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

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

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

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Overview

Date Run: October 29, 2018

Request Description: The purpose of this report was to compare the frequency of diagnoses of gout using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. ICD-10-CM code definitions were determined by mapping from ICD-9-CM code definitions using the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). Forward-backward mapping (FBM) was used to map ICD-9-CM to ICD-10-CM codes.¹

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.4.4

Data Source: This request was run against a 5% sample of the IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 6.35 million members. Data from October 1, 2010 to September 30, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 30, 2016, 2) April 1, 2015 to September 30, 2015, and 3) April 1, 2016 to September 30, 2016. See Appendix A for the dates of available data used in this report.

Study Design: We examined the incidence and prevalence of gout across the ICD-9-CM era (October 2010 - September 2015) and ICD-10-CM era (October 2015 - September 2016) in the US. Incidence was additionally evaluated from April 2015 to September 2015 and April 2016 to September 2016. See Appendix B for specific codes.

Cohort Eligibility Criteria: Members included in the cohorts were required to be enrolled in plans with medical and drug coverage. The following age groups were included in the cohorts: 21-44, 45-64 and 65+ years.

Incident Cohorts: Members included in the incident cohorts were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to the first qualifying (index) gout diagnosis during which gaps in coverage of up to 45 days were allowed. Incident gout was defined as no previous gout diagnoses in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

Prevalent Cohorts: There was no enrollment requirement for members in the prevalent cohorts. All qualifying diagnosis codes that occurred between October 1, 2010 and September 30, 2016 were included.

Please refer to Appendix C for detailed specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define outcomes are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind. The MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented.²

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

¹Fung, K. W., et al. (2016). "Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions." EGEMS (Wash DC) 4(1): 1211.

²IBM Watson Health (2018). [online] ibm.com. Available at: <https://www.ibm.com/downloads/cas/OWZWJ0QO> [Accessed 01 Mar. 2019].

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

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

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 parameter.

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

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

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

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

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

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

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

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

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

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

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

Event Deduplication - specifies how events are counted by the 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 dispensing).

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

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

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 Caresetting/PDX parameter.

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

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

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 1. Comparison of Incident* Gout Diagnoses in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016)

	Members with Diagnosis	Eligible Members	Members with Diagnosis per 10,000 Eligible Members
Gout			
ICD-9 CM: April 1, 2015 - September 30, 2015	6,174	956,574	64.54
ICD-10 CM: April 1, 2016 - September 30, 2016	5,720	949,266	60.26

*Incidence defined by 183 day washout

Figure 1. Incidence of Gout Diagnoses, per 10,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout

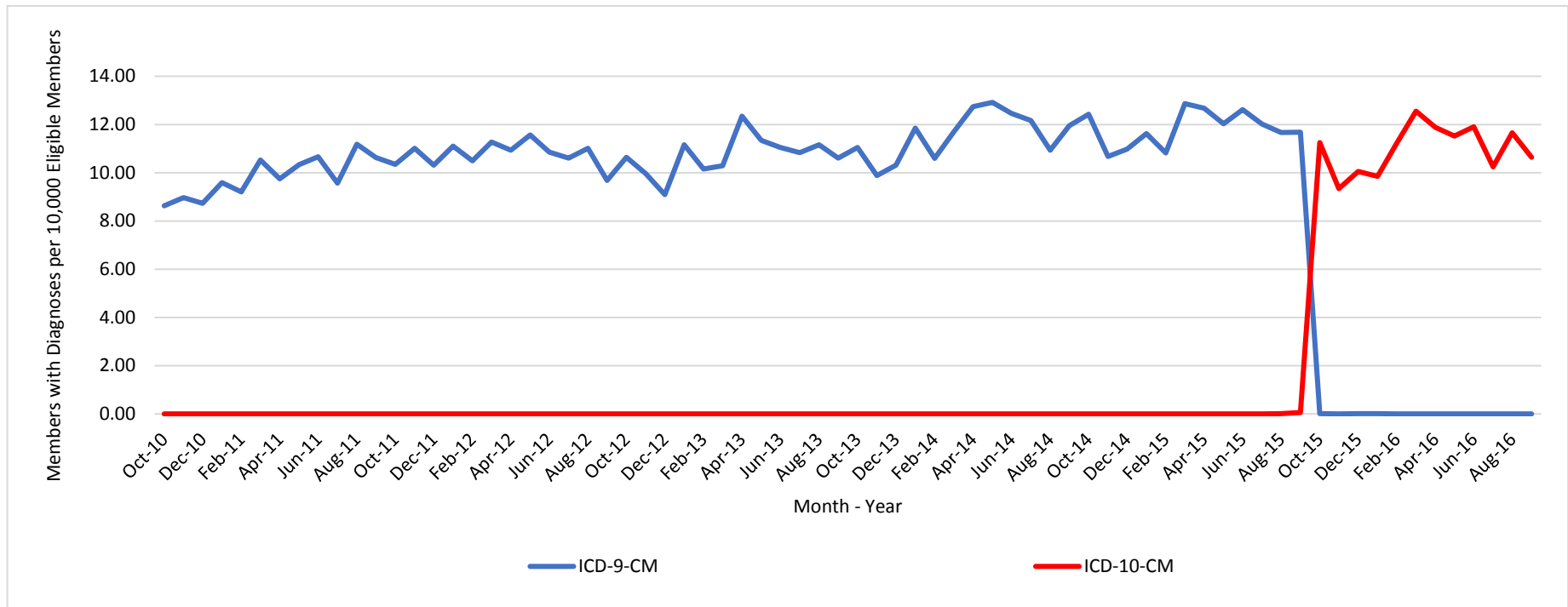
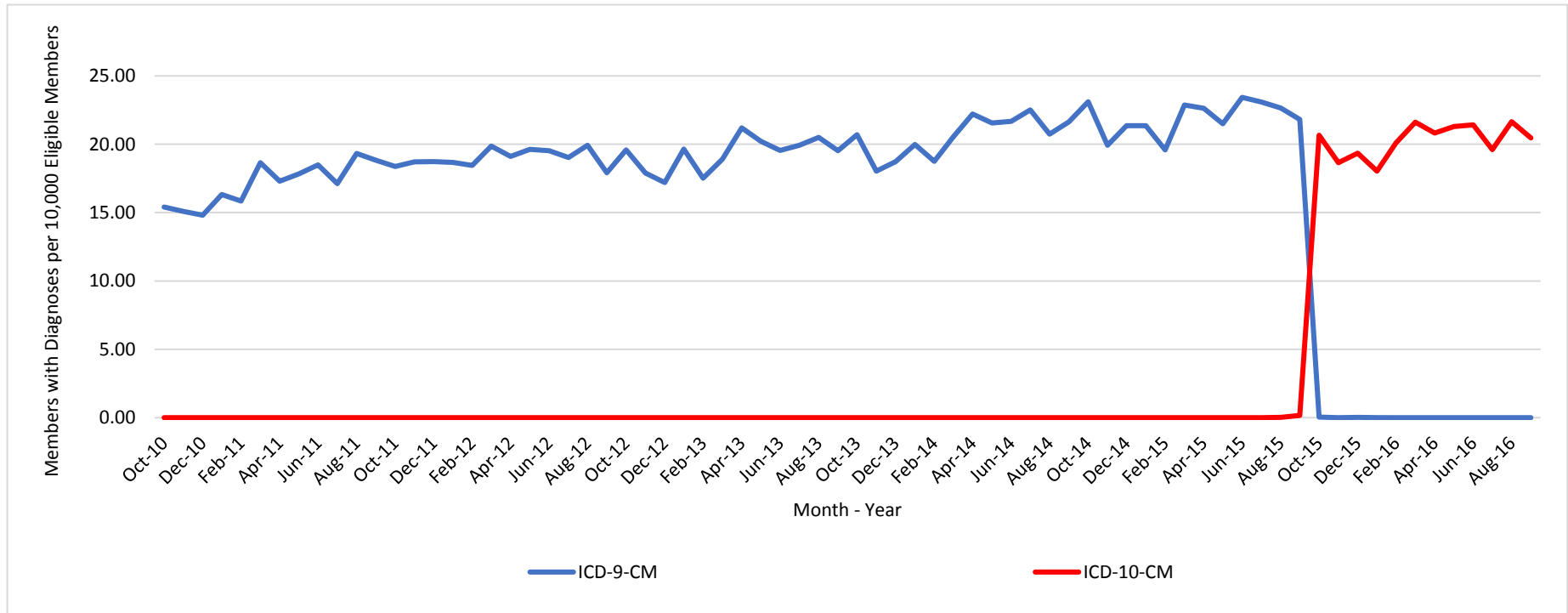


Figure 2. Prevalence of Gout Diagnoses per 10,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout



Appendix A. Dates Available for IBM® MarketScan® Commercial and Medicare Supplemental Databases

Databases	Start Date	End Date
IBM MarketScan Commercial and Medicare Supplemental Databases ¹	1/1/2010	9/30/2016

¹ The IBM MarketScan Databases includes a sample of 127.2 million employees, dependents, and retirees in the United States with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans. The IBM MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented. For more information on the IBM MarketScan Databases, please review the White Paper here: <https://www.ibm.com/downloads/cas/OWZWJ0QO>

Appendix B. 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

Code	Description	Code Type
ICD-9-CM		
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
ICD-10-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

Appendix B. 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

Code	Description	Code Type
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
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

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Code	Description	Code Type
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
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

Appendix B. 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

Code	Description	Code Type
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
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

Appendix B. 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

Code	Description	Code Type
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
M1A.2520	Drug-induced chronic gout, left hip, without tophus (tophi)	ICD-10-CM

Appendix B. 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

Code	Description	Code Type
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

Appendix B. 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

Code	Description	Code Type
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
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

Appendix B. 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

Code	Description	Code Type
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
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 C. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.4.4, was used to compare the frequency of diagnoses for gout using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) versus International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes.

Query Period: October 1, 2010 - September 30, 2016

Enrollment Gap: 45 Days

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

Enrollment Requirement: 183 days for incidence scenarios; 0 days for prevalence scenarios

Coverage Requirement: Medical & Drug Coverage

Scenario	Query Start Date	Query End Date	Event		Incident with Respect To:	Washout (days)	Cohort Definition	Care Setting
			Event	Event Code Type				
1	4/1/2015	9/30/2015	Gout	ICD-9-CM	ICD-9-CM	183	All valid events	Any
2	4/1/2016	9/30/2016	Gout	ICD-10-CM	ICD-10-CM	183	All valid events	Any
3	10/1/2010	9/30/2016	Gout	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	All valid events	Any
4	10/1/2010	9/30/2016	Gout	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	All valid events	Any
5	10/1/2010	9/30/2016	Gout	ICD-9-CM	N/A	0	All valid events	Any
6	10/1/2010	9/30/2016	Gout	ICD-10-CM	N/A	0	All valid events	Any

ICD-9-CM and ICD-10-CM are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.