

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

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).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

Overview for Request: cder_mpl1r_wp126

Request ID: cder_mpl1r_wp126_nsdp_v01

Request Description: The goal of this query was to estimate total cumulative exposure duration of febuxostat and allopurinol and cumulative exposure duration prior to switching between doses and generic names. This is report 3 of 3. Report 1 describes counts of individuals with gout diagnoses. Report 2 describes counts of febuxostat and allopurinol users and switching between doses and ULT drug products.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 6.0.0

Data Source: Data from January 1, 2009 to December 31, 2016 from 17 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed on October 25, 2018. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: This request was designed to calculate length of cumulative treatment episodes of febuxostat and allopurinol by generic name and dosage. Results were stratified by cumulative episode length, cumulative episode length by sex, and cumulative episode length by age group.

Exposures of Interest: The exposures of interest were febuxostat and allopurinol. Febuxostat exposure groups were defined by dispensings of 40 mg strength, 80 mg strength, and any dosage (40 or 80 mg). Allopurinol exposure groups were defined by dispensings of 100 mg strength, 300 mg strength, and any dosage (100, 200, or 300 mg and combination products). Exposure episodes were considered continuous if the gap in days supply was less than 30 days. Exposure episodes were included until the first occurrence of any of the following: 1) the end of the last exposure episode, 2) death, 3) disenrollment, or 4) end of Data Partner data availability. Cumulative exposure duration was calculated across all contributing enrollment spans. See Appendix B for a list of generic and brand names used to define exposures in this request.

Cohort Eligibility Criteria: Members included in the cohort were required to be enrolled in plans with medical and drug coverage for 183 days prior to the index dispensing date, during which gaps in coverage up to 45 days were allowed. Members were required to have a diagnosis of gout in the 183 days prior to the index dispensing date. See Appendix D for a 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) diagnosis codes used to define gout inclusion criteria. Index exposure episodes were excluded if there was evidence of febuxostat, allopurinol, probenecid, or pglotilase in the 6 months (183 days) prior to the exposure of interest. See Appendix C for a list of generic and brand names used to defined incidence criteria. The following age groups were included in the cohort: 21-44, 45-64, 65+ years.

Switching: Cumulative exposure duration prior to switching between doses and generic names was also assessed. The following switches among index exposure groups were captured:

- Febuxostat 40 mg, switch to 1) Febuxostat 80 mg, 2) Allopurinol 100 mg, or 3) Allopurinol 300 mg
- Febuxostat 80 mg, switch to 1) Febuxostat 40 mg, 2) Allopurinol 100 mg, or 3) Allopurinol 300 mg
- Febuxostat (any dose), switch to Allopurinol (any dose)
- Allopurinol 100 mg, switch to 1) Allopurinol 300 mg, 2) Febuxostat 40 mg, or 3) Febuxostat 80 mg
- Allopurinol 300 mg, switch to 1) Allopurinol 100 mg, 2) Febuxostat 40 mg, or 3) Febuxostat 80 mg
- Allopurinol (any dose), switch to Febuxostat (any dose)

Members included in the switching cohorts were required to have a dispensing of the switch exposure at any point after the index dispensing date. Exposure episodes were considered continuous if the gap in days supply was less than 30 days. Exposure episodes were included until the first occurrence of any of the following: 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability. Cumulative exposure duration was calculated across all contributing enrollment spans. See Appendix C for a list of generic and brand names used to define index exposures and switch exposures in this request.

Query End Date: The query period was January 1, 2009 to December 31, 2016, which binds index dates for initiation of cumulative exposure duration. However, cumulative episodes that began in the query period were allowed to continue past December 31, 2016 for Data Partners with additional data.

For cohorts observing cumulative exposure duration prior to switching, members were included in the cohort if they had a dispensing of the switch of interest after the index dispensing date. Due to varying dates of availability among the Data Partners in the SDD, this inclusion criteria may have occurred after the query period end date. To calculate the total cumulative exposure duration until the switch of interest, exposure episodes were not truncated at the query end date (December 31, 2016). See Appendix E for figures with further details.

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

Limitations: Algorithms used to define exposures and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. In addition, users were included in the switching analysis if there was evidence of the use of the switch exposure *at any point* following the index dispensing; thus, we cannot guarantee that the user was taking the index exposure at the time of the switch. If the index exposure ended before the switch drug was dispensed, episode duration would reflect the time until the episode end date.

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.

Table of Contents

<u>Glossary</u>	List of Terms Found in this Report and their Definitions
<u>Table 1a</u>	Distribution of Cumulative Exposure Duration, all Episodes, by Length Category
<u>Table 1b</u>	Descriptive Statistics of Cumulative Exposure Duration, all Episodes
<u>Table 2a</u>	Distribution of Cumulative Exposure Duration, all Episodes, by Length Category and Sex
<u>Table 2b</u>	Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Sex
<u>Table 3a</u>	Distribution of Cumulative Exposure Duration, all Episodes, by Length Category and Age Group
<u>Table 3b</u>	Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Age Group
<u>Table 4a</u>	Distribution of Cumulative Exposure Duration, all Episodes, by Length Category, Sex, and Age Group
<u>Table 4b</u>	Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Sex and Age Group
<u>Table 5a</u>	Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Length Category
<u>Table 5b</u>	Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date
<u>Table 6a</u>	Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Length Category and Sex
<u>Table 6b</u>	Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Sex
<u>Table 7a</u>	Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Length Category and Age Group
<u>Table 7b</u>	Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Age Group
<u>Table 8a</u>	Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Length Category, Sex, and Age Group
<u>Table 8b</u>	Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date, by Sex and Age Group
<u>Appendix A</u>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 30, 2018)
<u>Appendix B</u>	List of Generic and Brand Names Used to Define Exposures in this Request
<u>Appendix C</u>	List of Generic and Brand Names Used to Define Incidence Washout Criteria in this Request
<u>Appendix D</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) Diagnosis Codes Used to Define Inclusion Criteria in this Request
<u>Appendix E</u>	Figure Detailing Cumulative Exposure Duration, Censored at the Query End Date
<u>Appendix F</u>	Specifications Used in this Report

**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 (PDX), forms the Care Setting/PDX

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

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"

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

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 Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (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 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

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-

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. Distribution of Cumulative Exposure Duration, all Episodes, by Length Category

Exposure Duration	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Febuxostat 40 mg	66,682	100	2,351	3.5	22,911	34.4	10,034	15.0	10,106	15.2	15,498	23.2	4,535	6.8	1,247	1.9
Febuxostat 80 mg	14,657	100	432	2.9	4,810	32.8	2,376	16.2	2,531	17.3	3,485	23.8	829	5.7	194	1.3
Febuxostat (any dose) ¹	80,083	100	2,574	3.2	23,698	29.6	11,286	14.1	12,566	15.7	21,383	26.7	6,685	8.3	1,891	2.4
Allopurinol 100 mg	681,171	100	30,203	4.4	186,651	27.4	96,870	14.2	105,206	15.4	177,500	26.1	62,563	9.2	22,178	3.3
Allopurinol 300 mg	406,322	100	10,580	2.6	105,697	26	53,066	13.1	61,888	15.2	113,619	28.0	43,928	10.8	17,544	4.3
Allopurinol (any dose) ²	1,049,461	100	29,186	2.8	229,536	21.9	129,827	12.4	158,955	15.1	319,258	30.4	130,417	12.4	52,282	5.0

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 1b. Descriptive Statistics of Cumulative Exposure Duration, All Episodes

Exposure	Total Patients	Mean (days)	Standard					Max (days)
			Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	
Febuxostat 40 mg	66,682	363	459	1	60	165	496	3,246
Febuxostat 80 mg	14,657	343.8	420.09	1	60	180	460	3,098
Febuxostat (any dose) ¹	80,083	418	491.2	1	62	210	600	3,274
Allopurinol 100 mg	681,171	446.9	529.43	1	75	216	637	3,463
Allopurinol 300 mg	406,322	505.9	568.96	1	90	270	745	3,441
Allopurinol (any dose) ²	1,049,461	557.7	589.57	1	93	334	839	3,464

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 2a. Distribution of Cumulative Exposure Duration, all Episodes, by Length Category and Sex

Exposure Duration	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			month	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Febuxostat 40 mg	66,682	100	2,351	100	22,911	100	10,034	100	10,106	100	15,498	100	4,535	100	1,247	100
Female	25,485	38.2	946	40.2	8,225	35.9	3,647	36.3	3,880	38.4	6,277	40.5	2,009	44.3	501	40.2
Male	41,195	61.8	1,405	59.8	14,685	64.1	6,386	63.6	6,226	61.6	9,221	59.5	2,526	55.7	746	59.8
Other	2	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0
Febuxostat 80 mg	14,657	100	432	100	4,810	100	2,376	100	2,531	100	3,485	100	829	100	194	100
Female	3,990	27.2	125	28.9	1,267	26.3	586	24.7	713	28.2	976	28	256	30.9	67	34.5
Male	10,667	72.8	307	71.1	3,543	73.7	1,790	75.3	1,818	71.8	2,509	72	573	69.1	127	65.5
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Febuxostat (any dose) ¹	80,083	100	2,574	100	23,698	100	11,286	100	12,566	100	21,383	100	6,685	100	1,891	100
Female	29,120	36.4	1,010	39.2	8,256	34.8	3,886	34.4	4,549	36.2	8,006	37.4	2,725	40.8	688	36.4
Male	50,961	63.6	1,564	60.8	15,442	65.2	7,399	65.6	8,017	63.8	13,376	62.6	3,960	59.2	1,203	63.6
Other	2	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0
Allopurinol 100 mg	681,171	100	30,203	100	186,651	100	96,870	100	105,206	100	177,500	100	62,563	100	22,178	100
Female	260,528	38.2	10,536	34.9	67,368	36.1	35,044	36.2	39,304	37.4	72,202	40.7	27,090	43.3	8,984	40.5
Male	420,621	61.7	19,667	65.1	119,280	63.9	61,825	63.8	65,895	62.6	105,291	59.3	35,470	56.7	13,193	59.5
Other	22	0	0	0	3	0	1	0	7	0	7	0	3	0	1	0
Allopurinol 300 mg	406,322	100	10,580	100	105,697	100	53,066	100	61,888	100	113,619	100	43,928	100	17,544	100
Female	109,322	26.9	3,023	28.6	30,505	28.9	13,876	26.1	15,862	25.6	29,759	26.2	11,996	27.3	4,301	24.5
Male	296,982	73.1	7,556	71.4	75,189	71.1	39,186	73.8	46,023	74.4	83,856	73.8	31,930	72.7	13,242	75.5
Other	18	0	1	0	3	0	4	0	3	0	4	0	2	0	1	0
Allopurinol (any dose) ²	1,049,461	100	29,186	100	229,536	100	129,827	100	158,955	100	319,258	100	130,417	100	52,282	100
Female	359,523	34.3	10,203	35	79,081	34.5	43,193	33.3	52,690	33.1	110,321	34.6	46,967	36	17,068	32.6
Male	689,900	65.7	18,982	65	150,449	65.5	86,631	66.7	106,257	66.8	208,924	65.4	83,445	64	35,212	67.4
Other	38	0	1	0	6	0	3	0	8	0	13	0	5	0	2	0

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 2b. Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Sex

Exposure	Total Patients	Standard						Max (days)
		Mean (days)	Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	
Febuxostat 40 mg	66,682	363	459	1	60	165	496	3,246
Female	25,485	387.4	469.97	1	60	181	545	3,027
Male	41,195	347.9	451.43	1	60	153	465	3,246
Other	2	105	106.07	30	30	105	180	180
Febuxostat 80 mg	14,657	343.8	420.09	1	60	180	460	3,098
Female	3,990	363.3	438.7	1	60	184	488	3,098
Male	10,667	336.6	412.7	1	60	172	450	3,080
Other	0	-	-	-	-	-	-	-
Febuxostat (any dose) ¹	80,083	418	491.2	1	62	210	600	3,274
Female	29,120	435.8	496.6	1	65	229	640	3,274
Male	50,961	407.9	487.82	1	61	203	575	3,246
Other	2	345	233.35	180	180	345	510	510
Allopurinol 100 mg	681,171	446.9	529.43	1	75	216	637	3,463
Female	260,528	477.3	540.19	1	90	254	703	3,463
Male	420,621	428	521.75	1	67	201	597	3,450
Other	22	570.4	546.65	30	237	357	858	2,217
Allopurinol 300 mg	406,322	505.9	568.96	1	90	270	745	3,441
Female	109,322	492.1	556.96	1	90	261	733	3,427
Male	296,982	511	573.22	1	90	276	749	3,441
Other	18	515.4	609.34	14	100	273	767	2,278
Allopurinol (any dose) ²	1,049,461	557.7	589.57	1	93	334	839	3,464
Female	359,523	561.1	582.89	1	92	345	856	3,463
Male	689,900	556	593.01	1	94	330	830	3,464
Other	38	600.8	593.97	14	181	397	858	2,278

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 3a. Distribution of Cumulative Exposure Duration, all Episodes, by Length Category and Age Group

Exposure Duration	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			month	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Febuxostat 40 mg	66,682	100	2,351	100	22,911	100	10,034	100	10,106	100	15,498	100	4,535	100	1,247	100
21-44 Years	5,041	7.6	180	7.7	2,334	10.2	775	7.7	681	6.7	812	5.2	186	4.1	73	5.9
45-64 Years	16,447	24.7	583	24.8	6,203	27.1	2,561	25.5	2,398	23.7	3,462	22.3	916	20.2	324	26
65+ Years	45,194	67.8	1,588	67.5	14,374	62.7	6,698	66.8	7,027	69.5	11,224	72.4	3,433	75.7	850	68.2
Febuxostat 80 mg	14,657	100	432	100	4,810	100	2,376	100	2,531	100	3,485	100	829	100	194	100
21-44 Years	1,595	10.9	59	13.7	610	12.7	277	11.7	266	10.5	313	9	56	6.8	14	7.2
45-64 Years	4,679	31.9	124	28.7	1,686	35.1	757	31.9	785	31	1,028	29.5	230	27.7	69	35.6
65+ Years	8,383	57.2	249	57.6	2,514	52.3	1,342	56.5	1,480	58.5	2,144	61.5	543	65.5	111	57.2
Febuxostat (any dose) ¹	80,083	100	2,574	100	23,698	100	11,286	100	12,566	100	21,383	100	6,685	100	1,891	100
21-44 Years	6,503	8.1	226	8.8	2,515	10.6	972	8.6	966	7.7	1,367	6.4	333	5	124	6.6
45-64 Years	20,722	25.9	657	25.5	6,690	28.2	3,003	26.6	3,176	25.3	5,161	24.1	1,483	22.2	552	29.2
65+ Years	52,858	66	1,691	65.7	14,493	61.2	7,311	64.8	8,424	67	14,855	69.5	4,869	72.8	1,215	64.3
Allopurinol 100 mg	681,171	100	30,203	100	186,651	100	96,870	100	105,206	100	177,500	100	62,563	100	22,178	100
21-44 Years	51,313	7.5	3,074	10.2	20,152	10.8	8,709	9	7,616	7.2	8,865	5	2,143	3.4	754	3.4
45-64 Years	169,497	24.9	8,113	26.9	51,612	27.7	26,431	27.3	26,809	25.5	39,781	22.4	12,157	19.4	4,594	20.7
65+ Years	460,361	67.6	19,016	63	114,887	61.6	61,730	63.7	70,781	67.3	128,854	72.6	48,263	77.1	16,830	75.9
Allopurinol 300 mg	406,322	100	10,580	100	105,697	100	53,066	100	61,888	100	113,619	100	43,928	100	17,544	100
21-44 Years	41,978	10.3	1,267	12	14,475	13.7	6,527	12.3	6,665	10.8	9,351	8.2	2,635	6	1,058	6
45-64 Years	129,899	32	3,267	30.9	35,078	33.2	18,400	34.7	20,722	33.5	35,143	30.9	11,997	27.3	5,292	30.2
65+ Years	234,445	57.7	6,046	57.1	56,144	53.1	28,139	53	34,501	55.7	69,125	60.8	29,296	66.7	11,194	63.8
Allopurinol (any dose) ²	1,049,461	100	29,186	100	229,536	100	129,827	100	158,955	100	319,258	100	130,417	100	52,282	100
21-44 Years	88,682	8.5	2,915	10	27,643	12	13,349	10.3	14,078	8.9	21,626	6.8	6,464	5	2,607	5
45-64 Years	286,874	27.3	7,815	26.8	67,670	29.5	38,460	29.6	45,352	28.5	83,457	26.1	30,504	23.4	13,616	26
65+ Years	673,905	64.2	18,456	63.2	134,223	58.5	78,018	60.1	99,525	62.6	214,175	67.1	93,449	71.7	36,059	69

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 3b. Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Age Group

Exposures	Total Patients	Standard						
		Mean (days)	Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	
Febuxostat 40 mg	66,682	363	459	1	60	165	496	3,246
21-44 Years	5,041	259.7	396.72	1	30	92	298	3,099
45-64 Years	16,447	334.1	455.62	1	41	135	433	3,246
65+ Years	45,194	385	464.52	1	60	182	542	3,184
Febuxostat 80 mg	14,657	343.8	420.09	1	60	180	460	3,098
21-44 Years	1,595	275.2	363.59	1	30	129	354	2,642
45-64 Years	4,679	323.3	418.81	1	60	151	428	2,955
65+ Years	8,383	368.3	428.73	1	76	190	506	3,098
Febuxostat (any dose) ¹	80,083	418	491.2	1	62	210	600	3,274
21-44 Years	6,503	323.2	444.74	1	30	135	420	3,099
45-64 Years	20,722	396.8	497.81	1	60	183	547	3,246
65+ Years	52,858	438	492.34	1	79	238	640	3,274
Allopurinol 100 mg	681,171	446.9	529.43	1	75	216	637	3,463
21-44 Years	51,313	279.7	407.76	1	30	107	327	3,275
45-64 Years	169,497	391.3	501.16	1	60	180	523	3,450
65+ Years	460,361	486	545.85	1	90	267	716	3,463
Allopurinol 300 mg	406,322	505.9	568.96	1	90	270	745	3,441
21-44 Years	41,978	366.4	484.68	1	60	164	473	3,329
45-64 Years	129,899	474.3	560.39	1	90	243	669	3,441
65+ Years	234,445	548.4	582.34	1	90	318	832	3,441
Allopurinol (any dose) ²	1,049,461	557.7	589.57	1	93	334	839	3,464
21-44 Years	88,682	403	509.79	1	60	187	543	3,364
45-64 Years	286,874	521.3	585.36	1	90	292	755	3,464
65+ Years	673,905	593.6	596.85	1	110	381	907	3,463

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 4a. Distribution of Cumulative Exposure Duration, all Episodes, by Length Category, Sex, and Age Group

Exposure Duration	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Febuxostat 40 mg	66,682	100	2,351	100	22,911	100	10,034	100	10,106	100	15,498	100	4,535	100	1,247	100
Female	25,485	38.2	946	40.2	8,225	35.9	3,647	36.3	3,880	38.4	6,277	40.5	2,009	44.3	501	40.2
21-44 Years	364	0.5	15	0.6	167	0.7	55	0.5	44	0.4	62	0.4	15	0.3	6	0.5
45-64 Years	3,720	5.6	131	5.6	1,292	5.6	552	5.5	580	5.7	859	5.5	240	5.3	66	5.3
65+ Years	21,401	32.1	800	34	6,766	29.5	3,040	30.3	3,256	32.2	5,356	34.6	1,754	38.7	429	34.4
Male	41,195	61.8	1,405	59.8	14,685	64.1	6,386	63.6	6,226	61.6	9,221	59.5	2,526	55.7	746	59.8
21-44 Years	4,677	7	165	7	2,167	9.5	720	7.2	637	6.3	750	4.8	171	3.8	67	5.4
45-64 Years	12,726	19.1	452	19.2	4,911	21.4	2,008	20	1,818	18	2,603	16.8	676	14.9	258	20.7
65+ Years	23,792	35.7	788	33.5	7,607	33.2	3,658	36.5	3,771	37.3	5,868	37.9	1,679	37	421	33.8
Other	2	0	0	-	1	0	1	0	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	1	0	0	-	0	-	1	0	0	-	0	-	0	-	0	-
65+ Years	1	0	0	-	1	0	0	-	0	-	0	-	0	-	0	-
Febuxostat 80 mg	14,657	100	432	100	4,810	100	2,376	100	2,531	100	3,485	100	829	100	194	100
Female	3,990	27.2	125	28.9	1,267	26.3	586	24.7	713	28.2	976	28	256	30.9	67	34.5
21-44 Years	84	0.6	3	0.7	34	0.7	7	0.3	17	0.7	18	0.5	4	0.5	1	0.5
45-64 Years	795	5.4	28	6.5	287	6	106	4.5	146	5.8	184	5.3	34	4.1	10	5.2
65+ Years	3,111	21.2	94	21.8	946	19.7	473	19.9	550	21.7	774	22.2	218	26.3	56	28.9
Male	10,667	72.8	307	71.1	3,543	73.7	1,790	75.3	1,818	71.8	2,509	72	573	69.1	127	65.5
21-44 Years	1,511	10.3	56	13	576	12	270	11.4	249	9.8	295	8.5	52	6.3	13	6.7
45-64 Years	3,884	26.5	96	22.2	1,399	29.1	651	27.4	639	25.2	844	24.2	196	23.6	59	30.4
65+ Years	5,272	36	155	35.9	1,568	32.6	869	36.6	930	36.7	1,370	39.3	325	39.2	55	28.4
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-

Table 4a. Distribution of Cumulative Exposure Duration, all Episodes, by Length Category, Sex, and Age Group

Exposure Duration	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			month	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Febuxostat (any dose) ¹	80,083	100	2,574	100	23,698	100	11,286	100	12,566	100	21,383	100	6,685	100	1,891	100
Female	29,120	36.4	1,010	39.2	8,256	34.8	3,886	34.4	4,549	36.2	8,006	37.4	2,725	40.8	688	36.4
21-44 Years	441	0.6	17	0.7	174	0.7	59	0.5	59	0.5	98	0.5	25	0.4	9	0.5
45-64 Years	4,459	5.6	154	6	1,371	5.8	602	5.3	723	5.8	1,152	5.4	350	5.2	107	5.7
65+ Years	24,220	30.2	839	32.6	6,711	28.3	3,225	28.6	3,767	30	6,756	31.6	2,350	35.2	572	30.2
Male	50,961	63.6	1,564	60.8	15,442	65.2	7,399	65.6	8,017	63.8	13,376	62.6	3,960	59.2	1,203	63.6
21-44 Years	6,062	7.6	209	8.1	2,341	9.9	913	8.1	907	7.2	1,269	5.9	308	4.6	115	6.1
45-64 Years	16,262	20.3	503	19.5	5,319	22.4	2,400	21.3	2,453	19.5	4,009	18.7	1,133	16.9	445	23.5
65+ Years	28,637	35.8	852	33.1	7,782	32.8	4,086	36.2	4,657	37.1	8,098	37.9	2,519	37.7	643	34
Other	2	0	0	-	0	-	1	0	0	-	1	0	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	1	0	0	-	0	-	1	0	0	-	0	-	0	-	0	-
65+ Years	1	0	0	-	0	-	0	-	0	-	1	0	0	-	0	-
Allopurinol 100 mg	681,171	100	30,203	100	186,651	100	96,870	100	105,206	100	177,500	100	62,563	100	22,178	100
Female	260,528	38.2	10,536	34.9	67,368	36.1	35,044	36.2	39,304	37.4	72,202	40.7	27,090	43.3	8,984	40.5
21-44 Years	4,387	0.6	248	0.8	1,766	0.9	651	0.7	610	0.6	811	0.5	236	0.4	65	0.3
45-64 Years	41,058	6	1,808	6	11,936	6.4	6,098	6.3	6,370	6.1	10,276	5.8	3,413	5.5	1,157	5.2
65+ Years	215,083	31.6	8,480	28.1	53,666	28.8	28,295	29.2	32,324	30.7	61,115	34.4	23,441	37.5	7,762	35
Male	420,621	61.7	19,667	65.1	119,280	63.9	61,825	63.8	65,895	62.6	105,291	59.3	35,470	56.7	13,193	59.5
21-44 Years	46,926	6.9	2,826	9.4	18,386	9.9	8,058	8.3	7,006	6.7	8,054	4.5	1,907	3	689	3.1
45-64 Years	128,432	18.9	6,305	20.9	39,674	21.3	20,333	21	20,437	19.4	29,503	16.6	8,743	14	3,437	15.5
65+ Years	245,263	36	10,536	34.9	61,220	32.8	33,434	34.5	38,452	36.5	67,734	38.2	24,820	39.7	9,067	40.9
Other	22	0	0	-	3	0	1	0	7	0	7	0	3	0	1	0
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	7	0	0	-	2	0	0	-	2	0	2	0	1	0	0	-
65+ Years	15	0	0	-	1	0	1	0	5	0	5	0	2	0	1	0

Table 4a. Distribution of Cumulative Exposure Duration, all Episodes, by Length Category, Sex, and Age Group

Exposure Duration	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Allopurinol 300 mg	406,322	100	10,580	100	105,697	100	53,066	100	61,888	100	113,619	100	43,928	100	17,544	100
Female	109,322	26.9	3,023	28.6	30,505	28.9	13,876	26.1	15,862	25.6	29,759	26.2	11,996	27.3	4,301	24.5
21-44 Years	2,514	0.6	81	0.8	1,042	1	374	0.7	336	0.5	471	0.4	157	0.4	53	0.3
45-64 Years	22,484	5.5	627	5.9	6,571	6.2	3,202	6	3,393	5.5	5,818	5.1	2,085	4.7	788	4.5
65+ Years	84,324	20.8	2,315	21.9	22,892	21.7	10,300	19.4	12,133	19.6	23,470	20.7	9,754	22.2	3,460	19.7
Male	296,982	73.1	7,556	71.4	75,189	71.1	39,186	73.8	46,023	74.4	83,856	73.8	31,930	72.7	13,242	75.5
21-44 Years	39,462	9.7	1,186	11.2	13,432	12.7	6,153	11.6	6,329	10.2	8,879	7.8	2,478	5.6	1,005	5.7
45-64 Years	107,406	26.4	2,640	25	28,506	27	15,196	28.6	17,327	28	29,322	25.8	9,912	22.6	4,503	25.7
65+ Years	150,114	36.9	3,730	35.3	33,251	31.5	17,837	33.6	22,367	36.1	45,655	40.2	19,540	44.5	7,734	44.1
Other	18	0	1	0	3	0	4	0	3	0	4	0	2	0	1	0
21-44 Years	2	0	0	-	1	0	0	-	0	-	1	0	0	-	0	-
45-64 Years	9	0	0	-	1	0	2	0	2	0	3	0	0	-	1	0
65+ Years	7	0	1	0	1	0	2	0	1	0	0	-	2	0	0	-
Allopurinol (any dose) ²	1,049,461	100	29,186	100	229,536	100	129,827	100	158,955	100	319,258	100	130,417	100	52,282	100
Female	359,523	34.3	10,203	35	79,081	34.5	43,193	33.3	52,690	33.1	110,321	34.6	46,967	36	17,068	32.6
21-44 Years	6,697	0.6	265	0.9	2,432	1.1	938	0.7	948	0.6	1,468	0.5	485	0.4	161	0.3
45-64 Years	61,644	5.9	1,795	6.2	14,950	6.5	8,241	6.3	9,378	5.9	17,793	5.6	6,822	5.2	2,665	5.1
65+ Years	291,182	27.7	8,143	27.9	61,699	26.9	34,014	26.2	42,364	26.7	91,060	28.5	39,660	30.4	14,242	27.2
Male	689,900	65.7	18,982	65	150,449	65.5	86,631	66.7	106,257	66.8	208,924	65.4	83,445	64	35,212	67.4
21-44 Years	81,983	7.8	2,650	9.1	25,210	11	12,411	9.6	13,130	8.3	20,157	6.3	5,979	4.6	2,446	4.7
45-64 Years	225,215	21.5	6,020	20.6	52,717	23	30,218	23.3	35,970	22.6	65,659	20.6	23,681	18.2	10,950	20.9
65+ Years	382,702	36.5	10,312	35.3	72,522	31.6	44,002	33.9	57,157	36	123,108	38.6	53,785	41.2	21,816	41.7
Other	38	0	1	0	6	0	3	0	8	0	13	0	5	0	2	0
21-44 Years	2	0	0	-	1	0	0	-	0	-	1	0	0	-	0	-
45-64 Years	15	0	0	-	3	0	1	0	4	0	5	0	1	0	1	0
65+ Years	21	0	1	0	2	0	2	0	4	0	7	0	4	0	1	0

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 4b. Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard					Max (days)
			Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	
Febuxostat 40 mg	66,682	363	459	1	60	165	496	3,246
Female	25,485	387.36	469.97	1	60	181	545	3,027
21-44 Years	364	270.18	406.86	3	30	92	316	2,472
45-64 Years	3,720	354.09	447.19	1	60	162	487	2,954
65+ Years	21,401	395.14	474.32	1	60	186	560	3,027
Male	41,195	347.94	451.43	1	60	153	465	3,246
21-44 Years	4,677	258.88	395.96	1	30	92	297	3,099
45-64 Years	12,726	328.28	457.93	1	32	128	419	3,246
65+ Years	23,792	375.96	455.34	1	60	180	527	3,184
Other	2	105	106.07	30	30	105	180	180
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	1	180	-	180	180	180	180	180
65+ Years	1	30	-	30	30	30	30	30
Febuxostat 80 mg	14,657	343.83	420.09	1	60	180	460	3,098
Female	3,990	363.28	438.7	1	60	184	488	3,098
21-44 Years	84	309.46	396.65	4	30	142	376	1,890
45-64 Years	795	312.17	397.08	1	50	167	443	2,376
65+ Years	3,111	377.79	448.82	1	69	193	505	3,098
Male	10,667	336.55	412.7	1	60	172	450	3,080
21-44 Years	1,511	273.31	361.71	1	30	128	351	2,642
45-64 Years	3,884	325.59	423.13	1	60	150	427	2,955
65+ Years	5,272	362.76	416.37	1	83	189	507	3,080
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-
Febuxostat (any dose) ¹	80,083	418.05	491.2	1	62	210	600	3,274
Female	29,120	435.81	496.6	1	65	229	640	3,274
21-44 Years	441	334.56	447.26	3	30	132	438	2,472
45-64 Years	4,459	406.01	485.74	1	60	204	581	3,122
65+ Years	24,220	443.14	499.04	1	70	240	652	3,274
Male	50,961	407.9	487.82	1	61	203	575	3,246
21-44 Years	6,062	322.36	444.58	1	30	136	419	3,099
45-64 Years	16,262	394.35	501.07	1	60	180	540	3,246
65+ Years	28,637	433.69	486.57	1	86	237	631	3,184
Other	2	345	233.35	180	180	345	510	510
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	1	180	-	180	180	180	180	180
65+ Years	1	510	-	510	510	510	510	510

Table 4b. Descriptive Statistics of Cumulative Exposure Duration, all Episodes, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard					
			Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Allopurinol 100 mg	681,171	446.87	529.43	1	75	216	637	3,463
Female	260,528	477.33	540.19	1	90	254	703	3,463
21-44 Years	4,387	298.44	423.98	1	30	113	373	3,113
45-64 Years	41,058	418.36	512.71	1	61	198	585	3,443
65+ Years	215,083	492.23	545.97	1	90	270	732	3,463
Male	420,621	428	521.75	1	67	201	597	3,450
21-44 Years	46,926	277.93	406.17	1	30	106	322	3,275
45-64 Years	128,432	382.69	497.11	1	60	180	504	3,450
65+ Years	245,263	480.43	545.68	1	90	258	700	3,425
Other	22	570.36	546.65	30	237	357	858	2,217
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	7	436.71	442.05	30	60	314	569	1,328
65+ Years	15	632.73	592.79	90	237	377	963	2,217
Allopurinol 300 mg	406,322	505.91	568.96	1	90	270	745	3,441
Female	109,322	492.08	556.96	1	90	261	733	3,427
21-44 Years	2,514	326.95	462.36	2	30	120	400	2,832
45-64 Years	22,484	451.99	542.07	1	75	215	644	3,427
65+ Years	84,324	507.69	562.1	1	90	270	763	3,330
Male	296,982	510.99	573.22	1	90	276	749	3,441
21-44 Years	39,462	368.93	485.97	1	60	168	477	3,329
45-64 Years	107,406	478.91	564.03	1	90	249	673	3,441
65+ Years	150,114	571.3	592.19	1	94	352	867	3,441
Other	18	515.39	609.34	14	100	273	767	2,278
21-44 Years	2	413.5	499.92	60	60	414	767	767
45-64 Years	9	577.22	680.88	51	150	362	586	2,278
65+ Years	7	465	616.49	14	30	181	1,244	1,468
Allopurinol (any dose) ²	1,049,461	557.75	589.57	1	93	334	839	3,464
Female	359,523	561.07	582.89	1	92	345	856	3,463
21-44 Years	6,697	367.12	486.07	1	48	150	483	3,164
45-64 Years	61,644	514.52	573.47	1	90	284	759	3,443
65+ Years	291,182	575.38	585.59	1	100	361	883	3,463
Male	689,900	556.02	593.01	1	94	330	830	3,464
21-44 Years	81,983	405.97	511.57	1	60	191	548	3,364
45-64 Years	225,215	523.12	588.56	1	90	293	753	3,464
65+ Years	382,702	607.52	604.91	1	120	393	925	3,456
Other	38	600.84	593.97	14	181	397	858	2,278
21-44 Years	2	414.5	498.51	62	62	415	767	767
45-64 Years	15	582.53	599.69	30	131	362	773	2,278
65+ Years	21	631.67	619.51	14	200	416	963	2,217

¹Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

²Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 5a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
Febuxostat 40 mg																
Switch to Febuxostat 80 mg	9,598	100	902	9.4	3,475	36.2	1,920	20	1,548	16.1	1,479	15.4	242	2.5	32	0.3
Switch to Allopurinol 100 mg	11,354	100	1,433	12.6	4,712	41.5	1,703	15	1,492	13.1	1,682	14.8	292	2.6	40	0.4
Switch to Allopurinol 300 mg	7,464	100	723	9.7	3,359	45	1,201	16.1	961	12.9	1,023	13.7	174	2.3	23	0.3
Febuxostat 80 mg																
Switch to Febuxostat 40 mg	1,994	100	132	6.6	581	29.1	358	18	348	17.5	468	23.5	90	4.5	17	0.9
Switch to Allopurinol 100 mg	1,836	100	164	8.9	772	42	297	16.2	271	14.8	291	15.8	34	1.9	7	0.4
Switch to Allopurinol 300 mg	2,066	100	173	8.4	894	43.3	326	15.8	289	14	331	16	47	2.3	6	0.3
Febuxostat (any dose)²																
Switch to Allopurinol (any dose) ³	19,363	100	2,261	11.7	7,220	37.3	2,930	15.1	2,747	14.2	3,433	17.7	671	3.5	101	0.5
Allopurinol 100 mg																
Switch to Allopurinol 300 mg	145,823	100	22,217	15.2	46,871	32.1	26,567	18.2	22,379	15.3	22,660	15.5	4,364	3	765	0.5
Switch to Febuxostat 40 mg	32,022	100	3,785	11.8	11,962	37.4	5,562	17.4	4,786	14.9	4,820	15.1	924	2.9	183	0.6
Switch to Febuxostat 80 mg	10,311	100	726	7	4,390	42.6	1,921	18.6	1,594	15.5	1,453	14.1	200	1.9	27	0.3
Allopurinol 300 mg																
Switch to Allopurinol 100 mg	63,279	100	8,053	12.7	16,410	25.9	9,159	14.5	9,965	15.7	14,725	23.3	4,043	6.4	924	1.5
Dswitch to Febuxostat 40 mg	16,821	100	1,563	9.3	6,577	39.1	2,850	16.9	2,403	14.3	2,756	16.4	571	3.4	101	0.6
Switch to Febuxostat 80 mg	8,437	100	504	6	3,264	38.7	1,539	18.2	1,350	16	1,443	17.1	282	3.3	55	0.7
Allopurinol (any dose)³																
Switch to Febuxostat (any dose) ²	56,401	100	5,240	9.3	17,736	31.4	9,669	17.1	9,180	16.3	11,370	20.2	2,654	4.7	552	1

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 5b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Febuxostat 40 mg								
Switch to Febuxostat 80 mg	9,598	223.9	300.27	1	46	108	267	2,781
Switch to Allopurinol 100 mg	11,354	209.4	308.82	1	30	90	244	2,533
Switch to Allopurinol 300 mg	7,464	200.9	298.33	1	30	90	219	2,536
Febuxostat 80 mg								
Switch to Febuxostat 40 mg	1,994	316.5	383.14	1	60	173	433	2,498
Switch to Allopurinol 100 mg	1,836	215.8	298.07	1	30	90	264	2,162
Switch to Allopurinol 300 mg	2,066	211.6	293.31	1	30	90	270	2,055
Febuxostat (any dose)²								
Switch to Allopurinol (any dose) ³	19,363	247.3	345.58	1	30	95	308	2,536
Allopurinol 100 mg								
Switch to Allopurinol 300 mg	145,823	230.9	329.31	1	32	100	272	3,226
Switch to Febuxostat 40 mg	32,022	228.2	328.22	1	30	93	270	2,903
Switch to Febuxostat 80 mg	10,311	207.1	284.08	1	30	92	245	2,656
Allopurinol 300 mg								
Switch to Allopurinol 100 mg	63,279	346.2	441.82	1	48	165	472	3,312
Switch to Febuxostat 40 mg	16,821	244.4	344.55	1	31	97	285	3,114
Switch to Febuxostat 80 mg	8,437	253.1	340.19	1	57	120	304	2,571
Allopurinol (any dose)³								
Switch to Febuxostat (any dose) ²	56,401	296.8	389.02	1	53	134	378	3,114

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 6a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category and Sex

Exposure	Number of Patients											
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years	
			months	%	months	%	months	%	<1 year	%	years	%
Febuxostat 40 mg												
Switch to Febuxostat 80 mg	9,598	100	902	100	3,475	100	1,920	100	1,548	100	1,479	100
Female	2,980	31	275	30.5	1,052	30.3	567	29.5	476	30.7	518	35
Male	6,617	68.9	626	69.4	2,423	69.7	1,353	70.5	1,072	69.3	961	65
Other	1	0	1	0.1	0	0	0	0	0	0	0	0
Switch to Allopurinol 100 mg	11,354	100	1,433	100	4,712	100	1,703	100	1,492	100	1,682	100
Female	4,626	40.7	661	46.1	1,809	38.4	690	40.5	583	39.1	733	43.6
Male	6,727	59.2	772	53.9	2,902	61.6	1,013	59.5	909	60.9	949	56.4
Other	1	0	0	0	1	0	0	0	0	0	0	0
Switch to Allopurinol 300 mg	7,464	100	723	100	3,359	100	1,201	100	961	100	1,023	100
Female	2,110	28.3	229	31.7	905	26.9	348	29	252	26.2	322	31.5
Male	5,354	71.7	494	68.3	2,454	73.1	853	71	709	73.8	701	68.5
Other	0	0	0	0	0	0	0	0	0	0	0	0
Febuxostat 80 mg												
Switch to Febuxostat 40 mg	1,994	100	132	100	581	100	358	100	348	100	468	100
Female	676	33.9	39	29.5	198	34.1	94	26.3	125	35.9	176	37.6
Male	1,318	66.1	93	70.5	383	65.9	264	73.7	223	64.1	292	62.4
Other	0	0	0	0	0	0	0	0	0	0	0	0
Switch to Allopurinol 100 mg	1,836	100	164	100	772	100	297	100	271	100	291	100
Female	550	30	56	34.1	238	30.8	77	25.9	83	30.6	85	29.2
Male	1,286	70	108	65.9	534	69.2	220	74.1	188	69.4	206	70.8
Other	0	0	0	0	0	0	0	0	0	0	0	0
Switch to Allopurinol 300 mg	2,066	100	173	100	894	100	326	100	289	100	331	100
Female	444	21.5	53	30.6	183	20.5	50	15.3	65	22.5	77	23.3
Male	1,622	78.5	120	69.4	711	79.5	276	84.7	224	77.5	254	76.7
Other	0	0	0	0	0	0	0	0	0	0	0	0
Febuxostat (any dose)²												
Switch to Allopurinol (any dose) ³	19,363	100	2,261	100	7,220	100	2,930	100	2,747	100	3,433	100
Female	6,745	34.8	928	41	2,423	33.6	968	33	917	33.4	1,242	36.2
Male	12,617	65.2	1,333	59	4,797	66.4	1,962	67	1,830	66.6	2,190	63.8
Other	1	0	0	0	0	0	0	0	0	1	0	0

Table 6a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category and Sex

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years			
			month	%	months	%	months	%	<1 year	%	years	%	years	%		
Allopurinol 100 mg																
Switch to Allopurinol 300 mg	145,823	100	22,217	100	46,871	100	26,567	100	22,379	100	22,660	100	4,364	100	765	100
Female	42,738	29.3	6,362	28.6	13,010	27.8	7,401	27.9	6,584	29.4	7,530	33.2	1,606	36.8	245	32
Male	103,083	70.7	15,855	71.4	33,861	72.2	19,166	72.1	15,793	70.6	15,130	66.8	2,758	63.2	520	68
Other	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Switch to Febuxostat 40 mg	32,022	100	3,785	100	11,962	100	5,562	100	4,786	100	4,820	100	924	100	183	100
Female	13,233	41.3	1,710	45.2	4,978	41.6	2,207	39.7	1,863	38.9	1,979	41.1	425	46	71	39
Male	18,787	58.7	2,075	54.8	6,984	58.4	3,355	60.3	2,921	61	2,841	58.9	499	54	112	61
Other	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Switch to Febuxostat 80 mg	10,311	100	726	100	4,390	100	1,921	100	1,594	100	1,453	100	200	100	27	100
Female	3,284	31.8	248	34.2	1,417	32.3	563	29.3	495	31.1	481	33.1	71	35.5	9	33
Male	7,026	68.1	478	65.8	2,973	67.7	1,358	70.7	1,098	68.9	972	66.9	129	64.5	18	67
Other	1	0	0	0	0	0	0	0	1	0.1	0	0	0	0	0	0
Allopurinol 300 mg																
Switch to Allopurinol 100 mg	63,279	100	8,053	100	16,410	100	9,159	100	9,965	100	14,725	100	4,043	100	924	100
Female	19,526	30.9	2,430	30.2	5,449	33.2	2,728	29.8	2,932	29.4	4,456	30.3	1,271	31.4	260	28
Male	43,747	69.1	5,623	69.8	10,959	66.8	6,430	70.2	7,033	70.6	10,266	69.7	2,772	68.6	664	72
Other	6	0	0	0	2	0	1	0	0	0	3	0	0	0	0	0
Switch to Febuxostat 40 mg	16,821	100	1,563	100	6,577	100	2,850	100	2,403	100	2,756	100	571	100	101	100
Female	5,503	32.7	629	40.2	2,463	37.4	868	30.5	596	24.8	751	27.2	174	30.5	22	22
Male	11,318	67.3	934	59.8	4,114	62.6	1,982	69.5	1,807	75.2	2,005	72.8	397	69.5	79	78
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Switch to Febuxostat 80 mg	8,437	100	504	100	3,264	100	1,539	100	1,350	100	1,443	100	282	100	55	100
Female	2,042	24.2	148	29.4	916	28.1	345	22.4	253	18.7	302	20.9	64	22.7	14	26
Male	6,395	75.8	356	70.6	2,348	71.9	1,194	77.6	1,097	81.3	1,141	79.1	218	77.3	41	75
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 6a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category and Sex

Exposure	Number of Patients															
			<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
	Total	%	month	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Allopurinol (any dose) ³																
Switch to Febuxostat (any dose) ²	56,401	100	5,240	100	17,736	100	9,669	100	9,180	100	11,370	100	2,654	100	552	100
Female	20,659	36.6	2,281	43.5	6,994	39.4	3,407	35.2	3,017	32.9	3,828	33.7	964	36.3	168	30
Male	35,740	63.4	2,959	56.5	10,742	60.6	6,262	64.8	6,162	67.1	7,541	66.3	1,690	63.7	384	70
Other	2	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 6b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Febuxostat 40 mg								
Switch to Febuxostat 80 mg	9,598	223.9	300.27	1	46	108	267	2,781
Female	2,980	236.6	308.67	1	49	115	294	2,781
Male	6,617	218.3	296.27	1	45	104	253	2,473
Other	1	27	-	27	27	27	27	27
Switch to Allopurinol 100 mg	11,354	209.4	308.82	1	30	90	244	2,533
Female	4,626	218.9	320.65	1	30	90	267	2,383
Male	6,727	202.8	300.28	1	30	90	232	2,533
Other	1	30	-	30	30	30	30	30
Switch to Allopurinol 300 mg	7,464	200.9	298.33	1	30	90	219	2,536
Female	2,110	206.4	296.44	1	30	90	237	2,418
Male	5,354	198.7	299.07	1	30	90	215	2,536
Other	0	-	-	-	-	-	-	-
Febuxostat 80 mg								
Switch to Febuxostat 40 mg	1,994	316.5	383.14	1	60	173	433	2,498
Female	676	344.6	401.34	1	61	186	494	2,257
Male	1,318	302.1	372.8	1	60	158	390	2,498
Other	0	-	-	-	-	-	-	-
Switch to Allopurinol 100 mg	1,836	215.8	298.07	1	30	90	264	2,162
Female	550	208.2	288.53	1	30	90	259	2,056
Male	1,286	219.1	302.11	1	30	91	270	2,162
Other	0	-	-	-	-	-	-	-
Switch to Allopurinol 300 mg	2,066	211.6	293.31	1	30	90	270	2,055
Female	444	228.5	314.82	1	30	90	297	2,014
Male	1,622	206.9	287.07	1	30	90	253	2,055
Other	0	-	-	-	-	-	-	-
Febuxostat (any dose)²								
Switch to Allopurinol (any dose) ³	19,363	247.3	345.58	1	30	95	308	2,536
Female	6,745	248.2	345.37	1	30	91	320	2,418
Male	12,617	246.8	345.71	1	30	96	304	2,536
Other	1	510	-	510	510	510	510	510
Allopurinol 100 mg								
Switch to Allopurinol 300 mg	145,823	230.9	329.31	1	32	100	272	3,226
Female	42,738	255.7	352.96	1	36	110	313	3,226
Male	103,083	220.7	318.43	1	31	97	259	3,115
Other	2	259	31.11	237	237	259	281	281
Switch to Febuxostat 40 mg	32,022	228.2	328.22	1	30	93	270	2,903
Female	13,233	229.1	334.67	1	30	90	270	2,820
Male	18,787	227.5	323.63	1	30	99	269	2,903
Other	2	275.5	54.45	237	237	276	314	314
Switch to Febuxostat 80 mg	10,311	207.1	284.08	1	30	92	245	2,656
Female	3,284	211	291.16	1	30	90	257	2,635
Male	7,026	205.3	280.73	1	30	93	241	2,656
Other	1	237	-	237	237	237	237	237

Table 6b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Allopurinol 300 mg								
Switch to Allopurinol 100 mg	63,279	346.2	441.82	1	48	165	472	3,312
Female	19,526	340.7	438.02	1	43	153	463	3,312
Male	43,747	348.6	443.49	1	50	171	476	3,149
Other	6	431	411.01	48	60	335	790	1,018
Switch to Febuxostat 40 mg	16,821	244.4	344.55	1	31	97	285	3,114
Female	5,503	213.6	328.36	1	30	90	218	3,025
Male	11,318	259.4	351.18	1	44	119	311	3,114
Other	0	-	-	-	-	-	-	-
Switch to Febuxostat 80 mg	8,437	253.1	340.19	1	57	120	304	2,571
Female	2,042	230.8	336.3	1	34	90	264	2,571
Male	6,395	260.2	341.15	1	60	123	318	2,555
Other	0	-	-	-	-	-	-	-
Allopurinol (any dose)³								
Switch to Febuxostat (any dose) ²	56,401	296.8	389.02	1	53	134	378	3,114
Female	20,659	279.8	383.06	1	38	116	349	3,025
Male	35,740	306.6	392.1	1	60	150	394	3,114
Other	2	365	72.12	314	314	365	416	416

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 7a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category and Age Group

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Febuxostat 40 mg																
Switch to Febuxostat 80 mg	9,598	100	902	100	3,475	100	1,920	100	1,548	100	1,479	100	242	100	32	100
21-44 Years	963	10	98	10.9	383	11	188	9.8	153	9.9	116	7.8	20	8.3	5	16
45-64 Years	2,808	29.3	256	28.4	1,065	30.6	571	29.7	442	28.6	394	26.6	70	28.9	10	31
65+ Years	5,827	60.7	548	60.8	2,027	58.3	1,161	60.5	953	61.6	969	65.5	152	62.8	17	53
Switch to Allopurinol 100 mg	11,354	100	1,433	100	4,712	100	1,703	100	1,492	100	1,682	100	292	100	40	100
21-44 Years	824	7.3	74	5.2	431	9.1	114	6.7	85	5.7	97	5.8	22	7.5	1	2.5
45-64 Years	2,670	23.5	301	21	1,167	24.8	434	25.5	335	22.5	353	21	69	23.6	11	28
65+ Years	7,860	69.2	1,058	73.8	3,114	66.1	1,155	67.8	1,072	71.8	1,232	73.2	201	68.8	28	70
Switch to Allopurinol 300 mg	7,464	100	723	100	3,359	100	1,201	100	961	100	1,023	100	174	100	23	100
21-44 Years	900	12.1	92	12.7	458	13.6	132	11	108	11.2	93	9.1	13	7.5	4	17
45-64 Years	2,397	32.1	207	28.6	1,145	34.1	391	32.6	305	31.7	287	28.1	54	31	8	35
65+ Years	4,167	55.8	424	58.6	1,756	52.3	678	56.5	548	57	643	62.9	107	61.5	11	48
Febuxostat 80 mg																
Switch to Febuxostat 40 mg	1,994	100	132	100	581	100	358	100	348	100	468	100	90	100	17	100
21-44 Years	158	7.9	8	6.1	48	8.3	36	10.1	27	7.8	32	6.8	6	6.7	1	5.9
45-64 Years	587	29.4	46	34.8	188	32.4	102	28.5	103	29.6	124	26.5	15	16.7	9	53
65+ Years	1,249	62.6	78	59.1	345	59.4	220	61.5	218	62.6	312	66.7	69	76.7	7	41
Switch to Allopurinol 100 mg	1,836	100	164	100	772	100	297	100	271	100	291	100	34	100	7	100
21-44 Years	171	9.3	11	6.7	81	10.5	36	12.1	19	7	22	7.6	2	5.9	0	0
45-64 Years	540	29.4	42	25.6	247	32	77	25.9	77	28.4	83	28.5	10	29.4	4	57
65+ Years	1,125	61.3	111	67.7	444	57.5	184	62	175	64.6	186	63.9	22	64.7	3	43
Switch to Allopurinol 300 mg	2,066	100	173	100	894	100	326	100	289	100	331	100	47	100	6	100
21-44 Years	298	14.4	24	13.9	142	15.9	51	15.6	35	12.1	42	12.7	3	6.4	1	17
45-64 Years	760	36.8	55	31.8	345	38.6	122	37.4	104	36	112	33.8	20	42.6	2	33
65+ Years	1,008	48.8	94	54.3	407	45.5	153	46.9	150	51.9	177	53.5	24	51.1	3	50
Febuxostat (any dose)²																
Switch to Allopurinol (any dose) ³	19,363	100	2,261	100	7,220	100	2,930	100	2,747	100	3,433	100	671	100	101	100
21-44 Years	1,773	9.2	177	7.8	789	10.9	266	9.1	216	7.9	267	7.8	49	7.3	9	8.9
45-64 Years	5,335	27.6	537	23.8	2,110	29.2	845	28.8	746	27.2	869	25.3	192	28.6	36	36
65+ Years	12,255	63.3	1,547	68.4	4,321	59.8	1,819	62.1	1,785	65	2,297	66.9	430	64.1	56	55

Table 7a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category and Age Group

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Allopurinol 100 mg																
Switch to Allopurinol 300 mg	145,823	100	22,217	100	46,871	100	26,567	100	22,379	100	22,660	100	4,364	100	765	100
21-44 Years	16,057	11	2,503	11.3	5,929	12.6	3,085	11.6	2,367	10.6	1,860	8.2	258	5.9	55	7.2
45-64 Years	45,039	30.9	6,687	30.1	15,071	32.2	8,434	31.7	6,919	30.9	6,567	29	1,145	26.2	216	28
65+ Years	84,727	58.1	13,027	58.6	25,871	55.2	15,048	56.6	13,093	58.5	14,233	62.8	2,961	67.9	494	65
Switch to Febuxostat 40 mg	32,022	100	3,785	100	11,962	100	5,562	100	4,786	100	4,820	100	924	100	183	100
21-44 Years	2,251	7	249	6.6	959	8	414	7.4	334	7	254	5.3	32	3.5	9	4.9
45-64 Years	7,209	22.5	781	20.6	2,849	23.8	1,337	24	1,072	22.4	972	20.2	162	17.5	36	20
65+ Years	22,562	70.5	2,755	72.8	8,154	68.2	3,811	68.5	3,380	70.6	3,594	74.6	730	79	138	75
Switch to Febuxostat 80 mg	10,311	100	726	100	4,390	100	1,921	100	1,594	100	1,453	100	200	100	27	100
21-44 Years	1,072	10.4	68	9.4	536	12.2	197	10.3	147	9.2	111	7.6	11	5.5	2	7.4
45-64 Years	2,958	28.7	201	27.7	1,285	29.3	579	30.1	469	29.4	369	25.4	49	24.5	6	22
65+ Years	6,281	60.9	457	62.9	2,569	58.5	1,145	59.6	978	61.4	973	67	140	70	19	70
Allopurinol 300 mg																
Switch to Allopurinol 100 mg	63,279	100	8,053	100	16,410	100	9,159	100	9,965	100	14,725	100	4,043	100	924	100
21-44 Years	6,807	10.8	840	10.4	1,901	11.6	1,110	12.1	1,227	12.3	1,360	9.2	305	7.5	64	6.9
45-64 Years	18,400	29.1	2,364	29.4	4,834	29.5	2,803	30.6	2,932	29.4	4,139	28.1	1,022	25.3	306	33
65+ Years	38,072	60.2	4,849	60.2	9,675	59	5,246	57.3	5,806	58.3	9,226	62.7	2,716	67.2	554	60
Switch to Febuxostat 40 mg	16,821	100	1,563	100	6,577	100	2,850	100	2,403	100	2,756	100	571	100	101	100
21-44 Years	1,824	10.8	106	6.8	735	11.2	342	12	299	12.4	303	11	32	5.6	7	6.9
45-64 Years	4,931	29.3	456	29.2	1,860	28.3	884	31	761	31.7	781	28.3	152	26.6	37	37
65+ Years	10,066	59.8	1,001	64	3,982	60.5	1,624	57	1,343	55.9	1,672	60.7	387	67.8	57	56
Switch to Febuxostat 80 mg	8,437	100	504	100	3,264	100	1,539	100	1,350	100	1,443	100	282	100	55	100
21-44 Years	1,225	14.5	43	8.5	473	14.5	230	14.9	228	16.9	212	14.7	30	10.6	9	16
45-64 Years	2,941	34.9	166	32.9	1,143	35	545	35.4	487	36.1	490	34	93	33	17	31
65+ Years	4,271	50.6	295	58.5	1,648	50.5	764	49.6	635	47	741	51.4	159	56.4	29	53

Table 7a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category and Age Group

Exposure	Number of Patients															
	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years					
	Total	%	month	%	months	%	months	%	<1 year	%	years	%				
Allopurinol (any dose) ³																
Switch to Febuxostat (any dose) ²	56,401	100	5,240	100	17,736	100	9,669	100	9,180	100	11,370	100	2,654	100	552	100
21-44 Years	5,062	9	312	6	1,713	9.7	929	9.6	891	9.7	1,019	9	153	5.8	45	8.2
45-64 Years	14,711	26.1	1,210	23.1	4,692	26.5	2,666	27.6	2,509	27.3	2,865	25.2	619	23.3	150	27
65+ Years	36,628	64.9	3,718	71	11,331	63.9	6,074	62.8	5,780	63	7,486	65.8	1,882	70.9	357	65

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 7b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Febuxostat 40 mg								
Switch to Febuxostat 80 mg	9,598	223.9	300.27	1	46	108	267	2,781
21-44 Years	963	203.4	301.63	1	30	91	229	2,339
45-64 Years	2,808	214.7	296.1	1	44	100	243	2,260
65+ Years	5,827	231.8	301.81	1	50	115	281	2,781
Switch to Allopurinol 100 mg	11,354	209.4	308.82	1	30	90	244	2,533
21-44 Years	824	181.6	291.76	1	30	60	181	1,864
45-64 Years	2,670	202	312.41	1	30	86	222	2,533
65+ Years	7,860	214.8	309.17	1	30	90	262	2,383
Switch to Allopurinol 300 mg	7,464	200.9	298.33	1	30	90	219	2,536
21-44 Years	900	163.7	269.21	1	30	60	179	2,195
45-64 Years	2,397	189.8	293.47	1	30	80	201	2,536
65+ Years	4,167	215.3	306.08	1	30	90	249	2,418
Febuxostat 80 mg								
Switch to Febuxostat 40 mg	1,994	316.5	383.14	1	60	173	433	2,498
21-44 Years	158	286.4	354.34	1	60	149	358	1,957
45-64 Years	587	284	380.54	1	60	148	369	2,498
65+ Years	1,249	335.7	386.85	1	62	180	482	2,257
Switch to Allopurinol 100 mg	1,836	215.8	298.07	1	30	90	264	2,162
21-44 Years	171	174.2	236.18	1	30	73	192	1,263
45-64 Years	540	220.3	323.69	1	30	90	259	2,162
65+ Years	1,125	220.1	293.38	1	30	92	273	2,072
Switch to Allopurinol 300 mg	2,066	211.6	293.31	1	30	90	270	2,055
21-44 Years	298	180	256.26	1	30	76	215	1,957
45-64 Years	760	205.1	294.15	1	30	90	254	2,055
65+ Years	1,008	225.8	302.17	1	30	92	290	2,014
Febuxostat (any dose)²								
Switch to Allopurinol (any dose) ³	19,363	247.3	345.58	1	30	95	308	2,536
21-44 Years	1,773	214.4	324.02	1	30	78	246	2,195
45-64 Years	5,335	243.9	353.22	1	30	92	290	2,536
65+ Years	12,255	253.5	344.97	1	30	100	329	2,418
Allopurinol 100 mg								
Switch to Allopurinol 300 mg	145,823	230.9	329.31	1	32	100	272	3,226
21-44 Years	16,057	181.5	269.24	1	30	90	209	2,854
45-64 Years	45,039	217.3	313.5	1	30	97	254	3,108
65+ Years	84,727	247.6	346.16	1	37	107	299	3,226
Switch to Febuxostat 40 mg	32,022	228.2	328.22	1	30	93	270	2,903
21-44 Years	2,251	182.4	276.55	1	30	90	205	2,656
45-64 Years	7,209	208.2	304.67	1	30	90	238	2,820
65+ Years	22,562	239.1	339.35	1	30	98	285	2,903
Switch to Febuxostat 80 mg	10,311	207.1	284.08	1	30	92	245	2,656
21-44 Years	1,072	164.8	241.37	1	30	82	188	2,656
45-64 Years	2,958	191.6	262.98	1	30	90	220	2,416
65+ Years	6,281	221.7	298.93	1	38	99	270	2,635

Table 7b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Allopurinol 300 mg								
Switch to Allopurinol 100 mg	63,279	346.2	441.82	1	48	165	472	3,312
21-44 Years	6,807	290.9	385.83	1	32	135	369	2,941
45-64 Years	18,400	333	438.61	1	39	152	450	3,149
65+ Years	38,072	362.4	451.63	1	55	180	506	3,312
Switch to Febuxostat 40 mg	16,821	244.4	344.55	1	31	97	285	3,114
21-44 Years	1,824	223.8	294.18	1	41	104	270	2,323
45-64 Years	4,931	240.7	343.86	1	30	100	281	3,114
65+ Years	10,066	250	353.1	1	32	92	291	3,025
Switch to Febuxostat 80 mg	8,437	253.1	340.19	1	57	120	304	2,571
21-44 Years	1,225	245.7	325.6	1	60	120	299	2,518
45-64 Years	2,941	245.5	331.02	1	57	116	298	2,555
65+ Years	4,271	260.4	350.29	1	57	120	316	2,571
Allopurinol (any dose)³								
Switch to Febuxostat (any dose) ²	56,401	296.8	389.02	1	53	134	378	3,114
21-44 Years	5,062	273.7	352.87	1	60	136	348	2,656
45-64 Years	14,711	288	380.79	1	56	133	362	3,114
65+ Years	36,628	303.5	396.79	1	51	134	392	3,025

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients																	
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years			
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%	years	%
Febuxostat 40 mg																		
Switch to Febuxostat 80 mg	9,598	100	902	100	3,475	100	1,920	100	1,548	100	1,479	100	242	100	32	100		
Female	2,980	31	275	30.5	1,052	30.3	567	29.5	476	30.7	518	35	81	33.5	11	34		
21-44 Years	58	0.6	9	1	22	0.6	11	0.6	10	0.6	6	0.4	0	-	0	-		
45-64 Years	526	5.5	46	5.1	192	5.5	88	4.6	91	5.9	92	6.2	13	5.4	4	13		
65+ Years	2,396	25	220	24.4	838	24.1	468	24.4	375	24.2	420	28.4	68	28.1	7	22		
Male	6,617	68.9	626	69.4	2,423	69.7	1,353	70.5	1,072	69.3	961	65	161	66.5	21	66		
21-44 Years	905	9.4	89	9.9	361	10.4	177	9.2	143	9.2	110	7.4	20	8.3	5	16		
45-64 Years	2,282	23.8	210	23.3	873	25.1	483	25.2	351	22.7	302	20.4	57	23.6	6	19		
65+ Years	3,430	35.7	327	36.3	1,189	34.2	693	36.1	578	37.3	549	37.1	84	34.7	10	31		
Other	1	0	1	0.1	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	1	0	1	0.1	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Switch to Allopurinol 100 mg	11,354	100	1,433	100	4,712	100	1,703	100	1,492	100	1,682	100	292	100	40	100		
Female	4,626	40.7	661	46.1	1,809	38.4	690	40.5	583	39.1	733	43.6	131	44.9	19	48		
21-44 Years	74	0.7	11	0.8	35	0.7	7	0.4	8	0.5	10	0.6	2	0.7	1	2.5		
45-64 Years	655	5.8	102	7.1	245	5.2	109	6.4	81	5.4	96	5.7	19	6.5	3	7.5		
65+ Years	3,897	34.3	548	38.2	1,529	32.4	574	33.7	494	33.1	627	37.3	110	37.7	15	38		
Male	6,727	59.2	772	53.9	2,902	61.6	1,013	59.5	909	60.9	949	56.4	161	55.1	21	53		
21-44 Years	750	6.6	63	4.4	396	8.4	107	6.3	77	5.2	87	5.2	20	6.8	0	-		
45-64 Years	2,015	17.7	199	13.9	922	19.6	325	19.1	254	17	257	15.3	50	17.1	8	20		
65+ Years	3,962	34.9	510	35.6	1,584	33.6	581	34.1	578	38.7	605	36	91	31.2	13	33		
Other	1	0	0	-	1	0	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	1	0	0	-	1	0	0	-	0	-	0	-	0	-	0	-	0	-

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Switch to Allopurinol 300 mg	7,464	100	723	100	3,359	100	1,201	100	961	100	1,023	100	174	100	23	100
Female	2,110	28.3	229	31.7	905	26.9	348	29	252	26.2	322	31.5	50	28.7	4	17
21-44 Years	47	0.6	4	0.6	23	0.7	7	0.6	8	0.8	3	0.3	2	1.1	0	-
45-64 Years	388	5.2	43	5.9	170	5.1	66	5.5	51	5.3	50	4.9	7	4	1	4.3
65+ Years	1,675	22.4	182	25.2	712	21.2	275	22.9	193	20.1	269	26.3	41	23.6	3	13
Male	5,354	71.7	494	68.3	2,454	73.1	853	71	709	73.8	701	68.5	124	71.3	19	83
21-44 Years	853	11.4	88	12.2	435	13	125	10.4	100	10.4	90	8.8	11	6.3	4	17
45-64 Years	2,009	26.9	164	22.7	975	29	325	27.1	254	26.4	237	23.2	47	27	7	30
65+ Years	2,492	33.4	242	33.5	1,044	31.1	403	33.6	355	36.9	374	36.6	66	37.9	8	35
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Febuxostat 80 mg																
Switch to Febuxostat 40 mg	1,994	100	132	100	581	100	358	100	348	100	468	100	90	100	17	100
Female	676	33.9	39	29.5	198	34.1	94	26.3	125	35.9	176	37.6	37	41.1	7	41
21-44 Years	10	0.5	0	-	4	0.7	2	0.6	2	0.6	2	0.4	0	-	0	-
45-64 Years	120	6	8	6.1	40	6.9	12	3.4	27	7.8	29	6.2	2	2.2	2	12
65+ Years	546	27.4	31	23.5	154	26.5	80	22.3	96	27.6	145	31	35	38.9	5	29
Male	1,318	66.1	93	70.5	383	65.9	264	73.7	223	64.1	292	62.4	53	58.9	10	59
21-44 Years	148	7.4	8	6.1	44	7.6	34	9.5	25	7.2	30	6.4	6	6.7	1	5.9
45-64 Years	467	23.4	38	28.8	148	25.5	90	25.1	76	21.8	95	20.3	13	14.4	7	41
65+ Years	703	35.3	47	35.6	191	32.9	140	39.1	122	35.1	167	35.7	34	37.8	2	12
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Switch to Allopurinol 100 mg	1,836	100	164	100	772	100	297	100	271	100	291	100	34	100	7	100
Female	550	30	56	34.1	238	30.8	77	25.9	83	30.6	85	29.2	10	29.4	1	14
21-44 Years	6	0.3	1	0.6	2	0.3	1	0.3	0	-	2	0.7	0	-	0	-
45-64 Years	93	5.1	7	4.3	42	5.4	12	4	14	5.2	17	5.8	1	2.9	0	-
65+ Years	451	24.6	48	29.3	194	25.1	64	21.5	69	25.5	66	22.7	9	26.5	1	14
Male	1,286	70	108	65.9	534	69.2	220	74.1	188	69.4	206	70.8	24	70.6	6	86
21-44 Years	165	9	10	6.1	79	10.2	35	11.8	19	7	20	6.9	2	5.9	0	-
45-64 Years	447	24.3	35	21.3	205	26.6	65	21.9	63	23.2	66	22.7	9	26.5	4	57
65+ Years	674	36.7	63	38.4	250	32.4	120	40.4	106	39.1	120	41.2	13	38.2	2	29
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Switch to Allopurinol 300 mg	2,066	100	173	100	894	100	326	100	289	100	331	100	47	100	6	100
Female	444	21.5	53	30.6	183	20.5	50	15.3	65	22.5	77	23.3	15	31.9	1	17
21-44 Years	14	0.7	3	1.7	6	0.7	1	0.3	2	0.7	2	0.6	0	-	0	-
45-64 Years	105	5.1	13	7.5	39	4.4	13	4	18	6.2	20	6	2	4.3	0	-
65+ Years	325	15.7	37	21.4	138	15.4	36	11	45	15.6	55	16.6	13	27.7	1	17
Male	1,622	78.5	120	69.4	711	79.5	276	84.7	224	77.5	254	76.7	32	68.1	5	83
21-44 Years	284	13.7	21	12.1	136	15.2	50	15.3	33	11.4	40	12.1	3	6.4	1	17
45-64 Years	655	31.7	42	24.3	306	34.2	109	33.4	86	29.8	92	27.8	18	38.3	2	33
65+ Years	683	33.1	57	32.9	269	30.1	117	35.9	105	36.3	122	36.9	11	23.4	2	33
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients																	
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years			
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%	years	%
Febuxostat (any dose) ²																		
Switch to Allopurinol (any dose) ³	19,363	100	2,261	100	7,220	100	2,930	100	2,747	100	3,433	100	671	100	101	100		
Female	6,745	34.8	928	41	2,423	33.6	968	33	917	33.4	1,242	36.2	237	35.3	30	30		
21-44 Years	117	0.6	18	0.8	47	0.7	12	0.4	14	0.5	21	0.6	4	0.6	1	1		
45-64 Years	1,070	5.5	151	6.7	371	5.1	161	5.5	155	5.6	192	5.6	36	5.4	4	4		
65+ Years	5,558	28.7	759	33.6	2,005	27.8	795	27.1	748	27.2	1,029	30	197	29.4	25	25		
Male	12,617	65.2	1,333	59	4,797	66.4	1,962	67	1,830	66.6	2,190	63.8	434	64.7	71	70		
21-44 Years	1,656	8.6	159	7	742	10.3	254	8.7	202	7.4	246	7.2	45	6.7	8	7.9		
45-64 Years	4,265	22	386	17.1	1,739	24.1	684	23.3	591	21.5	677	19.7	156	23.2	32	32		
65+ Years	6,696	34.6	788	34.9	2,316	32.1	1,024	34.9	1,037	37.8	1,267	36.9	233	34.7	31	31		
Other	1	0	0	-	0	-	0	-	0	-	1	0	0	-	0	-		
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-		
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-		
65+ Years	1	0	0	-	0	-	0	-	0	-	1	0	0	-	0	-		
Allopurinol 100 mg																		
Switch to Allopurinol 300 mg	145,823	100	22,217	100	46,871	100	26,567	100	22,379	100	22,660	100	4,364	100	765	100		
Female	42,738	29.3	6,362	28.6	13,010	27.8	7,401	27.9	6,584	29.4	7,530	33.2	1,606	36.8	245	32		
21-44 Years	829	0.6	106	0.5	294	0.6	157	0.6	122	0.5	127	0.6	23	0.5	0	-		
45-64 Years	8,461	5.8	1,200	5.4	2,709	5.8	1,521	5.7	1,297	5.8	1,406	6.2	275	6.3	53	6.9		
65+ Years	33,448	22.9	5,056	22.8	10,007	21.4	5,723	21.5	5,165	23.1	5,997	26.5	1,308	30	192	25		
Male	103,083	70.7	15,855	71.4	33,861	72.2	19,166	72.1	15,793	70.6	15,130	66.8	2,758	63.2	520	68		
21-44 Years	15,228	10.4	2,397	10.8	5,635	12	2,928	11	2,245	10	1,733	7.6	235	5.4	55	7.2		
45-64 Years	36,578	25.1	5,487	24.7	12,362	26.4	6,913	26	5,622	25.1	5,161	22.8	870	19.9	163	21		
65+ Years	51,277	35.2	7,971	35.9	15,864	33.8	9,325	35.1	7,926	35.4	8,236	36.3	1,653	37.9	302	40		
Other	2	0	0	-	0	-	0	-	2	0	0	-	0	-	0	-		
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-		
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-		
65+ Years	2	0	0	-	0	-	0	-	2	0	0	-	0	-	0	-		

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Switch to Febuxostat 40 mg	32,022	100	3,785	100	11,962	100	5,562	100	4,786	100	4,820	100	924	100	183	100
Female	13,233	41.3	1,710	45.2	4,978	41.6	2,207	39.7	1,863	38.9	1,979	41.1	425	46	71	39
21-44 Years	177	0.6	19	0.5	77	0.6	22	0.4	34	0.7	17	0.4	7	0.8	1	0.5
45-64 Years	1,969	6.1	247	6.5	745	6.2	367	6.6	270	5.6	282	5.9	49	5.3	9	4.9
65+ Years	11,087	34.6	1,444	38.2	4,156	34.7	1,818	32.7	1,559	32.6	1,680	34.9	369	39.9	61	33
Male	18,787	58.7	2,075	54.8	6,984	58.4	3,355	60.3	2,921	61	2,841	58.9	499	54	112	61
21-44 Years	2,074	6.5	230	6.1	882	7.4	392	7	300	6.3	237	4.9	25	2.7	8	4.4
45-64 Years	5,239	16.4	534	14.1	2,104	17.6	970	17.4	801	16.7	690	14.3	113	12.2	27	15
65+ Years	11,474	35.8	1,311	34.6	3,998	33.4	1,993	35.8	1,820	38	1,914	39.7	361	39.1	77	42
Other	2	0	0	-	0	-	0	-	2	0	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	1	0	0	-	0	-	0	-	1	0	0	-	0	-	0	-
65+ Years	1	0	0	-	0	-	0	-	1	0	0	-	0	-	0	-
Switch to Febuxostat 80 mg	10,311	100	726	100	4,390	100	1,921	100	1,594	100	1,453	100	200	100	27	100
Female	3,284	31.8	248	34.2	1,417	32.3	563	29.3	495	31.1	481	33.1	71	35.5	9	33
21-44 Years	62	0.6	4	0.6	28	0.6	8	0.4	14	0.9	7	0.5	1	0.5	0	-
45-64 Years	634	6.1	46	6.3	268	6.1	113	5.9	110	6.9	84	5.8	12	6	1	3.7
65+ Years	2,588	25.1	198	27.3	1,121	25.5	442	23	371	23.3	390	26.8	58	29	8	30
Male	7,026	68.1	478	65.8	2,973	67.7	1,358	70.7	1,098	68.9	972	66.9	129	64.5	18	67
21-44 Years	1,010	9.8	64	8.8	508	11.6	189	9.8	133	8.3	104	7.2	10	5	2	7.4
45-64 Years	2,324	22.5	155	21.3	1,017	23.2	466	24.3	359	22.5	285	19.6	37	18.5	5	19
65+ Years	3,692	35.8	259	35.7	1,448	33	703	36.6	606	38	583	40.1	82	41	11	41
Other	1	0	0	-	0	-	0	-	1	0.1	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	1	0	0	-	0	-	0	-	1	0.1	0	-	0	-	0	-

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients													
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%
Allopurinol 300 mg														
Switch to Allopurinol 100 mg	63,279	100	8,053	100	16,410	100	9,159	100	9,965	100	14,725	100	4,043	100
Female	19,526	30.9	2,430	30.2	5,449	33.2	2,728	29.8	2,932	29.4	4,456	30.3	1,271	31.4
21-44 Years	373	0.6	43	0.5	110	0.7	63	0.7	72	0.7	60	0.4	21	0.5
45-64 Years	3,505	5.5	406	5	987	6	533	5.8	543	5.4	789	5.4	195	4.8
65+ Years	15,648	24.7	1,981	24.6	4,352	26.5	2,132	23.3	2,317	23.3	3,607	24.5	1,055	26.1
Male	43,747	69.1	5,623	69.8	10,959	66.8	6,430	70.2	7,033	70.6	10,266	69.7	2,772	68.6
21-44 Years	6,433	10.2	797	9.9	1,790	10.9	1,047	11.4	1,155	11.6	1,300	8.8	284	7
45-64 Years	14,892	23.5	1,958	24.3	3,847	23.4	2,269	24.8	2,389	24	3,348	22.7	827	20.5
65+ Years	22,422	35.4	2,868	35.6	5,322	32.4	3,114	34	3,489	35	5,618	38.2	1,661	41.1
Other	6	0	0	-	2	0	1	0	0	-	3	0	0	-
21-44 Years	1	0	0	-	1	0	0	-	0	-	0	-	0	-
45-64 Years	3	0	0	-	0	-	1	0	0	-	2	0	0	-
65+ Years	2	0	0	-	1	0	0	-	0	-	1	0	0	-
Switch to Febuxostat 40 mg	16,821	100	1,563	100	6,577	100	2,850	100	2,403	100	2,756	100	571	100
Female	5,503	32.7	629	40.2	2,463	37.4	868	30.5	596	24.8	751	27.2	174	30.5
21-44 Years	110	0.7	13	0.8	54	0.8	14	0.5	15	0.6	14	0.5	0	-
45-64 Years	952	5.7	112	7.2	392	6	170	6	112	4.7	135	4.9	25	4.4
65+ Years	4,441	26.4	504	32.2	2,017	30.7	684	24	469	19.5	602	21.8	149	26.1
Male	11,318	67.3	934	59.8	4,114	62.6	1,982	69.5	1,807	75.2	2,005	72.8	397	69.5
21-44 Years	1,714	10.2	93	6	681	10.4	328	11.5	284	11.8	289	10.5	32	5.6
45-64 Years	3,979	23.7	344	22	1,468	22.3	714	25.1	649	27	646	23.4	127	22.2
65+ Years	5,625	33.4	497	31.8	1,965	29.9	940	33	874	36.4	1,070	38.8	238	41.7
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-

Table 8a. Distribution of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Length Category, Sex, and Age Group

Exposure	Number of Patients															
	Total	%	<1 month		1 - <3 months		3 - <6 months		6 months - <1 year		1 - <3 years		3 - <5 years		5+ years	
			months	%	months	%	months	%	<1 year	%	years	%	years	%	years	%
Switch to Febuxostat 80 mg	8,437	100	504	100	3,264	100	1,539	100	1,350	100	1,443	100	282	100	55	100
Female	2,042	24.2	148	29.4	916	28.1	345	22.4	253	18.7	302	20.9	64	22.7	14	26
21-44 Years	57	0.7	6	1.2	25	0.8	7	0.5	9	0.7	9	0.6	1	0.4	0	-
45-64 Years	454	5.4	23	4.6	209	6.4	82	5.3	62	4.6	64	4.4	12	4.3	2	3.6
65+ Years	1,531	18.1	119	23.6	682	20.9	256	16.6	182	13.5	229	15.9	51	18.1	12	22
Male	6,395	75.8	356	70.6	2,348	71.9	1,194	77.6	1,097	81.3	1,141	79.1	218	77.3	41	75
21-44 Years	1,168	13.8	37	7.3	448	13.7	223	14.5	219	16.2	203	14.1	29	10.3	9	16
45-64 Years	2,487	29.5	143	28.4	934	28.6	463	30.1	425	31.5	426	29.5	81	28.7	15	27
65+ Years	2,740	32.5	176	34.9	966	29.6	508	33	453	33.6	512	35.5	108	38.3	17	31
Other	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
65+ Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Allopurinol (any dose)³																
Switch to Febuxostat (any dose) ²	56,401	100	5,240	100	17,736	100	9,669	100	9,180	100	11,370	100	2,654	100	552	100
Female	20,659	36.6	2,281	43.5	6,994	39.4	3,407	35.2	3,017	32.9	3,828	33.7	964	36.3	168	30
21-44 Years	338	0.6	35	0.7	130	0.7	46	0.5	59	0.6	53	0.5	14	0.5	1	0.2
45-64 Years	3,379	6	342	6.5	1,112	6.3	613	6.3	506	5.5	633	5.6	142	5.4	31	5.6
65+ Years	16,942	30	1,904	36.3	5,752	32.4	2,748	28.4	2,452	26.7	3,142	27.6	808	30.4	136	25
Male	35,740	63.4	2,959	56.5	10,742	60.6	6,262	64.8	6,162	67.1	7,541	66.3	1,690	63.7	384	70
21-44 Years	4,724	8.4	277	5.3	1,583	8.9	883	9.1	832	9.1	966	8.5	139	5.2	44	8
45-64 Years	11,331	20.1	868	16.6	3,580	20.2	2,053	21.2	2,002	21.8	2,232	19.6	477	18	119	22
65+ Years	19,685	34.9	1,814	34.6	5,579	31.5	3,326	34.4	3,328	36.3	4,343	38.2	1,074	40.5	221	40
Other	2	0	0	-	0	-	0	-	1	0	1	0	0	-	0	-
21-44 Years	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
45-64 Years	1	0	0	-	0	-	0	-	1	0	0	-	0	-	0	-
65+ Years	1	0	0	-	0	-	0	-	0	-	1	0	0	-	0	-

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Table 8b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Febuxostat 40 mg								
Switch to Febuxostat 80 mg	9,598	223.94	300.27	1	46	108	267	2,781
Female	2,980	236.6	308.67	1	49	115	294	2,781
21-44 Years	58	159.1	217.28	8	30	87	195	1,018
45-64 Years	526	241.73	318.39	1	50	118	304	2,187
65+ Years	2,396	237.35	308.24	1	50	116	294	2,781
Male	6,617	218.27	296.27	1	45	104	253	2,473
21-44 Years	905	206.28	306.11	1	30	92	233	2,339
45-64 Years	2,282	208.53	290.44	1	42	97	232	2,260
65+ Years	3,430	227.92	297.24	1	50	114	274	2,473
Other	1	27	-	27	27	27	27	27
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	1	27	-	27	27	27	27	27
Switch to Allopurinol 100 mg	11,354	209.36	308.82	1	30	90	244	2,533
Female	4,626	218.89	320.65	1	30	90	267	2,383
21-44 Years	74	217.82	364.68	1	30	60	237	1,864
45-64 Years	655	212.28	323.07	1	30	90	234	2,375
65+ Years	3,897	220.02	319.43	1	30	90	270	2,383
Male	6,727	202.83	300.28	1	30	90	232	2,533
21-44 Years	750	177.99	283.6	1	30	60	180	1,768
45-64 Years	2,015	198.69	308.87	1	30	85	215	2,533
65+ Years	3,962	209.65	298.7	1	30	90	252	2,303
Other	1	30	-	30	30	30	30	30
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	1	30	-	30	30	30	30	30
Switch to Allopurinol 300 mg	7,464	200.86	298.33	1	30	90	219	2,536
Female	2,110	206.35	296.44	1	30	90	237	2,418
21-44 Years	47	163.66	265.45	1	30	71	199	1,414
45-64 Years	388	188.97	277.27	1	30	86	222	1,970
65+ Years	1,675	211.58	301.42	1	30	90	240	2,418
Male	5,354	198.69	299.07	1	30	90	215	2,536
21-44 Years	853	163.67	269.57	1	30	60	175	2,195
45-64 Years	2,009	189.95	296.56	1	30	79	199	2,536
65+ Years	2,492	217.72	309.2	1	30	90	261	2,124
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-

Table 8b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Febuxostat 80 mg								
Switch to Febuxostat 40 mg	1,994	316.53	383.14	1	60	173	433	2,498
Female	676	344.58	401.34	1	61	186	494	2,257
21-44 Years	10	208.7	170.3	30	90	113	342	533
45-64 Years	120	286.51	352.49	1	53	183	408	1,965
65+ Years	546	359.84	413	1	64	188	520	2,257
Male	1,318	302.15	372.8	1	60	158	390	2,498
21-44 Years	148	291.67	363.16	1	60	151	364	1,957
45-64 Years	467	283.3	387.77	1	60	140	362	2,498
65+ Years	703	316.87	364.45	1	61	179	442	1,925
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-
Switch to Allopurinol 100 mg	1,836	215.85	298.07	1	30	90	264	2,162
Female	550	208.2	288.53	1	30	90	259	2,056
21-44 Years	6	210.17	273.67	1	30	83	369	695
45-64 Years	93	207.7	270.31	1	30	77	275	1,371
65+ Years	451	208.27	292.9	1	30	90	249	2,056
Male	1,286	219.12	302.11	1	30	91	270	2,162
21-44 Years	165	172.9	235.57	2	30	73	180	1,263
45-64 Years	447	222.88	333.94	1	30	90	259	2,162
65+ Years	674	227.94	293.65	1	30	101	294	2,072
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-
Switch to Allopurinol 300 mg	2,066	211.56	293.31	1	30	90	270	2,055
Female	444	228.5	314.82	1	30	90	297	2,014
21-44 Years	14	196.57	298.1	9	30	45	336	1,030
45-64 Years	105	215.72	256.61	1	30	100	311	1,229
65+ Years	325	234	332.7	1	30	90	290	2,014
Male	1,622	206.93	287.07	1	30	90	253	2,055
21-44 Years	284	179.21	254.6	1	30	83	206	1,957
45-64 Years	655	203.41	299.87	1	30	90	229	2,055
65+ Years	683	221.83	286.68	1	30	99	289	1,961
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-

Table 8b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Febuxostat (any dose)²								
Switch to Allopurinol (any dose) ³	19,363	247.29	345.58	1	30	95	308	2,536
Female	6,745	248.24	345.37	1	30	91	320	2,418
21-44 Years	117	237.84	353.62	1	30	71	310	1,864
45-64 Years	1,070	242.97	335.54	1	30	97	312	2,375
65+ Years	5,558	249.47	347.1	1	30	91	322	2,418
Male	12,617	246.77	345.71	1	30	96	304	2,536
21-44 Years	1,656	212.79	321.88	1	30	81	244	2,195
45-64 Years	4,265	244.07	357.56	1	30	91	285	2,536
65+ Years	6,696	256.88	343.19	1	30	112	330	2,303
Other	1	510	-	510	510	510	510	510
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	1	510	-	510	510	510	510	510
Allopurinol 100 mg								
Switch to Allopurinol 300 mg	145,823	230.93	329.31	1	32	100	272	3,226
Female	42,738	255.66	352.96	1	36	110	313	3,226
21-44 Years	829	216.83	293.83	1	30	97	254	1,756
45-64 Years	8,461	243.83	344.39	1	32	105	292	3,021
65+ Years	33,448	259.61	356.32	1	37	112	321	3,226
Male	103,083	220.68	318.43	1	31	97	259	3,115
21-44 Years	15,228	179.61	267.72	1	30	89	207	2,854
45-64 Years	36,578	211.11	305.58	1	30	94	246	3,108
65+ Years	51,277	239.7	339.14	1	36	104	285	3,115
Other	2	259	31.11	237	237	259	281	281
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	2	259	31.11	237	237	259	281	281
Switch to Febuxostat 40 mg	32,022	228.17	328.22	1	30	93	270	2,903
Female	13,233	229.06	334.67	1	30	90	270	2,820
21-44 Years	177	214.97	350.05	1	30	90	228	2,378
45-64 Years	1,969	212.07	311.72	1	30	90	240	2,820
65+ Years	11,087	232.31	338.27	1	30	90	272	2,819
Male	18,787	227.53	323.63	1	30	99	269	2,903
21-44 Years	2,074	179.67	269.28	1	30	90	201	2,656
45-64 Years	5,239	206.72	302.03	1	30	90	237	2,700
65+ Years	11,474	245.69	340.3	1	37	109	298	2,903
Other	2	275.5	54.45	237	237	276	314	314
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	1	314	-	314	314	314	314	314
65+ Years	1	237	-	237	237	237	237	237

Table 8b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Switch to Febuxostat 80 mg	10,311	207.13	284.08	1	30	92	245	2,656
Female	3,284	211.04	291.16	1	30	90	257	2,635
21-44 Years	62	192.63	256.21	1	30	90	245	1,389
45-64 Years	634	199.47	262.5	1	30	91	236	1,845
65+ Years	2,588	214.31	298.53	1	30	90	262	2,635
Male	7,026	205.3	280.73	1	30	93	241	2,656
21-44 Years	1,010	163.07	240.46	1	30	79	180	2,656
45-64 Years	2,324	189.4	263.12	1	30	90	217	2,416
65+ Years	3,692	226.86	299.18	1	48	109	273	2,163
Other	1	237	-	237	237	237	237	237
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	1	237	-	237	237	237	237	237
Allopurinol 300 mg								
Switch to Allopurinol 100 mg	63,279	346.2	441.82	1	48	165	472	3,312
Female	19,526	340.7	438.02	1	43	153	463	3,312
21-44 Years	373	287.82	392.55	1	37	121	334	2,048
45-64 Years	3,505	331.87	434.74	1	43	150	456	2,916
65+ Years	15,648	343.94	439.7	1	44	155	467	3,312
Male	43,747	348.64	443.49	1	50	171	476	3,149
21-44 Years	6,433	291.13	385.48	1	32	136	373	2,941
45-64 Years	14,892	333.27	439.55	1	39	153	449	3,149
65+ Years	22,422	375.35	459.33	1	60	181	533	3,124
Other	6	431	411.01	48	60	335	790	1,018
21-44 Years	1	60	-	60	60	60	60	60
45-64 Years	3	486.67	321.3	150	150	520	790	790
65+ Years	2	533	685.89	48	48	533	1,018	1,018
Switch to Febuxostat 40 mg	16,821	244.42	344.55	1	31	97	285	3,114
Female	5,503	213.55	328.36	1	30	90	218	3,025
21-44 Years	110	156.21	209.39	1	30	67	197	1,010
45-64 Years	952	218.21	331.52	1	30	90	234	2,617
65+ Years	4,441	213.97	330.01	1	30	90	216	3,025
Male	11,318	259.43	351.18	1	44	119	311	3,114
21-44 Years	1,714	228.13	298.32	1	45	109	276	2,323
45-64 Years	3,979	246.04	346.57	1	31	110	289	3,114
65+ Years	5,625	278.43	367.86	1	51	120	353	2,571
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-

Table 8b. Descriptive Statistics of Cumulative Exposure Duration, among Patients with Evidence of Switch Exposure Dispensing after Index Date¹, by Sex and Age Group

Exposures	Total Patients	Mean (days)	Standard Deviation	Min (days)	Q1 (days)	Median (days)	Q3 (days)	Max (days)
Switch to Febuxostat 80 mg	8,437	253.07	340.19	1	57	120	304	2,571
Female	2,042	230.83	336.3	1	34	90	264	2,571
21-44 Years	57	216.77	293.76	4	30	90	257	1,347
45-64 Years	454	216.62	309.63	1	53	90	264	2,507
65+ Years	1,531	235.57	345.31	1	32	90	270	2,571
Male	6,395	260.17	341.15	1	60	123	318	2,555
21-44 Years	1,168	247.15	327.12	1	60	120	301	2,518
45-64 Years	2,487	250.77	334.57	1	57	120	302	2,555
65+ Years	2,740	274.26	352.34	1	60	132	343	2,538
Other	0	-	-	-	-	-	-	-
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	0	-	-	-	-	-	-	-
65+ Years	0	-	-	-	-	-	-	-
Allopurinol (any dose)³								
Switch to Febuxostat (any dose) ²	56,401	296.77	389.02	1	53	134	378	3,114
Female	20,659	279.75	383.06	1	38	116	349	3,025
21-44 Years	338	248.71	354.85	1	31	95	296	2,378
45-64 Years	3,379	276.87	377.15	1	42	119	351	2,820
65+ Years	16,942	280.94	384.75	1	38	116	352	3,025
Male	35,740	306.6	392.1	1	60	150	394	3,114
21-44 Years	4,724	275.52	352.7	1	60	139	354	2,656
45-64 Years	11,331	291.29	381.83	1	59	141	364	3,114
65+ Years	19,685	322.87	405.88	1	60	156	426	2,941
Other	2	365	72.12	314	314	365	416	416
21-44 Years	0	-	-	-	-	-	-	-
45-64 Years	1	314	-	314	314	314	314	314
65+ Years	1	416	-	416	416	416	416	416

¹Cohort entry required inclusion criteria of a dispensing of the switch exposure after index dispensing date. Index exposure episodes were truncated at the first occurrence of 1) dispensing of the switch exposure, 2) the end of the last exposure episode, 3) death, 4) disenrollment, or 5) end of Data Partner data availability.

²Febuxostat (any dose) includes Febuxostat dispensings of 40 mg and 80 mg strength.

³Allopurinol (any dose) includes Allopurinol dispensings of 100 mg, 200 mg, and 300 mg strength and combination products.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 30, 2018)

DPID	DP Start Date	DP End Date
DP01	06/01/2007	01/31/2018
DP02	01/01/2000	06/30/2017
DP03	01/01/2000	03/31/2018
DP04	01/01/2008	03/31/2018
DP05	01/01/2006	12/31/2017
DP06	01/01/2000	10/31/2017
DP07	01/01/2008	09/30/2017
DP08	01/01/2010	12/31/2016
DP09	01/01/2005	09/30/2017
DP10	01/01/2000	03/31/2016
DP11	01/01/2000	05/31/2015
DP12	01/01/2000	03/31/2018
DP13	01/01/2000	12/31/2017
DP14	01/01/2000	06/30/2018
DP15	01/01/2004	05/31/2018
DP16	01/01/2000	12/31/2016
DP17	01/01/2012	06/30/2017

¹Start Date and End Date are first calculated by individual table (enrollment, dispensing, etc). End Date is defined as the greatest year-month with a record count that is within 80% of the previous year-month. After Start Dates and End Dates are calculated by individual tables, the overall DP End Date is the minimum of all the table End Dates.

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

Generic Name	Brand Name
allopurinol	allopurinol
allopurinol	Zyloprim
lesinurad/allopurinol	Duzallo
febuxostat	Uloric

Appendix C. List of Generic and Brand Names Used to Define Incidence Washout Criteria in this Request

Generic Name	Brand Name
allopurinol	allopurinol
allopurinol	Zyloprim
lesinurad/allopurinol	Duzallo
febuxostat	Uloric
probenecid	probenecid
probenecid/colchicine	probenecid-colchicine
pegloticase	Krystexxa

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
274	Gout	ICD-9-CM
274.0	Gouty arthropathy	ICD-9-CM
274.00	Gouty arthropathy, unspecified	ICD-9-CM
274.01	Acute gouty arthropathy	ICD-9-CM
274.02	Chronic gouty arthropathy without mention of tophus (tophi)	ICD-9-CM
274.03	Chronic gouty arthropathy with tophus (tophi)	ICD-9-CM
274.1	Gouty nephropathy	ICD-9-CM
274.10	Gouty nephropathy, unspecified	ICD-9-CM
274.11	Uric acid nephrolithiasis	ICD-9-CM
274.19	Other gouty nephropathy	ICD-9-CM
274.8	Gout with other specified manifestations	ICD-9-CM
274.81	Gouty tophi of ear	ICD-9-CM
274.82	Gouty tophi of other sites	ICD-9-CM
274.89	Gout with other specified manifestations	ICD-9-CM
274.9	Gout, unspecified	ICD-9-CM
M10.00	Idiopathic gout, unspecified site	ICD-10-CM
M10.011	Idiopathic gout, right shoulder	ICD-10-CM
M10.012	Idiopathic gout, left shoulder	ICD-10-CM
M10.019	Idiopathic gout, unspecified shoulder	ICD-10-CM
M10.021	Idiopathic gout, right elbow	ICD-10-CM
M10.022	Idiopathic gout, left elbow	ICD-10-CM
M10.029	Idiopathic gout, unspecified elbow	ICD-10-CM
M10.031	Idiopathic gout, right wrist	ICD-10-CM
M10.032	Idiopathic gout, left wrist	ICD-10-CM
M10.039	Idiopathic gout, unspecified wrist	ICD-10-CM
M10.041	Idiopathic gout, right hand	ICD-10-CM
M10.042	Idiopathic gout, left hand	ICD-10-CM
M10.049	Idiopathic gout, unspecified hand	ICD-10-CM
M10.051	Idiopathic gout, right hip	ICD-10-CM
M10.052	Idiopathic gout, left hip	ICD-10-CM
M10.059	Idiopathic gout, unspecified hip	ICD-10-CM
M10.061	Idiopathic gout, right knee	ICD-10-CM
M10.062	Idiopathic gout, left knee	ICD-10-CM
M10.069	Idiopathic gout, unspecified knee	ICD-10-CM
M10.071	Idiopathic gout, right ankle and foot	ICD-10-CM
M10.072	Idiopathic gout, left ankle and foot	ICD-10-CM
M10.079	Idiopathic gout, unspecified ankle and foot	ICD-10-CM
M10.08	Idiopathic gout, vertebrae	ICD-10-CM
M10.09	Idiopathic gout, multiple sites	ICD-10-CM
M10.10	Lead-induced gout, unspecified site	ICD-10-CM
M10.111	Lead-induced gout, right shoulder	ICD-10-CM
M10.112	Lead-induced gout, left shoulder	ICD-10-CM
M10.119	Lead-induced gout, unspecified shoulder	ICD-10-CM
M10.121	Lead-induced gout, right elbow	ICD-10-CM
M10.122	Lead-induced gout, left elbow	ICD-10-CM
M10.129	Lead-induced gout, unspecified elbow	ICD-10-CM
M10.131	Lead-induced gout, right wrist	ICD-10-CM
M10.132	Lead-induced gout, left wrist	ICD-10-CM
M10.139	Lead-induced gout, unspecified wrist	ICD-10-CM
M10.141	Lead-induced gout, right hand	ICD-10-CM
M10.142	Lead-induced gout, left hand	ICD-10-CM
M10.149	Lead-induced gout, unspecified hand	ICD-10-CM
M10.151	Lead-induced gout, right hip	ICD-10-CM

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
M10.152	Lead-induced gout, left hip	ICD-10-CM
M10.159	Lead-induced gout, unspecified hip	ICD-10-CM
M10.161	Lead-induced gout, right knee	ICD-10-CM
M10.162	Lead-induced gout, left knee	ICD-10-CM
M10.169	Lead-induced gout, unspecified knee	ICD-10-CM
M10.171	Lead-induced gout, right ankle and foot	ICD-10-CM
M10.172	Lead-induced gout, left ankle and foot	ICD-10-CM
M10.179	Lead-induced gout, unspecified ankle and foot	ICD-10-CM
M10.18	Lead-induced gout, vertebrae	ICD-10-CM
M10.19	Lead-induced gout, multiple sites	ICD-10-CM
M10.20	Drug-induced gout, unspecified site	ICD-10-CM
M10.211	Drug-induced gout, right shoulder	ICD-10-CM
M10.212	Drug-induced gout, left shoulder	ICD-10-CM
M10.219	Drug-induced gout, unspecified shoulder	ICD-10-CM
M10.221	Drug-induced gout, right elbow	ICD-10-CM
M10.222	Drug-induced gout, left elbow	ICD-10-CM
M10.229	Drug-induced gout, unspecified elbow	ICD-10-CM
M10.231	Drug-induced gout, right wrist	ICD-10-CM
M10.232	Drug-induced gout, left wrist	ICD-10-CM
M10.239	Drug-induced gout, unspecified wrist	ICD-10-CM
M10.241	Drug-induced gout, right hand	ICD-10-CM
M10.242	Drug-induced gout, left hand	ICD-10-CM
M10.249	Drug-induced gout, unspecified hand	ICD-10-CM
M10.251	Drug-induced gout, right hip	ICD-10-CM
M10.252	Drug-induced gout, left hip	ICD-10-CM
M10.259	Drug-induced gout, unspecified hip	ICD-10-CM
M10.261	Drug-induced gout, right knee	ICD-10-CM
M10.262	Drug-induced gout, left knee	ICD-10-CM
M10.269	Drug-induced gout, unspecified knee	ICD-10-CM
M10.271	Drug-induced gout, right ankle and foot	ICD-10-CM
M10.272	Drug-induced gout, left ankle and foot	ICD-10-CM
M10.279	Drug-induced gout, unspecified ankle and foot	ICD-10-CM
M10.28	Drug-induced gout, vertebrae	ICD-10-CM
M10.29	Drug-induced gout, multiple sites	ICD-10-CM
M10.30	Gout due to renal impairment, unspecified site	ICD-10-CM
M10.311	Gout due to renal impairment, right shoulder	ICD-10-CM
M10.312	Gout due to renal impairment, left shoulder	ICD-10-CM
M10.319	Gout due to renal impairment, unspecified shoulder	ICD-10-CM
M10.321	Gout due to renal impairment, right elbow	ICD-10-CM
M10.322	Gout due to renal impairment, left elbow	ICD-10-CM
M10.329	Gout due to renal impairment, unspecified elbow	ICD-10-CM
M10.331	Gout due to renal impairment, right wrist	ICD-10-CM
M10.332	Gout due to renal impairment, left wrist	ICD-10-CM
M10.339	Gout due to renal impairment, unspecified wrist	ICD-10-CM
M10.341	Gout due to renal impairment, right hand	ICD-10-CM
M10.342	Gout due to renal impairment, left hand	ICD-10-CM
M10.349	Gout due to renal impairment, unspecified hand	ICD-10-CM
M10.351	Gout due to renal impairment, right hip	ICD-10-CM
M10.352	Gout due to renal impairment, left hip	ICD-10-CM
M10.359	Gout due to renal impairment, unspecified hip	ICD-10-CM
M10.361	Gout due to renal impairment, right knee	ICD-10-CM
M10.362	Gout due to renal impairment, left knee	ICD-10-CM
M10.369	Gout due to renal impairment, unspecified knee	ICD-10-CM

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
M10.371	Gout due to renal impairment, right ankle and foot	ICD-10-CM
M10.372	Gout due to renal impairment, left ankle and foot	ICD-10-CM
M10.379	Gout due to renal impairment, unspecified ankle and foot	ICD-10-CM
M10.38	Gout due to renal impairment, vertebrae	ICD-10-CM
M10.39	Gout due to renal impairment, multiple sites	ICD-10-CM
M10.40	Other secondary gout, unspecified site	ICD-10-CM
M10.411	Other secondary gout, right shoulder	ICD-10-CM
M10.412	Other secondary gout, left shoulder	ICD-10-CM
M10.419	Other secondary gout, unspecified shoulder	ICD-10-CM
M10.421	Other secondary gout, right elbow	ICD-10-CM
M10.422	Other secondary gout, left elbow	ICD-10-CM
M10.429	Other secondary gout, unspecified elbow	ICD-10-CM
M10.431	Other secondary gout, right wrist	ICD-10-CM
M10.432	Other secondary gout, left wrist	ICD-10-CM
M10.439	Other secondary gout, unspecified wrist	ICD-10-CM
M10.441	Other secondary gout, right hand	ICD-10-CM
M10.442	Other secondary gout, left hand	ICD-10-CM
M10.449	Other secondary gout, unspecified hand	ICD-10-CM
M10.451	Other secondary gout, right hip	ICD-10-CM
M10.452	Other secondary gout, left hip	ICD-10-CM
M10.459	Other secondary gout, unspecified hip	ICD-10-CM
M10.461	Other secondary gout, right knee	ICD-10-CM
M10.462	Other secondary gout, left knee	ICD-10-CM
M10.469	Other secondary gout, unspecified knee	ICD-10-CM
M10.471	Other secondary gout, right ankle and foot	ICD-10-CM
M10.472	Other secondary gout, left ankle and foot	ICD-10-CM
M10.479	Other secondary gout, unspecified ankle and foot	ICD-10-CM
M10.48	Other secondary gout, vertebrae	ICD-10-CM
M10.49	Other secondary gout, multiple sites	ICD-10-CM
M10.9	Gout, unspecified	ICD-10-CM
M1A.00X0	Idiopathic chronic gout, unspecified site, without tophus (tophi)	ICD-10-CM
M1A.00X1	Idiopathic chronic gout, unspecified site, with tophus (tophi)	ICD-10-CM
M1A.0110	Idiopathic chronic gout, right shoulder, without tophus (tophi)	ICD-10-CM
M1A.0111	Idiopathic chronic gout, right shoulder, with tophus (tophi)	ICD-10-CM
M1A.0120	Idiopathic chronic gout, left shoulder, without tophus (tophi)	ICD-10-CM
M1A.0121	Idiopathic chronic gout, left shoulder, with tophus (tophi)	ICD-10-CM
M1A.0190	Idiopathic chronic gout, unspecified shoulder, without tophus (tophi)	ICD-10-CM
M1A.0191	Idiopathic chronic gout, unspecified shoulder, with tophus (tophi)	ICD-10-CM
M1A.0210	Idiopathic chronic gout, right elbow, without tophus (tophi)	ICD-10-CM
M1A.0211	Idiopathic chronic gout, right elbow, with tophus (tophi)	ICD-10-CM
M1A.0220	Idiopathic chronic gout, left elbow, without tophus (tophi)	ICD-10-CM
M1A.0221	Idiopathic chronic gout, left elbow, with tophus (tophi)	ICD-10-CM
M1A.0290	Idiopathic chronic gout, unspecified elbow, without tophus (tophi)	ICD-10-CM
M1A.0291	Idiopathic chronic gout, unspecified elbow, with tophus (tophi)	ICD-10-CM
M1A.0310	Idiopathic chronic gout, right wrist, without tophus (tophi)	ICD-10-CM
M1A.0311	Idiopathic chronic gout, right wrist, with tophus (tophi)	ICD-10-CM
M1A.0320	Idiopathic chronic gout, left wrist, without tophus (tophi)	ICD-10-CM
M1A.0321	Idiopathic chronic gout, left wrist, with tophus (tophi)	ICD-10-CM
M1A.0390	Idiopathic chronic gout, unspecified wrist, without tophus (tophi)	ICD-10-CM
M1A.0391	Idiopathic chronic gout, unspecified wrist, with tophus (tophi)	ICD-10-CM
M1A.0410	Idiopathic chronic gout, right hand, without tophus (tophi)	ICD-10-CM
M1A.0411	Idiopathic chronic gout, right hand, with tophus (tophi)	ICD-10-CM
M1A.0420	Idiopathic chronic gout, left hand, without tophus (tophi)	ICD-10-CM

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
M1A.0421	Idiopathic chronic gout, left hand, with tophus (tophi)	ICD-10-CM
M1A.0490	Idiopathic chronic gout, unspecified hand, without tophus (tophi)	ICD-10-CM
M1A.0491	Idiopathic chronic gout, unspecified hand, with tophus (tophi)	ICD-10-CM
M1A.0510	Idiopathic chronic gout, right hip, without tophus (tophi)	ICD-10-CM
M1A.0511	Idiopathic chronic gout, right hip, with tophus (tophi)	ICD-10-CM
M1A.0520	Idiopathic chronic gout, left hip, without tophus (tophi)	ICD-10-CM
M1A.0521	Idiopathic chronic gout, left hip, with tophus (tophi)	ICD-10-CM
M1A.0590	Idiopathic chronic gout, unspecified hip, without tophus (tophi)	ICD-10-CM
M1A.0591	Idiopathic chronic gout, unspecified hip, with tophus (tophi)	ICD-10-CM
M1A.0610	Idiopathic chronic gout, right knee, without tophus (tophi)	ICD-10-CM
M1A.0611	Idiopathic chronic gout, right knee, with tophus (tophi)	ICD-10-CM
M1A.0620	Idiopathic chronic gout, left knee, without tophus (tophi)	ICD-10-CM
M1A.0621	Idiopathic chronic gout, left knee, with tophus (tophi)	ICD-10-CM
M1A.0690	Idiopathic chronic gout, unspecified knee, without tophus (tophi)	ICD-10-CM
M1A.0691	Idiopathic chronic gout, unspecified knee, with tophus (tophi)	ICD-10-CM
M1A.0710	Idiopathic chronic gout, right ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.0711	Idiopathic chronic gout, right ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.0720	Idiopathic chronic gout, left ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.0721	Idiopathic chronic gout, left ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.0790	Idiopathic chronic gout, unspecified ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.0791	Idiopathic chronic gout, unspecified ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.08X0	Idiopathic chronic gout, vertebrae, without tophus (tophi)	ICD-10-CM
M1A.08X1	Idiopathic chronic gout, vertebrae, with tophus (tophi)	ICD-10-CM
M1A.09X0	Idiopathic chronic gout, multiple sites, without tophus (tophi)	ICD-10-CM
M1A.09X1	Idiopathic chronic gout, multiple sites, with tophus (tophi)	ICD-10-CM
M1A.20X0	Drug-induced chronic gout, unspecified site, without tophus (tophi)	ICD-10-CM
M1A.20X1	Drug-induced chronic gout, unspecified site, with tophus (tophi)	ICD-10-CM
M1A.2110	Drug-induced chronic gout, right shoulder, without tophus (tophi)	ICD-10-CM
M1A.2111	Drug-induced chronic gout, right shoulder, with tophus (tophi)	ICD-10-CM
M1A.2120	Drug-induced chronic gout, left shoulder, without tophus (tophi)	ICD-10-CM
M1A.2121	Drug-induced chronic gout, left shoulder, with tophus (tophi)	ICD-10-CM
M1A.2190	Drug-induced chronic gout, unspecified shoulder, without tophus (tophi)	ICD-10-CM
M1A.2191	Drug-induced chronic gout, unspecified shoulder, with tophus (tophi)	ICD-10-CM
M1A.2210	Drug-induced chronic gout, right elbow, without tophus (tophi)	ICD-10-CM
M1A.2211	Drug-induced chronic gout, right elbow, with tophus (tophi)	ICD-10-CM
M1A.2220	Drug-induced chronic gout, left elbow, without tophus (tophi)	ICD-10-CM
M1A.2221	Drug-induced chronic gout, left elbow, with tophus (tophi)	ICD-10-CM
M1A.2290	Drug-induced chronic gout, unspecified elbow, without tophus (tophi)	ICD-10-CM
M1A.2291	Drug-induced chronic gout, unspecified elbow, with tophus (tophi)	ICD-10-CM
M1A.2310	Drug-induced chronic gout, right wrist, without tophus (tophi)	ICD-10-CM
M1A.2311	Drug-induced chronic gout, right wrist, with tophus (tophi)	ICD-10-CM
M1A.2320	Drug-induced chronic gout, left wrist, without tophus (tophi)	ICD-10-CM
M1A.2321	Drug-induced chronic gout, left wrist, with tophus (tophi)	ICD-10-CM
M1A.2390	Drug-induced chronic gout, unspecified wrist, without tophus (tophi)	ICD-10-CM
M1A.2391	Drug-induced chronic gout, unspecified wrist, with tophus (tophi)	ICD-10-CM
M1A.2410	Drug-induced chronic gout, right hand, without tophus (tophi)	ICD-10-CM
M1A.2411	Drug-induced chronic gout, right hand, with tophus (tophi)	ICD-10-CM
M1A.2420	Drug-induced chronic gout, left hand, without tophus (tophi)	ICD-10-CM
M1A.2421	Drug-induced chronic gout, left hand, with tophus (tophi)	ICD-10-CM
M1A.2490	Drug-induced chronic gout, unspecified hand, without tophus (tophi)	ICD-10-CM
M1A.2491	Drug-induced chronic gout, unspecified hand, with tophus (tophi)	ICD-10-CM
M1A.2510	Drug-induced chronic gout, right hip, without tophus (tophi)	ICD-10-CM
M1A.2511	Drug-induced chronic gout, right hip, with tophus (tophi)	ICD-10-CM

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
M1A.2520	Drug-induced chronic gout, left hip, without tophus (tophi)	ICD-10-CM
M1A.2521	Drug-induced chronic gout, left hip, with tophus (tophi)	ICD-10-CM
M1A.2590	Drug-induced chronic gout, unspecified hip, without tophus (tophi)	ICD-10-CM
M1A.2591	Drug-induced chronic gout, unspecified hip, with tophus (tophi)	ICD-10-CM
M1A.2610	Drug-induced chronic gout, right knee, without tophus (tophi)	ICD-10-CM
M1A.2611	Drug-induced chronic gout, right knee, with tophus (tophi)	ICD-10-CM
M1A.2620	Drug-induced chronic gout, left knee, without tophus (tophi)	ICD-10-CM
M1A.2621	Drug-induced chronic gout, left knee, with tophus (tophi)	ICD-10-CM
M1A.2690	Drug-induced chronic gout, unspecified knee, without tophus (tophi)	ICD-10-CM
M1A.2691	Drug-induced chronic gout, unspecified knee, with tophus (tophi)	ICD-10-CM
M1A.2710	Drug-induced chronic gout, right ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.2711	Drug-induced chronic gout, right ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.2720	Drug-induced chronic gout, left ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.2721	Drug-induced chronic gout, left ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.2790	Drug-induced chronic gout, unspecified ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.2791	Drug-induced chronic gout, unspecified ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.28X0	Drug-induced chronic gout, vertebrae, without tophus (tophi)	ICD-10-CM
M1A.28X1	Drug-induced chronic gout, vertebrae, with tophus (tophi)	ICD-10-CM
M1A.29X0	Drug-induced chronic gout, multiple sites, without tophus (tophi)	ICD-10-CM
M1A.29X1	Drug-induced chronic gout, multiple sites, with tophus (tophi)	ICD-10-CM
M1A.30X0	Chronic gout due to renal impairment, unspecified site, without tophus (tophi)	ICD-10-CM
M1A.30X1	Chronic gout due to renal impairment, unspecified site, with tophus (tophi)	ICD-10-CM
M1A.3110	Chronic gout due to renal impairment, right shoulder, without tophus (tophi)	ICD-10-CM
M1A.3111	Chronic gout due to renal impairment, right shoulder, with tophus (tophi)	ICD-10-CM
M1A.3120	Chronic gout due to renal impairment, left shoulder, without tophus (tophi)	ICD-10-CM
M1A.3121	Chronic gout due to renal impairment, left shoulder, with tophus (tophi)	ICD-10-CM
M1A.3190	Chronic gout due to renal impairment, unspecified shoulder, without tophus (tophi)	ICD-10-CM
M1A.3191	Chronic gout due to renal impairment, unspecified shoulder, with tophus (tophi)	ICD-10-CM
M1A.3210	Chronic gout due to renal impairment, right elbow, without tophus (tophi)	ICD-10-CM
M1A.3211	Chronic gout due to renal impairment, right elbow, with tophus (tophi)	ICD-10-CM
M1A.3220	Chronic gout due to renal impairment, left elbow, without tophus (tophi)	ICD-10-CM
M1A.3221	Chronic gout due to renal impairment, left elbow, with tophus (tophi)	ICD-10-CM
M1A.3290	Chronic gout due to renal impairment, unspecified elbow, without tophus (tophi)	ICD-10-CM
M1A.3291	Chronic gout due to renal impairment, unspecified elbow, with tophus (tophi)	ICD-10-CM
M1A.3310	Chronic gout due to renal impairment, right wrist, without tophus (tophi)	ICD-10-CM
M1A.3311	Chronic gout due to renal impairment, right wrist, with tophus (tophi)	ICD-10-CM
M1A.3320	Chronic gout due to renal impairment, left wrist, without tophus (tophi)	ICD-10-CM
M1A.3321	Chronic gout due to renal impairment, left wrist, with tophus (tophi)	ICD-10-CM
M1A.3390	Chronic gout due to renal impairment, unspecified wrist, without tophus (tophi)	ICD-10-CM
M1A.3391	Chronic gout due to renal impairment, unspecified wrist, with tophus (tophi)	ICD-10-CM
M1A.3410	Chronic gout due to renal impairment, right hand, without tophus (tophi)	ICD-10-CM
M1A.3411	Chronic gout due to renal impairment, right hand, with tophus (tophi)	ICD-10-CM
M1A.3420	Chronic gout due to renal impairment, left hand, without tophus (tophi)	ICD-10-CM
M1A.3421	Chronic gout due to renal impairment, left hand, with tophus (tophi)	ICD-10-CM
M1A.3490	Chronic gout due to renal impairment, unspecified hand, without tophus (tophi)	ICD-10-CM
M1A.3491	Chronic gout due to renal impairment, unspecified hand, with tophus (tophi)	ICD-10-CM
M1A.3510	Chronic gout due to renal impairment, right hip, without tophus (tophi)	ICD-10-CM
M1A.3511	Chronic gout due to renal impairment, right hip, with tophus (tophi)	ICD-10-CM
M1A.3520	Chronic gout due to renal impairment, left hip, without tophus (tophi)	ICD-10-CM
M1A.3521	Chronic gout due to renal impairment, left hip, with tophus (tophi)	ICD-10-CM
M1A.3590	Chronic gout due to renal impairment, unspecified hip, without tophus (tophi)	ICD-10-CM
M1A.3591	Chronic gout due to renal impairment, unspecified hip, with tophus (tophi)	ICD-10-CM

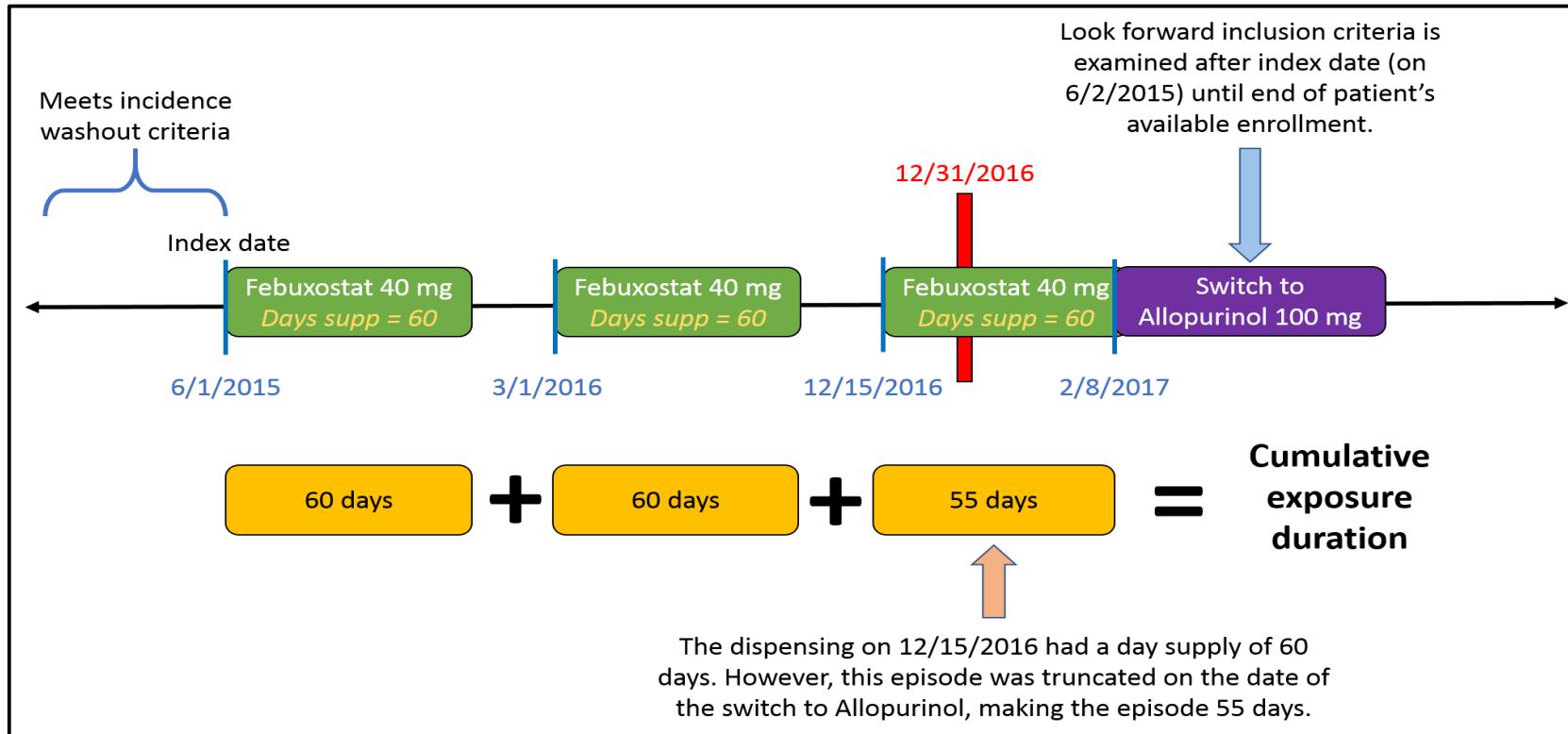
Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
M1A.3610	Chronic gout due to renal impairment, right knee, without tophus (tophi)	ICD-10-CM
M1A.3611	Chronic gout due to renal impairment, right knee, with tophus (tophi)	ICD-10-CM
M1A.3620	Chronic gout due to renal impairment, left knee, without tophus (tophi)	ICD-10-CM
M1A.3621	Chronic gout due to renal impairment, left knee, with tophus (tophi)	ICD-10-CM
M1A.3690	Chronic gout due to renal impairment, unspecified knee, without tophus (tophi)	ICD-10-CM
M1A.3691	Chronic gout due to renal impairment, unspecified knee, with tophus (tophi)	ICD-10-CM
M1A.3710	Chronic gout due to renal impairment, right ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.3711	Chronic gout due to renal impairment, right ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.3720	Chronic gout due to renal impairment, left ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.3721	Chronic gout due to renal impairment, left ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.3790	Chronic gout due to renal impairment, unspecified ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.3791	Chronic gout due to renal impairment, unspecified ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.38X0	Chronic gout due to renal impairment, vertebrae, without tophus (tophi)	ICD-10-CM
M1A.38X1	Chronic gout due to renal impairment, vertebrae, with tophus (tophi)	ICD-10-CM
M1A.39X0	Chronic gout due to renal impairment, multiple sites, without tophus (tophi)	ICD-10-CM
M1A.39X1	Chronic gout due to renal impairment, multiple sites, with tophus (tophi)	ICD-10-CM
M1A.40X0	Other secondary chronic gout, unspecified site, without tophus (tophi)	ICD-10-CM
M1A.40X1	Other secondary chronic gout, unspecified site, with tophus (tophi)	ICD-10-CM
M1A.4110	Other secondary chronic gout, right shoulder, without tophus (tophi)	ICD-10-CM
M1A.4111	Other secondary chronic gout, right shoulder, with tophus (tophi)	ICD-10-CM
M1A.4120	Other secondary chronic gout, left shoulder, without tophus (tophi)	ICD-10-CM
M1A.4121	Other secondary chronic gout, left shoulder, with tophus (tophi)	ICD-10-CM
M1A.4190	Other secondary chronic gout, unspecified shoulder, without tophus (tophi)	ICD-10-CM
M1A.4191	Other secondary chronic gout, unspecified shoulder, with tophus (tophi)	ICD-10-CM
M1A.4210	Other secondary chronic gout, right elbow, without tophus (tophi)	ICD-10-CM
M1A.4211	Other secondary chronic gout, right elbow, with tophus (tophi)	ICD-10-CM
M1A.4220	Other secondary chronic gout, left elbow, without tophus (tophi)	ICD-10-CM
M1A.4221	Other secondary chronic gout, left elbow, with tophus (tophi)	ICD-10-CM
M1A.4290	Other secondary chronic gout, unspecified elbow, without tophus (tophi)	ICD-10-CM
M1A.4291	Other secondary chronic gout, unspecified elbow, with tophus (tophi)	ICD-10-CM
M1A.4310	Other secondary chronic gout, right wrist, without tophus (tophi)	ICD-10-CM
M1A.4311	Other secondary chronic gout, right wrist, with tophus (tophi)	ICD-10-CM
M1A.4320	Other secondary chronic gout, left wrist, without tophus (tophi)	ICD-10-CM
M1A.4321	Other secondary chronic gout, left wrist, with tophus (tophi)	ICD-10-CM
M1A.4390	Other secondary chronic gout, unspecified wrist, without tophus (tophi)	ICD-10-CM
M1A.4391	Other secondary chronic gout, unspecified wrist, with tophus (tophi)	ICD-10-CM
M1A.4410	Other secondary chronic gout, right hand, without tophus (tophi)	ICD-10-CM
M1A.4411	Other secondary chronic gout, right hand, with tophus (tophi)	ICD-10-CM
M1A.4420	Other secondary chronic gout, left hand, without tophus (tophi)	ICD-10-CM
M1A.4421	Other secondary chronic gout, left hand, with tophus (tophi)	ICD-10-CM
M1A.4490	Other secondary chronic gout, unspecified hand, without tophus (tophi)	ICD-10-CM
M1A.4491	Other secondary chronic gout, unspecified hand, with tophus (tophi)	ICD-10-CM
M1A.4510	Other secondary chronic gout, right hip, without tophus (tophi)	ICD-10-CM
M1A.4511	Other secondary chronic gout, right hip, with tophus (tophi)	ICD-10-CM
M1A.4520	Other secondary chronic gout, left hip, without tophus (tophi)	ICD-10-CM
M1A.4521	Other secondary chronic gout, left hip, with tophus (tophi)	ICD-10-CM
M1A.4590	Other secondary chronic gout, unspecified hip, without tophus (tophi)	ICD-10-CM
M1A.4591	Other secondary chronic gout, unspecified hip, with tophus (tophi)	ICD-10-CM
M1A.4610	Other secondary chronic gout, right knee, without tophus (tophi)	ICD-10-CM
M1A.4611	Other secondary chronic gout, right knee, with tophus (tophi)	ICD-10-CM
M1A.4620	Other secondary chronic gout, left knee, without tophus (tophi)	ICD-10-CM
M1A.4621	Other secondary chronic gout, left knee, with tophus (tophi)	ICD-10-CM
M1A.4690	Other secondary chronic gout, unspecified knee, without tophus (tophi)	ICD-10-CM

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Type
M1A.4691	Other secondary chronic gout, unspecified knee, with tophus (tophi)	ICD-10-CM
M1A.4710	Other secondary chronic gout, right ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.4711	Other secondary chronic gout, right ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.4720	Other secondary chronic gout, left ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.4721	Other secondary chronic gout, left ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.4790	Other secondary chronic gout, unspecified ankle and foot, without tophus (tophi)	ICD-10-CM
M1A.4791	Other secondary chronic gout, unspecified ankle and foot, with tophus (tophi)	ICD-10-CM
M1A.48X0	Other secondary chronic gout, vertebrae, without tophus (tophi)	ICD-10-CM
M1A.48X1	Other secondary chronic gout, vertebrae, with tophus (tophi)	ICD-10-CM
M1A.49X0	Other secondary chronic gout, multiple sites, without tophus (tophi)	ICD-10-CM
M1A.49X1	Other secondary chronic gout, multiple sites, with tophus (tophi)	ICD-10-CM
M1A.9XX0	Chronic gout, unspecified, without tophus (tophi)	ICD-10-CM
M1A.9XX1	Chronic gout, unspecified, with tophus (tophi)	ICD-10-CM

Appendix E. Cumulative exposure duration of Febuxostat 40 mg, switch to Allopurinol 100 mg, censored at query end date¹ (12/31/2016)



¹Cumulative exposure duration of Febuxostat 40 mg is truncated at the switch of interest, Allopurinol 100 mg (2/8/2017). By not censoring at the query end date, we capture the total cumulative exposure duration until the switch of interest.

Appendix F. Specifications for Type 5 Request: cder_mpl1r_wp126

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool, version 6.0.0, to examine use and switching of urate-lowering therapies (specifically febuxostat and allopurinol of varying dosages) among the gout population in the Sentinel Distributed Database (SDD).

Query period: January 1, 2009 - December 31, 2016

Coverage requirement: Medical and Drug Coverage

Pre-index enrollment requirement: 183 days

Post-index enrollment requirement: 0 days

Enrollment gap: 45 days

Age groups: 21-44, 45-64, 65+ years

Cumulative exposure length categories: <1 month, 1-3 months, 3-6 months, 6 months-<1 year, 1-3 years, 3-5 years, 5+ years

Stratifications: Cumulative exposure length

Cumulative exposure length by sex

Cumulative exposure length by age group

Cumulative exposure length by sex by age group

Scenario	Index Exposure	Cohort definition	Exposure					Inclusion Criteria					Evaluation period start	Number of instances criteria should be found in evaluation period
			Incident exposure washout period	Incident with respect to:	Treatment episode gap	Care setting	Truncate exposure episode at evidence of:	Censor treatment episode at evidence of:	Inclusion group	Criteria	Care setting			
1	Febuxostat, 40 mg	Include all valid exposure episodes during query period; only the first valid exposure episode's incidence is assessed using washout criteria	183	Febuxostat (40 or 80 mg), Allopurinol (100, 200, or 300 mg), Probenecid, Pegoloticase	30 days	Any care setting	--	Death; Disenrollment; Data Partner end date	Gout	Inclusion	Any care setting	(-183, 0)	1	
2	Febuxostat, 80 mg	Include all valid exposure episodes during query period; only the first valid exposure episode's incidence is assessed using washout criteria	183	Febuxostat (40 or 80 mg), Allopurinol (100, 200, or 300 mg), Probenecid, Pegoloticase	30 days	Any care setting	--	Death; Disenrollment; Data Partner end date	Gout	Inclusion	Any care setting	(-183, 0)	1	
3	Febuxostat (any dose: 40 or 80 mg)	Include all valid exposure episodes during query period; only the first valid exposure episode's incidence is assessed using washout criteria	183	Febuxostat (40 or 80 mg), Allopurinol (100, 200, or 300 mg), Probenecid, Pegoloticase	30 days	Any care setting	--	Death; Disenrollment; Data Partner end date	Gout	Inclusion	Any care setting	(-183, 0)	1	
4	Allopurinol, 100 mg	Include all valid exposure episodes during query period; only the first valid exposure episode's incidence is assessed using washout criteria	183	Febuxostat (40 or 80 mg), Allopurinol (100, 200, or 300 mg), Probenecid, Pegoloticase	30 days	Any care setting	--	Death; Disenrollment; Data Partner end date	Gout	Inclusion	Any care setting	(-183, 0)	1	
5	Allopurinol, 300 mg	Include all valid exposure episodes during query period; only the first valid exposure episode's incidence is assessed using washout criteria	183	Febuxostat (40 or 80 mg), Allopurinol (100, 200, or 300 mg), Probenecid, Pegoloticase	30 days	Any care setting	--	Death; Disenrollment; Data Partner end date	Gout	Inclusion	Any care setting	(-183, 0)	1	
6	Allopurinol (any dose: 100, 200, or 300 mg)	Include all valid exposure episodes during query period; only the first valid exposure episode's incidence is assessed using washout criteria	183	Febuxostat (40 or 80 mg), Allopurinol (100, 200, or 300 mg), Probenecid, Pegoloticase	30 days	Any care setting	--	Death; Disenrollment; Data Partner end date	Gout	Inclusion	Any care setting	(-183, 0)	1	

