Disclaimer

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_wp036_nsdp_v01

Request ID: cder_mpl1r_wp036_nsdp_v01

Query Description: This report contains baseline characteristics of members receiving four tyrosine kinase inhibitors (TKIs) in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.0.2

Data Source: The query was run against the Sentinel Distributed Database (SDD) for the time period from January 1, 2006 - September 30, 2015. This request was distributed to 16 Data Partners on August 23, 2016. See Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: This request was designed to calculate baseline characteristics of patients receiving TKIs. The number of qualifying patients with the exposure of interest were calculated overall and stratified by age group, sex, comorbidity, and health service utilization intensity.

Exposure of Interest: The exposures of interest were TKIs, axitinib, pazopanib, sorafenib, and sunitinib, which were defined using National Drug Codes (NDCs). Please see Appendix B for generic and brand names used to define exposures in this request.

Cohort Eligibility Criteria: Those included in the cohort were required to be continuously enrolled in plans with both medical and drug coverage for at least 6 months (183 days) prior to their dispensing, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 18-44, 45-54, 55-64, 65-74 and 75+ years.

Baseline Covariates: The following covariates were assessed during the baseline period: age, sex, comorbidity score, and health service utilization. Occurrence of covariates was evaluated in the 6 months (183 days) prior to the date of TKI use. The following covariates were assessed during the baseline period: age, sex, comorbidity score, and health service utilization, as well as the following conditions: (1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5. Please see Appendix C for a list of diagnosis and procedure codes used to define covariates in this request.

Limitations: Algorithms to define exposures are imperfect and, therefore, may be misclassified.

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

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

Sentinel

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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. This is equivalent to the "RxAmt" value in the MSCDM.

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). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 1: Cohort includes only the first valid incident treatment episode during the query period; 2: Cohort includes all valid incident treatment episodes during the query period; 3: Cohort includes all valid incident treatment episodes during the query period until an event occurs.

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

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

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.

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

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled”

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

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 Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

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

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

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

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.

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

Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.

Users - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

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.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1. Baseline Characteristics of Cohort of Patients Receiving Tyrosine Kinase Inhibitors[1] from January 1, 2006 to September 30, 2015, 183 Day Washout

Characteristic	Axitinib		Pazopanib		Sunitinib		Sorafenib	
	N	%/Std Dev[2]	N	%/Std Dev[2]	N	%/Std Dev[2]	N	%/Std Dev[2]
Patients	354	100.0%	2764	100.0%	6082	100.0%	6709	100.0%
Patient Characteristics								
Mean age (std dev)	63.1	9.7	60.5	12	61.6	11.1	62.3	11.3
Age: 18-44 years	15	4.2%	298	10.8%	437	7.2%	450	6.7%
Age: 45-54 years	51	14.4%	530	19.2%	1161	19.1%	1087	16.2%
Age: 55-64 years	148	41.8%	936	33.9%	2264	37.2%	2549	38.0%
Age: 65-74 years	94	26.6%	664	24.0%	1421	23.4%	1604	23.9%
Age: 75+ years	46	13.0%	336	12.2%	799	13.1%	1019	15.2%
Gender (Female)	98	27.7%	1120	40.5%	2071	34.1%	1849	27.6%
Gender (Male)	256	72.3%	1644	59.5%	4011	65.9%	4860	72.4%
Recorded History of:								
Combined Comorbidity Score	7.5	2.8	7.2	2.6	6.7	2.8	5.6	3.2
(1) Gastrointestinal Cancer	10	2.8%	197	7.1%	811	13.3%	451	6.7%
(2) Pancreatic Cancer	7	2.0%	48	1.7%	365	6.0%	141	2.1%
(3) Hepatocellular Cancer	6	1.7%	93	3.4%	292	4.8%	4488	66.9%
(4) Thyroid Cancer	7	2.0%	69	2.5%	119	2.0%	333	5.0%
(5) Soft Tissue Cancer	5	1.4%	841	30.4%	631	10.4%	291	4.3%
(6) Any cancer (1-5)	31	8.8%	1079	39.0%	1660	27.3%	5235	78.0%
(7) Renal Cell Carcinoma (RCC)	349	98.6%	1723	62.3%	4351	71.5%	1000	14.9%
(8) Any cancer (1-5) and no RCC	2	0.6%	868	31.4%	1191	19.6%	5062	75.5%
(9) RCC and none of cancer (1-5)	320	90.4%	1512	54.7%	3882	63.8%	827	12.3%
(10) No RCC	2	0.6%	868	31.4%	1191	19.6%	5062	75.5%
(11) None of cancers (1-5)	320	90.4%	1512	54.7%	3882	63.8%	827	12.3%
Health Service Utilization Intensity:								
Mean number of generic drugs	10.4	5.7	9.4	5.6	8.8	5.5	9.5	5.5
Mean number of unique drug classes	9.8	5.1	8.7	5.1	8.1	4.9	8.9	5
Mean number of filled prescriptions	26.2	17.3	21.2	15.7	19.4	14.9	20.9	14.9
Mean number of inpatient hospital encounters (IP)	0.7	1.2	0.9	1.3	0.8	1.1	0.8	1.2
Mean number of non-acute institutional encounters (IS)	0.3	1.2	0.2	0.9	0.2	0.7	0.2	0.7
Mean number of emergency room encounters (ED)	0.6	1	0.7	1.5	0.6	1.2	0.7	1.1
Mean number of ambulatory encounters (AV)	23.3	13.5	23.4	14.3	18.8	12.4	19	13.2
Mean number of other ambulatory encounters (OA)	7.4	10.9	6.9	9.6	6.6	8	6.9	7.8

[1]See Appendix B for the list of codes used to define exposures

[2]Value represents standard deviation where no % follows the value

Table 2. Baseline Characteristics of Cohort of Patients Receiving Tyrosine Kinase Inhibitors[1] from January 1, 2006 to September 30, 2015, 365 Day Washout

Characteristic	Axitinib		Pazopanib		Sunitinib		Sorafenib	
	N	%/Std Dev[2]	N	%/Std Dev[2]	N	%/Std Dev[2]	N	%/Std Dev[2]
Patients	217	100.0%	2329	100.0%	5081	100.0%	5613	100.0%
Patient Characteristics								
Mean age (std dev)	63.3	9.7	60.7	12.1	62.1	11.1	62.7	11.4
Age: 18-44 years	10	4.6%	251	10.8%	344	6.8%	363	6.5%
Age: 45-54 years	27	12.4%	444	19.1%	914	18.0%	852	15.2%
Age: 55-64 years	93	42.9%	766	32.9%	1887	37.1%	2114	37.7%
Age: 65-74 years	57	26.3%	576	24.7%	1207	23.8%	1383	24.6%
Age: 75+ years	30	13.8%	292	12.5%	729	14.3%	901	16.1%
Gender (Female)	58	26.7%	969	41.6%	1738	34.2%	1534	27.3%
Gender (Male)	159	73.3%	1360	58.4%	3343	65.8%	4079	72.7%
Recorded History of:								
Combined Comorbidity Score	8.6	2.8	7.8	2.7	7.2	2.8	6.1	3.4
(1) Gastrointestinal Cancer	8	3.7%	217	9.3%	769	15.1%	411	7.3%
(2) Pancreatic Cancer	5	2.3%	61	2.6%	352	6.9%	127	2.3%
(3) Hepatocellular Cancer	5	2.3%	107	4.6%	304	6.0%	3891	69.3%
(4) Thyroid Cancer	4	1.8%	63	2.7%	116	2.3%	296	5.3%
(5) Soft Tissue Cancer	4	1.8%	767	32.9%	577	11.4%	258	4.6%
(6) Any cancer (1-5)	22	10.1%	1001	43.0%	1520	29.9%	4530	80.7%
(7) Renal Cell Carcinoma (RCC)	213	98.2%	1423	61.1%	3625	71.3%	760	13.5%
(8) Any cancer (1-5) and no RCC	2	0.9%	776	33.3%	1078	21.2%	4366	77.8%
(9) RCC and none of cancer (1-5)	193	88.9%	1198	51.4%	3183	62.6%	596	10.6%
(10) No RCC	2	0.9%	776	33.3%	1078	21.2%	4366	77.8%
(11) None of cancers (1-5)	193	88.9%	1198	51.4%	3183	62.6%	596	10.6%
Health Service Utilization Intensity:								
Mean number of generic drugs	13.5	7.1	12.5	7	11.3	6.7	12.2	6.8
Mean number of unique drug classes	12.3	6.2	11.3	6.1	10.2	5.8	11	5.9
Mean number of filled prescriptions	46.3	32.1	37.6	27.7	34.4	26.9	37	27.3
Mean number of inpatient hospital encounters (IP)	1.2	1.5	1.4	1.8	1.1	1.4	1.2	1.6
Mean number of non-acute institutional encounters (IS)	0.7	2.2	0.3	1.3	0.2	1	0.2	1
Mean number of emergency room encounters (ED)	1	1.4	1.1	2	0.8	1.4	1	1.6
Mean number of ambulatory encounters (AV)	41.8	24.5	39.6	25	29.2	20.5	30.2	22.1
Mean number of other ambulatory encounters (OA)	12.5	17.2	11.7	14.7	10.5	12.4	11.5	13

[1]See Appendix B for the list of codes used to define exposures

[2]Value represents standard deviation where no % follows the value

Appendix A: Latest Date of Available Data for Each Data Partner up to Request End Date (September 30, 2015)

DP ID	End Date
DP0001	9/30/2015
DP0002	9/30/2015
DP0003	9/30/2015
DP0004	6/30/2015
DP0005	9/30/2015
DP0006	5/31/2015
DP0007	6/30/2012
DP0008	9/30/2015
DP0009	6/30/2015
DP0010	6/30/2015
DP0011	9/30/2015
DP0012	9/30/2015
DP0013	9/30/2015
DP0014	9/30/2015
DP0015	9/30/2015
DP0016	9/30/2015

Appendix B: Generic and Brand Names used to Define Exposures in this Request

Generic Name	Brand Name
AXITINIB	Inlyta
PAZOPANIB HCL	Votrient
SUNITINIB MALATE	Sutent
SORAFENIB TOSYLATE	Nexavar

Appendix C: List of Diagnosis and Procedure Codes Used to Define Covariates in this Request

Code	Description	Code Type
Renal Cell Carcinoma		
189	Malignant neoplasm of kidney and other and unspecified urinary organs	ICD-9-CM Diagnosis
1890	Malignant neoplasm of kidney, except pelvis	ICD-9-CM Diagnosis
1891	Malignant neoplasm of renal pelvis	ICD-9-CM Diagnosis
Gastrointestinal Cancer		
150	Malignant neoplasm of esophagus	ICD-9-CM Diagnosis
150.0	Malignant neoplasm of cervical esophagus	ICD-9-CM Diagnosis
150.1	Malignant neoplasm of thoracic esophagus	ICD-9-CM Diagnosis
150.2	Malignant neoplasm of abdominal esophagus	ICD-9-CM Diagnosis
150.3	Malignant neoplasm of upper third of esophagus	ICD-9-CM Diagnosis
150.4	Malignant neoplasm of middle third of esophagus	ICD-9-CM Diagnosis
150.5	Malignant neoplasm of lower third of esophagus	ICD-9-CM Diagnosis
150.8	Malignant neoplasm of other specified part of esophagus	ICD-9-CM Diagnosis
150.9	Malignant neoplasm of esophagus, unspecified site	ICD-9-CM Diagnosis
151	Malignant neoplasm of stomach	ICD-9-CM Diagnosis
151.0	Malignant neoplasm of cardia	ICD-9-CM Diagnosis
151.1	Malignant neoplasm of pylorus	ICD-9-CM Diagnosis
151.2	Malignant neoplasm of pyloric antrum	ICD-9-CM Diagnosis
151.3	Malignant neoplasm of fundus of stomach	ICD-9-CM Diagnosis
151.4	Malignant neoplasm of body of stomach	ICD-9-CM Diagnosis
151.5	Malignant neoplasm of lesser curvature of stomach, unspecified	ICD-9-CM Diagnosis
151.6	Malignant neoplasm of greater curvature of stomach, unspecified	ICD-9-CM Diagnosis
151.8	Malignant neoplasm of other specified sites of stomach	ICD-9-CM Diagnosis
151.9	Malignant neoplasm of stomach, unspecified site	ICD-9-CM Diagnosis
152	Malignant neoplasm of small intestine, including duodenum	ICD-9-CM Diagnosis
152.0	Malignant neoplasm of duodenum	ICD-9-CM Diagnosis
152.1	Malignant neoplasm of jejunum	ICD-9-CM Diagnosis
152.2	Malignant neoplasm of ileum	ICD-9-CM Diagnosis
152.3	Malignant neoplasm of Meckel's diverticulum	ICD-9-CM Diagnosis
152.8	Malignant neoplasm of other specified sites of small intestine	ICD-9-CM Diagnosis
152.9	Malignant neoplasm of small intestine, unspecified site	ICD-9-CM Diagnosis
153	Malignant neoplasm of colon	ICD-9-CM Diagnosis
153.0	Malignant neoplasm of hepatic flexure	ICD-9-CM Diagnosis
153.1	Malignant neoplasm of transverse colon	ICD-9-CM Diagnosis
153.2	Malignant neoplasm of descending colon	ICD-9-CM Diagnosis
153.3	Malignant neoplasm of sigmoid colon	ICD-9-CM Diagnosis
153.4	Malignant neoplasm of cecum	ICD-9-CM Diagnosis
153.5	Malignant neoplasm of appendix	ICD-9-CM Diagnosis
153.6	Malignant neoplasm of ascending colon	ICD-9-CM Diagnosis
153.7	Malignant neoplasm of splenic flexure	ICD-9-CM Diagnosis
153.8	Malignant neoplasm of other specified sites of large intestine	ICD-9-CM Diagnosis
153.9	Malignant neoplasm of colon, unspecified site	ICD-9-CM Diagnosis
154	Malignant neoplasm of rectum, recto sigmoid junction, and anus	ICD-9-CM Diagnosis
154.0	Malignant neoplasm of recto sigmoid junction	ICD-9-CM Diagnosis

Appendix C: List of Diagnosis and Procedure Codes Used to Define Covariates in this Request

Code	Description	Code Type
154.1	Malignant neoplasm of rectum	ICD-9-CM Diagnosis
154.2	Malignant neoplasm of anal canal	ICD-9-CM Diagnosis
154.3	Malignant neoplasm of anus, unspecified site	ICD-9-CM Diagnosis
154.8	Malignant neoplasm of other sites of rectum, recto sigmoid junction, and anus	ICD-9-CM Diagnosis
209.10	Malignant carcinoid tumor of the large intestine, unspecified portion	ICD-9-CM Diagnosis
209.1	Malignant carcinoid tumor of the appendix	ICD-9-CM Diagnosis
209.1	Malignant carcinoid tumor of the cecum	ICD-9-CM Diagnosis
209.1	Malignant carcinoid tumor of the ascending colon	ICD-9-CM Diagnosis
209.1	Malignant carcinoid tumor of the transverse colon	ICD-9-CM Diagnosis
209.2	Malignant carcinoid tumor of the descending colon	ICD-9-CM Diagnosis
209.2	Malignant carcinoid tumor of the sigmoid colon	ICD-9-CM Diagnosis
209.2	Malignant carcinoid tumor of the rectum	ICD-9-CM Diagnosis
230.1	Carcinoma in situ of esophagus	ICD-9-CM Diagnosis
238.1	Neoplasm of uncertain behavior of connective and other soft tissue	ICD-9-CM Diagnosis
Pancreatic Cancer		
157	Malignant neoplasm of pancreas	ICD-9-CM Diagnosis
157.0	Malignant neoplasm of head of pancreas	ICD-9-CM Diagnosis
157.1	Malignant neoplasm of body of pancreas	ICD-9-CM Diagnosis
157.2	Malignant neoplasm of tail of pancreas	ICD-9-CM Diagnosis
157.3	Malignant neoplasm of pancreatic duct	ICD-9-CM Diagnosis
157.4	Malignant neoplasm of islets of Langerhans	ICD-9-CM Diagnosis
157.8	Malignant neoplasm of other specified sites of pancreas	ICD-9-CM Diagnosis
157.9	Malignant neoplasm of pancreas, part unspecified	ICD-9-CM Diagnosis
Hepatocellular Cancer		
155.0	Malignant neoplasm of liver, primary	ICD-9-CM Diagnosis
155.1	Malignant neoplasm of intrahepatic bile ducts	ICD-9-CM Diagnosis
155.2	Malignant neoplasm of liver, not specified as primary or secondary	ICD-9-CM Diagnosis
Thyroid Cancer		
193	Malignant neoplasm of thyroid gland	ICD-9-CM Diagnosis
Soft Tissue Cancer		
171	Malignant neoplasm of connective and other soft tissue	ICD-9-CM Diagnosis
171.0	Malignant neoplasm of connective and other soft tissue of head, face, and neck	ICD-9-CM Diagnosis
171.2	Malignant neoplasm of connective and other soft tissue of upper limb, including shoulder	ICD-9-CM Diagnosis
171.3	Malignant neoplasm of connective and other soft tissue of lower limb, including hip	ICD-9-CM Diagnosis
171.4	Malignant neoplasm of connective and other soft tissue of thorax	ICD-9-CM Diagnosis
171.5	Malignant neoplasm of connective and other soft tissue of abdomen	ICD-9-CM Diagnosis
171.6	Malignant neoplasm of connective and other soft tissue of pelvis	ICD-9-CM Diagnosis
171.7	Malignant neoplasm of connective and other soft tissue of trunk, unspecified site	ICD-9-CM Diagnosis
171.8	Malignant neoplasm of other specified sites of connective and other soft tissue	ICD-9-CM Diagnosis
171.9	Malignant neoplasm of connective and other soft tissue, site unspecified	ICD-9-CM Diagnosis

Appendix D: Modular Program Specifications for cder_mpl1r_wp036_nsdp_v01

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.0.2, will be used to identify use of four tyrosine kinase inhibitors (TKIs) in the Sentinel Distributed Database (SDD): axitinib, pazopanib, sunitinib, and sorafenib. In total, 8 scenarios will be examined with four different exposures and two different covariate evaluation windows.

Enrollment Gap: 45 days
Age Groups: 18-44, 45-54, 55-64, 65-74, 75+ years
Query Period: January 1, 2006 - September 30, 2015
Coverage Requirement: Both Drug and Medical Coverage
Enrollment Requirement: 183 days

	Drug/Exposure									Covariates			Pre-Existing Condition					Event/Outcome
Scenario	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Additoinal censoring criteria	Covariates	Care Setting	Covariate evaluation window (days)	Pre-Existing Condition	Care Setting/PDX	Include or Exclude	Lookback Start	Lookback End	Event/ Outcome
1	Axitinib	Axitinib, Pazopanib, Sunitinib, Sorafenib	183	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	183	Pazopanib, Sunitinib, Sorafenib	Any	Exclude	0	0	Dummy
2	Pazopanib	Axitinib, Pazopanib, Sunitinib, Sorafenib	183	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	183	Axitinib, Sunitinib, Sorafenib	Any	Exclude	0	0	Dummy
3	Sunitinib	Axitinib, Pazopanib, Sunitinib, Sorafenib	183	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	183	Axitinib, Pazopanib, Sorafenib	Any	Exclude	0	0	Dummy
4	Sorafenib	Axitinib, Pazopanib, Sunitinib, Sorafenib	183	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	183	Axitinib, Pazopanib, Sunitinib	Any	Exclude	0	0	Dummy
5	Axitinib	Axitinib, Pazopanib, Sunitinib, Sorafenib	365	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	365	Pazopanib, Sunitinib, Sorafenib	Any	Exclude	0	0	Dummy
6	Pazopanib	Axitinib, Pazopanib, Sunitinib, Sorafenib	365	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	365	Axitinib, Sunitinib, Sorafenib	Any	Exclude	0	0	Dummy
7	Sunitinib	Axitinib, Pazopanib, Sunitinib, Sorafenib	365	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	365	Axitinib, Pazopanib, Sorafenib	Any	Exclude	0	0	Dummy
8	Sorafenib	Axitinib, Pazopanib, Sunitinib, Sorafenib	365	Retain first valid episode per person	60	0	0	1	None	(1) gastrointestinal cancer (2) pancreatic cancer (3) hepatocellular cancer (4) thyroid cancer (5) soft tissue cancer (6) any of cancers 1-5 (7) renal cell carcinoma (RCC) (8) any of cancers 1-5 and No RCC (9) RCC and None of cancers 1-5 (10) No RCC (11) No cancers 1-5	Any	365	Axitinib, Pazopanib, Sunitinib	Any	Exclude	0	0	Dummy

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Edition, Clinical Modification (ICD-10-CM), Healthcare Common Procedure Coding System (HCPCS) , and Current Procedural Terminology, Fourth Revision (CPT-4) codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."