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Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request cder_mpl1r_wp058

Request ID: cder_mpl1r_wp058

Request Description: The goal of this request was to estimate the number of new users of mifepristone (brand names Korlym and Mifeprex) in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.1.3

Data Source: Data from January 1, 2000 to April 30, 2017 from 16 Data Partners contributing to the SDD were included in this report. This request was distributed on September 21, 2017. See Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: The request was designed to calculate baseline characteristics and background rates. The number of qualifying patients with the exposure of interest was calculated overall and stratified by age group, sex, and year.

Exposure of Interest: The exposure of interest was incident mifepristone use, which was defined as having no dispensing of mifepristone in the prior 183 days. Mifepristone was defined using National Drug Codes (NDCs). Please see Appendix B for generic and brand drug names used in this request.

Cohort Eligibility Criteria: Patients included in the cohort were required to be continuously enrolled in plans with medical and drug coverage for at least 183 days prior to their qualifying dispensing date of mifepristone, during which gaps in coverage of up to 45 days were allowed. Patients were excluded if they had the exposure of interest in the 183 days prior to their qualifying dispensing date. Only the first qualifying dispensing (index) per patient was included. The following age groups were included in the cohort: 0-1, 2-4, 5-9, 10-14, 15-18, 19-21, 22-44, 45-64, 65-74, and 75+ years.

Baseline Characteristics: The following characteristics were assessed at the patient's first qualifying dispensing date (index date): age, sex, year. The following characteristics were assessed throughout all available enrollment history prior to index date: Charlson/Elixhauser combined comorbidity score¹, health service utilization intensity, and history of the following: Cushing's syndrome or hypercortisolism, Cushing's syndrome or hypercortisolism *in addition* to a diagnosis of diabetes mellitus or glucose intolerance, Cushing's syndrome or hypercortisolism *in addition* to a diagnosis or treatment (e.g., dispensing) of diabetes mellitus or glucose intolerance, adrenal or pituitary surgery. Please refer to Appendix C for specific International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes, ICD-10 Procedure Codes (ICD-10-PCS) codes, and generic names used to define covariates.

Please see Appendix D for the specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define exposures and covariates are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

¹Gagne, J. J., Glynn, R. J., Avorn, J., Levin, R., Schneeweiss, S. (2011). "A combined comorbidity score predicted mortality in elderly patients better than existing scores." J Clin Epidemiol 64(7):749-759.

Table of Contents

<u>Glossary</u>	List of Terms Found in this Report and their Definitions
<u>Table 1a</u>	Baseline Characteristics for Mifepristone (Brand Name = Korlym) Use from January 1, 2000 to April 30, 2017
<u>Table 1b</u>	Baseline Characteristics for Mifepristone (Brand Name = Mifeprex) Use from January 1, 2000 to April 30, 2017
<u>Table 2</u>	Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name
<u>Table 3</u>	Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name and Age Group
<u>Table 4</u>	Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name and Sex
<u>Table 5</u>	Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name and Year
<u>Appendix A</u>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (September 21, 2017)
<u>Appendix B</u>	List of Generic and Brand Drug Names Used to Define Exposures in this Request
<u>Appendix C</u>	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request
<u>Appendix D</u>	Specifications for Parameters for this Request

Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Tool*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same

Event Deduplication - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions days are added after any episode gaps have been bridged

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1a. Baseline Characteristics for Mifepristone (Brand Name = Korlym) Use from January 1, 2000 to April 30, 2017

Brand Name = Korlym		
Characteristic	Number	%
Number of episodes	138	100.0%
Number of unique patients	138	100.0%
Patient Characteristics	Mean	Standard Deviation
Mean Age (Years)	49.7	13.7
	Number	%
Age (Years)		
15-18	0	0.0%
19-21	3	2.2%
22-44	46	33.3%
45-64	68	49.3%
65-74	18	13.0%
75+	3	220.0%
Sex		
Female	110	79.7%
Male	28	20.3%
Year		
2012	10	7.2%
2013	24	17.4%
2014	32	23.3%
2015	21	15.2%
2016	46	33.3%
2017	5	3.6%
Recorded History during Baseline Period:	Mean	Standard Deviation
Charlson/Elixhauser combined comorbidity score ¹	1.8	3
	Number	%
Cushing's syndrome or hypercortisolism	118	85.50%
Cushing's Syndrome or hypercortisolism <i>in addition to</i> a diagnosis of diabetes mellitus or glucose intolerance	71	51.40%
Cushing's syndrome or hypercortisolism <i>in addition to</i> a diagnosis or treatment (e.g., dispensing) of diabetes mellitus or glucose intolerance	99	71.70%
Adrenal or pituitary surgery	26	18.80%
Health Service Utilization Intensity:	Mean	Standard Deviation
Mean number of filled prescriptions	198.4	207.4
Mean number of unique drug classes	22.5	12.9

¹The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

Table 1b. Baseline Characteristics for Mifepristone (Brand Name = Mifeprex) Use from January 1, 2000 to April 30, 2017

Brand Name = Mifeprex			
Characteristic	Number	%	
Number of episodes	17		
Number of unique patients	17		
Patient Characteristics	Mean	Standard Deviation	
Mean Age (Years)	31.5	7.5	
	Number	%	
Age (Years)			
15-18	3	17.6%	
19-21	0	0.0%	
22-44	11	64.7%	
45-64	3	17.6%	
65-74	0	0.0%	
75+	0	0.0%	
Sex			
Female	17	100.0%	
Male	0	0.0%	
Year			
2001	1	5.9%	
2005	1	5.9%	
2006	1	5.9%	
2007	1	5.9%	
2008	3	17.6%	
2009	3	17.6%	
2010	2	11.8%	
2011	0	0.0%	
2012	1	5.9%	
2013	2	11.8%	
2014	1	5.9%	
2015	0	0.0%	
2016	1	5.9%	
Recorded History during Baseline Period:	Mean	Standard Deviation	
Charlson/Elixhauser combined comorbidity score ¹	0.6	0.3	
	Number	%	
Cushing's syndrome or hypercortisolism	0	0.00%	
Cushing's Syndrome or hypercortisolism <i>in addition to</i> a diagnosis of diabetes mellitus or glucose intolerance	0	0.00%	
Cushing's syndrome or hypercortisolism <i>in addition to</i> a diagnosis or treatment (e.g., dispensing) of diabetes mellitus or glucose intolerance	0	0.00%	
Adrenal or pituitary surgery	0	0.00%	
Health Service Utilization Intensity:	Mean	Standard Deviation	
Mean number of filled prescriptions	117.8	259.6	
Mean number of unique drug classes	15.2	9.6	

¹The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

Table 2. Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name

	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/ 1,000 Eligible Members	Days Supplied/ User	Dispensings /User	Days Supplied/ Dispensing
Korlym	138	138	3,943	5,745	130,412,748	381,222,560.6	0.00	28.57	1.00	28.57
Mifeprex	17	17	277	185	130,412,774	381,222,683.1	0.00	16.29	1.00	16.29

Table 3. Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name and Age Group

	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/ 1,000 Eligible Members	Days Supplied/ User	Dispensings /User	Days Supplied/ Dispensing
Korlym										
0-1 Years	0	0	0	0	6,740,629	6,199,387.5	0.00	---	---	---
2-4 Years	0	0	0	0	9,342,802	13,219,055.9	0.00	---	---	---
5-9 Years	0	0	0	0	12,937,314	23,670,473.5	0.00	---	---	---
10-14 Years	0	0	0	0	13,454,084	25,243,293.3	0.00	---	---	---
15-18 Years	0	0	0	0	12,370,435	21,109,452.5	0.00	---	---	---
19-21 Years	3	3	90	120	11,231,015	14,917,585.1	0.00	30.00	1.00	30.00
22-44 Years	46	46	1,324	1,984	55,145,543	118,878,310.4	0.00	28.78	1.00	28.78
45-64 Years	68	68	1,923	2,715	39,140,274	112,411,782.5	0.00	28.28	1.00	28.28
65-74 Years	18	18	509	776	9,545,164	26,489,746.5	0.00	28.28	1.00	28.28
75+ Years	3	3	97	150	5,153,220	19,083,473.4	0.00	32.33	1.00	32.33
Mifeprex										
0-1 Years	0	0	0	0	6,740,629	6,199,387.5	0.00	---	---	---
2-4 Years	0	0	0	0	9,342,802	13,219,055.9	0.00	---	---	---
5-9 Years	0	0	0	0	12,937,314	23,670,473.5	0.00	---	---	---
10-14 Years	0	0	0	0	13,454,084	25,243,293.3	0.00	---	---	---
15-18 Years	3	3	3	3	12,370,435	21,109,449.9	0.00	1.00	1.00	1.00
19-21 Years	0	0	0	0	11,231,012	14,917,583.2	0.00	---	---	---
22-44 Years	11	11	72	23	55,145,550	118,878,314.6	0.00	6.55	1.00	6.55
45-64 Years	3	3	202	159	39,140,300	112,411,873.8	0.00	67.33	1.00	67.33
65-74 Years	0	0	0	0	9,545,164	26,489,767.0	0.00	---	---	---
75+ Years	0	0	0	0	5,153,222	19,083,484.4	0.00	---	---	---

Table 4. Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017, by Brand Name and Sex

	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/ 1,000 Eligible Members	Days Supplied/ User	Dispensings /User	Days Supplied/ Dispensing
Korlym										
Female	110	110	3,155	4,714	66,052,173	196,242,746.6	0.00	28.68	1.00	28.68
Male	28	28	788	1,031	64,353,228	184,960,247.5	0.00	28.14	1.00	28.14
Unknown	0	0	0	0	7,347	19,566.5	0.00	---	---	---
Mifeprex										
Female	17	17	277	185	66,052,194	196,242,830.1	0.00	16.29	1.00	16.29
Male	0	0	0	0	64,353,233	184,960,286.5	0.00	---	---	---
Unknown	0	0	0	0	7,347	19,566.5	0.00	---	---	---

Table 5. Summary of Incident Mifepristone Use in the Sentinel Distributed Database from January 1, 2000 to April 30, 2017 by Brand Name and Year

	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/ 1,000 Eligible Members	Days Supplied/ User	Dispensings /User	Days Supplied/ Dispensing
Korlym										
2000	0	0	0	0	6,774,413	3,130,169.2	0.00	---	---	---
2001	0	0	0	0	7,379,902	6,211,612.9	0.00	---	---	---
2002	0	0	0	0	7,567,152	6,333,508.7	0.00	---	---	---
2003	0	0	0	0	7,559,432	6,330,415.6	0.00	---	---	---
2004	0	0	0	0	8,032,322	6,611,738.1	0.00	---	---	---
2005	0	0	0	0	8,318,548	6,935,061.8	0.00	---	---	---
2006	0	0	0	0	19,990,877	12,112,420.1	0.00	---	---	---
2007	0	0	0	0	24,330,046	17,864,873.7	0.00	---	---	---
2008	0	0	0	0	45,425,359	29,056,377.8	0.00	---	---	---
2009	0	0	0	0	46,893,568	36,803,537.6	0.00	---	---	---
2010	0	0	0	0	44,878,323	35,405,565.4	0.00	---	---	---
2011	0	0	0	0	43,580,989	34,704,166.9	0.00	---	---	---
2012	10	10	229	666	44,210,340	34,908,107.3	0.00	22.90	1.00	22.90
2013	24	24	702	1,009	44,461,258	35,390,305.6	0.00	29.25	1.00	29.25
2014	32	32	929	1,248	45,475,047	35,325,143.5	0.00	29.03	1.00	29.03
2015	21	21	578	720	45,862,753	36,089,764.9	0.00	27.52	1.00	27.52
2016	46	46	1,357	1,924	45,402,477	34,085,635.5	0.00	29.50	1.00	29.50
2017	5	5	148	178	21,715,047	3,924,155.8	0.00	29.60	1.00	29.60
Mifeprex										
2000	0	0	0	0	6,774,413	3,130,169.2	0.00	---	---	---
2001	1	1	108	108	7,379,902	6,211,612.7	0.00	108.00	1.00	108.00
2002	0	0	0	0	7,567,151	6,333,508.3	0.00	---	---	---
2003	0	0	0	0	7,559,432	6,330,415.6	0.00	---	---	---
2004	0	0	0	0	8,032,322	6,611,738.1	0.00	---	---	---
2005	1	1	3	3	8,318,548	6,935,061.4	0.00	3.00	1.00	3.00
2006	1	1	1	1	19,990,876	12,112,418.5	0.00	1.00	1.00	1.00
2007	1	1	1	1	24,330,044	17,864,871.6	0.00	1.00	1.00	1.00
2008	3	3	32	34	45,425,356	29,056,373.2	0.00	10.67	1.00	10.67
2009	3	3	67	27	46,893,562	36,803,530.4	0.00	22.33	1.00	22.33
2010	2	2	2	4	44,878,314	35,405,557.9	0.00	1.00	1.00	1.00
2011	0	0	0	0	43,580,980	34,704,158.5	0.00	---	---	---
2012	0	0	0	0	44,210,334	34,908,104.5	0.00	---	---	---
2013	1	1	1	1	44,461,261	35,390,316.8	0.00	1.00	1.00	1.00
2014	2	2	31	2	45,475,076	35,325,171.3	0.00	15.50	1.00	15.50
2015	1	1	30	3	45,862,805	36,089,814.0	0.00	30.00	1.00	30.00
2016	0	0	0	0	45,402,534	34,085,698.9	0.00	---	---	---
2017	1	1	1	1	21,715,091	3,924,161.9	0.00	1.00	1.00	1.00

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (September 21, 2017)

DP ID	Start Date¹	End Date¹
DP0001	1/1/2008	3/31/2017
DP0002	1/1/2006	1/31/2017
DP0003	1/1/2004	3/31/2017
DP0004	1/1/2012	3/31/2016
DP0005	1/1/2000	6/30/2016
DP0006	1/1/2000	10/31/2015
DP0007	1/2/2000	5/31/2015
DP0008	1/1/2000	10/31/2014
DP0009	6/1/2007	10/31/2016
DP0010	1/1/2000	3/31/2017
DP0011	1/1/2000	3/31/2017
DP0012	1/1/2005	3/31/2017
DP0013	1/1/2000	3/31/2017
DP0014	1/1/2000	4/30/2017
DP0015	1/1/2008	9/30/2016
DP0016	1/1/2000	12/31/2015

¹The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures in this Request

Generic Name	Brand Name
mifepristone	Korlym
mifepristone	Mifeprex

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
Cushing's Syndrome or Hypercortisolism		
255.0	Cushing's syndrome (any source)	ICD-9-CM
E24.0	Pituitary dependent Cushing's syndrome	ICD-10-CM
E24.3	Ectopic ACTH syndrome	ICD-10-CM
E24.8	Other Cushing's syndrome (adrenal source)	ICD-10-CM
E24.9	Cushing's syndrome (unspecified source)	ICD-10-CM
C74.0	Adrenal carcinoma	ICD-10-CM
Diabetes Mellitus or Glucose Intolerance		
<i>Diagnosis Codes</i>		
249.**	Secondary diabetes mellitus	ICD-9-CM
790.21	Impaired fasting glucose (elevated glucose)	ICD-9-CM
790.22	Impaired glucose tolerance test (oral)	ICD-9-CM
790.29	Other abnormal glucose (including latent and pre-diabetes)	ICD-9-CM
251.10	Insulin resistance/hyperinsulinemia	ICD-9-CM
E08.8	Diabetes mellitus due to underlying condition with complications	ICD-10-CM
E08.9	Diabetes mellitus due to underlying condition without complications	ICD-10-CM
Z79.4	Any use of insulin	ICD-10-CM
R73.01	Impaired fasting glucose (elevated glucose)	ICD-10-CM
R73.02	Impaired glucose tolerance test (oral)	ICD-10-CM
R73.09	Other abnormal glucose (including latent and pre-diabetes)	ICD-10-CM
R73.9	Hyperglycemia unspecified	ICD-10-CM
E16.1	Insulin resistance/hyperinsulinemia	ICD-10-CM
<i>Generic Names</i>		
	Acetohexamide	
	Acarbose	
	Albiglutide	
	Alogliptin Benzoate	
	Alogliptin Benzoate/Metformin Hcl	
	Alogliptin Benzoate/Pioglitazone Hcl	
	Canagliflozin	
	Canagliflozin/Metformin Hcl	
	Chlorpropamide	
	Dapagliflozin Propanediol	
	Dapagliflozin Propanediol/Metformin Hcl	
	Dulaglutide	
	Empagliflozin	
	Empagliflozin/Metformin Hcl	
	Exenatide	
	Exenatide Microspheres	
	Glimepiride	

Note: Codes containing "***" indicate wildcards. Wildcards are used to represent a digit 0-9 or a letter A-Z. For example, "250**" will always expand into a five-digit code.

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
	Glipizide	
	Glipizide/Metformin Hcl	
	Glyburide	
	Glyburide,Micronized	
	Glyburide/Metformin Hcl	
	Insulin Aspart	
	Insulin Aspart Protamine Human/Insulin Aspart	
	Insulin Degludec	
	Insulin Degludec/Liraglutide	
	Insulin Detemir	
	Insulin Glargine,Human Recombinant Analog	
	Insulin Glargine,Human Recombinant Analog/Lixisenatide	
	Insulin Glulisine	
	Insulin Lispro	
	Insulin Lispro Protamine And Insulin Lispro	
	Insulin Nph Human Isophane/Insulin Regular, Human	
	Insulin Regular, Human	
	Insulin Regular, Human/Insulin Release Unit	
	Insulin Regular, Human/Insulin Release Unit/Chamber/Inhaler	
	Insulin Regular,Beef-Pork	
	Insulin Regular,Human Buffered	
	Linagliptin	
	Linagliptin/Metformin Hcl	
	Liraglutide	
	Metformin Hcl	
	Miglitol	
	Nateglinide	
	Pioglitazone Hcl	
	Pioglitazone Hcl/Glimepiride	
	Pioglitazone Hcl/Metformin Hcl	
	Pramlintide Acetate	
	Repaglinide	
	Repaglinide/Metformin Hcl	
	Rosiglitazone Maleate	
	Rosiglitazone Maleate/Glimepiride	
	Rosiglitazone Maleate/Metformin Hcl	
	Saxagliptin Hcl	
	Saxagliptin Hcl/Metformin Hcl	
	Sitagliptin Phosphate	
	Sitagliptin Phosphate/Metformin Hcl	
	Sitagliptin Phosphate/Simvastatin	
	Tolazamide	
	Tolbutamide	

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
Adrenal or Pituitary Surgery		
07.00	Exploration of adrenal field, not otherwise specified	ICD-9-CM
07.01	Unilateral exploration of adrenal field	ICD-9-CM
07.02	Bilateral exploration of adrenal field	ICD-9-CM
07.11	Closed (percutaneous) (needle) biopsy of adrenal gland	ICD-9-CM
07.12	Open biopsy of adrenal gland	ICD-9-CM
07.13	Biopsy of pituitary gland, transfrontal approach	ICD-9-CM
07.14	Biopsy of pituitary gland, transsphenoidal approach	ICD-9-CM
07.15	Biopsy of pituitary gland, unspecified approach	ICD-9-CM
07.19	Other diagnostic procedures on adrenal glands, pituitary gland, pineal gland, and thymus	ICD-9-CM
07.21	Excision of lesion of adrenal gland	ICD-9-CM
07.22	Unilateral adrenalectomy	ICD-9-CM
07.29	Other partial adrenalectomy	ICD-9-CM
07.41	Incision of adrenal gland	ICD-9-CM
07.42	Division of nerves to adrenal glands	ICD-9-CM
07.43	Ligation of adrenal vessels	ICD-9-CM
07.44	Repair of adrenal gland	ICD-9-CM
07.45	Reimplantation of adrenal tissue	ICD-9-CM
07.49	Other operations on adrenal glands, nerves, and vessels	ICD-9-CM
07.61	Partial excision of pituitary gland, transfrontal approach	ICD-9-CM
07.62	Partial excision of pituitary gland, transsphenoidal approach	ICD-9-CM
07.63	Partial excision of pituitary gland, unspecified approach	ICD-9-CM
07.64	Total excision of pituitary gland, transfrontal approach	ICD-9-CM
07.65	Total excision of pituitary gland, transsphenoidal approach	ICD-9-CM
07.68	Total excision of pituitary gland, other specified approach	ICD-9-CM
07.69	Total excision of pituitary gland, unspecified approach	ICD-9-CM
07.71	Exploration of pituitary fossa	ICD-9-CM
07.72	Incision of pituitary gland	ICD-9-CM
07.79	Other operations on hypophysis	ICD-9-CM
0GJ50ZZ	Inspection of Adrenal Gland, Open Approach	ICD-10-PCS
0GJ53ZZ	Inspection of Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GJ54ZZ	Inspection of Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G923ZX	Drainage of Left Adrenal Gland, Percutaneous Approach, Diagnostic	ICD-10-PCS
0G924ZX	Drainage of Left Adrenal Gland, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0G933ZX	Drainage of Right Adrenal Gland, Percutaneous Approach, Diagnostic	ICD-10-PCS
0G934ZX	Drainage of Right Adrenal Gland, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0G943ZX	Drainage of Bilateral Adrenal Glands, Percutaneous Approach, Diagnostic	ICD-10-PCS
0G944ZX	Drainage of Bilateral Adrenal Glands, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0GB23ZX	Excision of Left Adrenal Gland, Percutaneous Approach, Diagnostic	ICD-10-PCS
0GB24ZX	Excision of Left Adrenal Gland, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0GB33ZX	Excision of Right Adrenal Gland, Percutaneous Approach, Diagnostic	ICD-10-PCS
0GB34ZX	Excision of Right Adrenal Gland, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0GB43ZX	Excision of Bilateral Adrenal Glands, Percutaneous Approach, Diagnostic	ICD-10-PCS

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
0GB44ZX	Excision of Bilateral Adrenal Glands, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0G920ZX	Drainage of Left Adrenal Gland, Open Approach, Diagnostic	ICD-10-PCS
0G930ZX	Drainage of Right Adrenal Gland, Open Approach, Diagnostic	ICD-10-PCS
0G940ZX	Drainage of Bilateral Adrenal Glands, Open Approach, Diagnostic	ICD-10-PCS
0GB20ZX	Excision of Left Adrenal Gland, Open Approach, Diagnostic	ICD-10-PCS
0GB30ZX	Excision of Right Adrenal Gland, Open Approach, Diagnostic	ICD-10-PCS
0GB40ZX	Excision of Bilateral Adrenal Glands, Open Approach, Diagnostic	ICD-10-PCS
0GB00ZX	Excision of Pituitary Gland, Open Approach, Diagnostic	ICD-10-PCS
0G900ZX	Drainage of Pituitary Gland, Open Approach, Diagnostic	ICD-10-PCS
0G903ZX	Drainage of Pituitary Gland, Percutaneous Approach, Diagnostic	ICD-10-PCS
0G904ZX	Drainage of Pituitary Gland, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
0GB03ZX	Excision of Pituitary Gland, Percutaneous Approach, Diagnostic	ICD-10-PCS
0GB04ZX	Excision of Pituitary Gland, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS
07JM3ZZ	Inspection of Thymus, Percutaneous Approach	ICD-10-PCS
0G520ZZ	Destruction of Left Adrenal Gland, Open Approach	ICD-10-PCS
0G523ZZ	Destruction of Left Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0G524ZZ	Destruction of Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G530ZZ	Destruction of Right Adrenal Gland, Open Approach	ICD-10-PCS
0G533ZZ	Destruction of Right Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0G534ZZ	Destruction of Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G540ZZ	Destruction of Bilateral Adrenal Glands, Open Approach	ICD-10-PCS
0G543ZZ	Destruction of Bilateral Adrenal Glands, Percutaneous Approach	ICD-10-PCS
0G544ZZ	Destruction of Bilateral Adrenal Glands, Percutaneous Endoscopic Approach	ICD-10-PCS
0GB20ZZ	Excision of Left Adrenal Gland, Open Approach	ICD-10-PCS
0GB23ZZ	Excision of Left Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GB24ZZ	Excision of Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GB30ZZ	Excision of Right Adrenal Gland, Open Approach	ICD-10-PCS
0GB33ZZ	Excision of Right Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GB34ZZ	Excision of Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GB40ZZ	Excision of Bilateral Adrenal Glands, Open Approach	ICD-10-PCS
0GB43ZZ	Excision of Bilateral Adrenal Glands, Percutaneous Approach	ICD-10-PCS
0GB44ZZ	Excision of Bilateral Adrenal Glands, Percutaneous Endoscopic Approach	ICD-10-PCS
0GT20ZZ	Resection of Left Adrenal Gland, Open Approach	ICD-10-PCS
0GT24ZZ	Resection of Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GT30ZZ	Resection of Right Adrenal Gland, Open Approach	ICD-10-PCS
0GT34ZZ	Resection of Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G9200Z	Drainage of Left Adrenal Gland with Drainage Device, Open Approach	ICD-10-PCS
0G920ZZ	Drainage of Left Adrenal Gland, Open Approach	ICD-10-PCS
0G9240Z	Drainage of Left Adrenal Gland with Drainage Device, Percutaneous Endoscopic Approach	ICD-10-PCS
0G924ZZ	Drainage of Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G9300Z	Drainage of Right Adrenal Gland with Drainage Device, Open Approach	ICD-10-PCS
0G930ZZ	Drainage of Right Adrenal Gland, Open Approach	ICD-10-PCS
0G9340Z	Drainage of Right Adrenal Gland with Drainage Device, Percutaneous Endoscopic Approach	ICD-10-PCS

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
0G934ZZ	Drainage of Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G9400Z	Drainage of Bilateral Adrenal Glands with Drainage Device, Open Approach	ICD-10-PCS
0G940ZZ	Drainage of Bilateral Adrenal Glands, Open Approach	ICD-10-PCS
0G9440Z	Drainage of Bilateral Adrenal Glands with Drainage Device, Percutaneous Endoscopic Approach	ICD-10-PCS
0G944ZZ	Drainage of Bilateral Adrenal Glands, Percutaneous Endoscopic Approach	ICD-10-PCS
0GC20ZZ	Extirpation of Matter from Left Adrenal Gland, Open Approach	ICD-10-PCS
0GC23ZZ	Extirpation of Matter from Left Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GC24ZZ	Extirpation of Matter from Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GC30ZZ	Extirpation of Matter from Right Adrenal Gland, Open Approach	ICD-10-PCS
0GC33ZZ	Extirpation of Matter from Right Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GC34ZZ	Extirpation of Matter from Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GC40ZZ	Extirpation of Matter from Bilateral Adrenal Glands, Open Approach	ICD-10-PCS
0GC43ZZ	Extirpation of Matter from Bilateral Adrenal Glands, Percutaneous Approach	ICD-10-PCS
0GC44ZZ	Extirpation of Matter from Bilateral Adrenal Glands, Percutaneous Endoscopic Approach	ICD-10-PCS
0GHS02Z	Insertion of Monitoring Device into Endocrine Gland, Open Approach	ICD-10-PCS
0GHS03Z	Insertion of Infusion Device into Endocrine Gland, Open Approach	ICD-10-PCS
0GHS32Z	Insertion of Monitoring Device into Endocrine Gland, Percutaneous Approach	ICD-10-PCS
0GHS33Z	Insertion of Infusion Device into Endocrine Gland, Percutaneous Approach	ICD-10-PCS
0GHS42Z	Insertion of Monitoring Device into Endocrine Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GHS43Z	Insertion of Infusion Device into Endocrine Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GP500Z	Removal of Drainage Device from Adrenal Gland, Open Approach	ICD-10-PCS
0GP530Z	Removal of Drainage Device from Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GP540Z	Removal of Drainage Device from Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GW500Z	Revision of Drainage Device in Adrenal Gland, Open Approach	ICD-10-PCS
0GW530Z	Revision of Drainage Device in Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GW540Z	Revision of Drainage Device in Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
018M0ZZ	Division of Abdominal Sympathetic Nerve, Open Approach	ICD-10-PCS
018M3ZZ	Division of Abdominal Sympathetic Nerve, Percutaneous Approach	ICD-10-PCS
018M4ZZ	Division of Abdominal Sympathetic Nerve, Percutaneous Endoscopic Approach	ICD-10-PCS
06L90ZZ	Occlusion of Right Renal Vein, Open Approach	ICD-10-PCS
06L93ZZ	Occlusion of Right Renal Vein, Percutaneous Approach	ICD-10-PCS
06L94ZZ	Occlusion of Right Renal Vein, Percutaneous Endoscopic Approach	ICD-10-PCS
06LB0ZZ	Occlusion of Left Renal Vein, Open Approach	ICD-10-PCS
06LB3ZZ	Occlusion of Left Renal Vein, Percutaneous Approach	ICD-10-PCS
06LB4ZZ	Occlusion of Left Renal Vein, Percutaneous Endoscopic Approach	ICD-10-PCS
0GM20ZZ	Reattachment of Left Adrenal Gland, Open Approach	ICD-10-PCS
0GM24ZZ	Reattachment of Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GM30ZZ	Reattachment of Right Adrenal Gland, Open Approach	ICD-10-PCS
0GM34ZZ	Reattachment of Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GN20ZZ	Release Left Adrenal Gland, Open Approach	ICD-10-PCS
0GN23ZZ	Release Left Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GN24ZZ	Release Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GN30ZZ	Release Right Adrenal Gland, Open Approach	ICD-10-PCS

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
0GN33ZZ	Release Right Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GN34ZZ	Release Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GN40ZZ	Release Bilateral Adrenal Glands, Open Approach	ICD-10-PCS
0GN43ZZ	Release Bilateral Adrenal Glands, Percutaneous Approach	ICD-10-PCS
0GN44ZZ	Release Bilateral Adrenal Glands, Percutaneous Endoscopic Approach	ICD-10-PCS
0GQ20ZZ	Repair Left Adrenal Gland, Open Approach	ICD-10-PCS
0GQ23ZZ	Repair Left Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GQ24ZZ	Repair Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GQ30ZZ	Repair Right Adrenal Gland, Open Approach	ICD-10-PCS
0GQ33ZZ	Repair Right Adrenal Gland, Percutaneous Approach	ICD-10-PCS
0GQ34ZZ	Repair Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GQ40ZZ	Repair Bilateral Adrenal Glands, Open Approach	ICD-10-PCS
0GQ43ZZ	Repair Bilateral Adrenal Glands, Percutaneous Approach	ICD-10-PCS
0GQ44ZZ	Repair Bilateral Adrenal Glands, Percutaneous Endoscopic Approach	ICD-10-PCS
0GS20ZZ	Reposition Left Adrenal Gland, Open Approach	ICD-10-PCS
0GS24ZZ	Reposition Left Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GS30ZZ	Reposition Right Adrenal Gland, Open Approach	ICD-10-PCS
0GS34ZZ	Reposition Right Adrenal Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G800ZZ	Division of Pituitary Gland, Open Approach	ICD-10-PCS
0G803ZZ	Division of Pituitary Gland, Percutaneous Approach	ICD-10-PCS
0G804ZZ	Division of Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GB00ZZ	Excision of Pituitary Gland, Open Approach	ICD-10-PCS
0G500ZZ	Destruction of Pituitary Gland, Open Approach	ICD-10-PCS
0G503ZZ	Destruction of Pituitary Gland, Percutaneous Approach	ICD-10-PCS
0G504ZZ	Destruction of Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GB03ZZ	Excision of Pituitary Gland, Percutaneous Approach	ICD-10-PCS
0GB04ZZ	Excision of Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GT00ZZ	Resection of Pituitary Gland, Open Approach	ICD-10-PCS
0GT04ZZ	Resection of Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GJ00ZZ	Inspection of Pituitary Gland, Open Approach	ICD-10-PCS
0GJ04ZZ	Inspection of Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0G9000Z	Drainage of Pituitary Gland with Drainage Device, Open Approach	ICD-10-PCS
0G900ZZ	Drainage of Pituitary Gland, Open Approach	ICD-10-PCS
0G9040Z	Drainage of Pituitary Gland with Drainage Device, Percutaneous Endoscopic Approach	ICD-10-PCS
0G904ZZ	Drainage of Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GC00ZZ	Extirpation of Matter from Pituitary Gland, Open Approach	ICD-10-PCS
0GC03ZZ	Extirpation of Matter from Pituitary Gland, Percutaneous Approach	ICD-10-PCS
0GC04ZZ	Extirpation of Matter from Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GP000Z	Removal of Drainage Device from Pituitary Gland, Open Approach	ICD-10-PCS
0GP030Z	Removal of Drainage Device from Pituitary Gland, Percutaneous Approach	ICD-10-PCS
0GP040Z	Removal of Drainage Device from Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
0GW000Z	Revision of Drainage Device in Pituitary Gland, Open Approach	ICD-10-PCS
0GW030Z	Revision of Drainage Device in Pituitary Gland, Percutaneous Approach	ICD-10-PCS

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), ICD-10 Procedure Codes (ICD-10-PCS) Codes and Generic Names Used to Define Covariates in this Request

Code	Description	Code Type
OGW040Z	Revision of Drainage Device in Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
OGQ00ZZ	Repair Pituitary Gland, Open Approach	ICD-10-PCS
OGQ03ZZ	Repair Pituitary Gland, Percutaneous Approach	ICD-10-PCS
OGQ04ZZ	Repair Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS
OGN00ZZ	Release Pituitary Gland, Open Approach	ICD-10-PCS
OGN03ZZ	Release Pituitary Gland, Percutaneous Approach	ICD-10-PCS
OGN04ZZ	Release Pituitary Gland, Percutaneous Endoscopic Approach	ICD-10-PCS

Appendix D. Specifications for Parameters for this Request

The Center for Drug Evaluation and Research requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.1.3, to examine baseline characteristics of new users of mifepristone.

Query Period: January 1, 2000 - April 30, 2017
Coverage Requirement: Medical and Drug Coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 Days
Age Groups: 0-1, 2-4, 5-9, 10-14, 15-18, 19-21, 22-44, 45-64, 65-74, 75+ Years
Results stratified by: Age, Sex, Calendar Year

Scenario	Exposure			Baseline Characteristics			
	Exposure	Cohort Definition	Incident w/ Respect to	Washout (Days)	Condition	Care Setting	Evaluation Window
1	Korlym	Include the first valid exposure per patient	Korlym	183 days	See characteristic specifications below		
2	Mifeprex	Include the first valid exposure per patient	Mifeprex	183 days	See characteristic specifications below		

Note: International Classification of Diseases, Ninth Revision (ICD-9), International Classification of Diseases, Tenth Revision (ICD-10), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360. National Drug Codes (NDC) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

Characteristics	Condition	Care Setting	Evaluation Window
1	Cushing's syndrome or hypercortisolism	Any	Any time prior to index date
2	Cushing's syndrome or hypercortisolism <i>and</i> diabetes mellitus or glucose intolerance (diagnosis codes only)	Any	Any time prior to index date
3	Cushing's syndrome or hypercortisolism <i>and</i> diabetes mellitus or glucose intolerance (includes diagnosis codes and NDCs for diabetes medications)	Any	Any time prior to index date
4	Adrenal or pituitary surgery	Any	Any time prior to index date