospital Inpatient Use (per 1000 persons) among US Adult Population with and without Diabetes from 2008-2017

		Rates	(95% C.I.)	
	2008*	2011	2014	2016/2017
Diabetes				
ED Visits				
Ratio	X			
Inpatient Stays				
Ratio	X			
Non-Diabetes				
ED Visits				
Ratio	X			
Inpatient Stays				
Ratio	X			
		Rate Rati	lo (95% C.I.)	
Diabetes/Non-Diabetes				
ED Visits				
T				

Inpatient Stays

All rates are age- and sex-standardized to the 2010 US Adult Population without Diabetes

- a. Ratios reflect rate ratios and 95% C.I. using 2008 rates as reference
- Reflects rate ratios using non-Diabetes health service use rates as reference





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Appendix 6. Table Shells for Aim 2 Results

Table 8. Age-Standardized Rates of Potentially Preventable Hospitalizations among U.S. Adults with Diagnosed Diabetes

Variable			Year		Change 2008-2016		
	2008	2011	2014	2016	Absolute	% Change	
					Change		

Short Term Diabetes

Complications

No. of Cases

No./1000 persons with

Diabetes

Long-Term Diabetes

Complications

No./1000 persons with

Diabetes

Uncontrolled Diabetes without

Complications

No./1000 persons with

Diabetes

Diabetes-related Lower-

Extremity Amputations

No./1000 persons with

Diabetes

Lower Extremity

Ulcers/inflammation/infections

No./1000 persons with

Diabetes

Hypoglycemia

No./1000 persons with

Diabetes

Lower Extremity

Ulcers/inflammation/infections

No./1000 persons with

Diabetes

Microvascular

Depression/Anxiety





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Table 9. % Change in rates of Potentially Preventable Hospitalizations by Sociodemographic Factors from 2008-2016

	Short-Term	Long-Term	Uncontrolled	Diabetes-related
	Diabetes	Diabetes	Diabetes without	Lower-Extremity
	Complications	Complications	Complications	Amputations
Age, years	*	*	•	*
18-29				
30-44				
45-64				
64-74				
75+				
Sex				
Female				
Male				
Race				
White				
Black				
Hispanic				
Asian or Pacific				
Islander				
Native American				
Region				
Northeast				
Midwest				
South				
West				
Rural/Urban				
Rural				
Urban				
Insurance				
Medicare				
Medicaid				
Private Insurance				
Self-Pay				
No Charge				
Other				
Comorbidities				
Macrovascular				
Microvascular				
Depression/				
Anxiety				





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Appendix 7. Table Shells for Aim 3 Results

Table 10. Demographic characteristics of sample, years 2008, 2011, 2014, 2016

Variable			Year		
	2008	2011	2014	2016	

Total database population

All patients with Diabetes, n

Age, years

Mean (SD)

Range

Sex, n (%)

Female

Male

Geographic Region, n (%)

Northeast

Midwest

South

West

Race, n (%)

White

Black

Other

Insurance, n (%)

Medicare

Medicaid

Private Insurance

Self-Pay

No Charge

Other

Comorbidities, n (%)

Macrovascular

Microvascular

Depression/Anxiety

Table 11. Number of People with Diabetes Prescribed Cardiovascular-Modifying and Antidepressant Medications in Years 2008, 2011, 2014, and 2016

2008	2011	2014	2016	Absolute Change	% Change
n (%)	n (%)	n (%)	n (%)		





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Antihyperglycemic agents

Antihyperlipidemic

agents

Antihypertensive

agents

Antiplatelet

agents

Antidepressant/

Anxiolytic Agents





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Table 12. % Change in Cardiovascular-Modifying Drugs Prescribed to People with Diabetes by Sociodemographic Characteristics from 2008-2016

Antihyperglycemic	Hyperlipidemia Drugs	Hypertension Agents	Antiplatelets Agents	
A ma vianes	Drugs	Agents	Agents	
Age, years 18-44				
45-64				
65+				
Sex				
Female				
Male				
Geographic Region Northeast				
Midwest				
South				
West				
Race				
White				
Black				
Other				
Insurance				
Medicare				
Medicaid				
Private Insurance				
Self-Pay				
No Charge				
Other				
Comorbidities, n (%)				
Macrovascular				
Microvascular				
Depression/Anxiety				

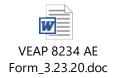




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12 Attachments

Link to HCEI Form 2 Template







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13 SIGNATURES

13.1 Sponsor's Representative

PRINTED	
NAME	
TITLE	
SIGNATURE	
DATE SIGNED	



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13.2 Investigator

I agree to conduct this study in accordance with the design outlined in this protocol and to abide by all provisions of this protocol (including other manuals and documents referenced from this protocol); changes from the protocol are acceptable only with a mutually agreed upon protocol amendment. I agree to conduct the study in accordance with generally accepted standards of Good Pharmacoepidemiology Practice. I also agree to report all information or data in accordance with the protocol and, in particular, I agree to report any serious adverse experiences as defined in Section 6 – Safety Reporting and Related Procedures. I understand that information that identifies me will be used and disclosed as described in the protocol, and that such information may be transferred to countries that do not have laws protecting such information. Since the information in this protocol is confidential, I understand that its disclosure to any third parties, other than those involved in approval, supervision, or conduct of the study is prohibited. I will ensure that the necessary precautions are taken to protect such information from loss, inadvertent disclosure, or access by third parties.

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13.3 Supplier

I agree to conduct this study in accordance with the design outlined in this protocol and to abide by all provisions of this protocol (including other manuals and documents referenced from this protocol); changes from the protocol are acceptable only with a mutually agreed upon protocol amendment. I agree to conduct the study in accordance with generally accepted standards of Good Pharmacoepidemiology Practice. I also agree to report all information or data in accordance with the protocol and, in particular, I agree to report any serious adverse experiences as defined in Section 6 – Safety and Product Quality Complaint Reporting and Related Procedures. I understand that information that identifies me will be used and disclosed as described in the protocol, and that such information may be transferred to countries that do not have laws protecting such information. Since the information in this protocol is confidential, I understand that its disclosure to any third parties, other than those involved in approval, supervision, or conduct of the study is prohibited. I will ensure that the necessary precautions are taken to protect such information from loss, inadvertent disclosure, or access by third parties.

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