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).

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Sentinel

Overview for Request: cder_mpl1r_wp101

Request ID: cder_mpl1r_wp101_nsdp_v01

Request Description: This report contains estimates of interleukin-1 (IL-1) and interleukin-6 (IL-6) inhibitor use and occurrence of pulmonary arterial hypertension (PAH), interstitial lung disease (ILD), and macrophage activation syndrome (MAS) among an adult cohort with Adult-Onset Still’s Disease (AOSD) and a pediatric cohort with Systemic Juvenile Idiopathic Arthritis (SJIA) in the Sentinel Distributed Database (SDD). This is report 2 of 2. Report 1 contains estimates of PAH, ILD, and MAS among an adult cohort with AOSD and a pediatric cohort with SJIA in the SDD.

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

Data Source: Data from October 1, 2015 to March 31, 2018 from 15 Data Partners contributing to the SDD were included in this report. See Appendix A for a list of dates of available data for each Data Partner. This request was distributed to Data Partners on August 15, 2018.

Purpose: The purpose of this request was to estimate the number of incident PAH, ILD, and MAS diagnoses among:

1) a cohort of adult members who were dispensed IL-1/-6 inhibitors and were previously diagnosed with AOSD
2) a cohort of pediatric members who were dispensed IL-1/-6 inhibitors and were previously diagnosed with SJIA

Member demographic characteristics and health service utilization intensity in the 183 days prior to their first qualifying dispensing, across different care settings, were additionally assessed for each cohort.

Exposures of Interest: The exposures of interest were IL-1 and IL-6 inhibitors; generic names of these drugs include anakinra, canakinumab, rilonacept, sarilumab, and tocilizumab. These exposures were identified using National Drug Codes (NDC) and Healthcare Common Procedure Coding System (HCPCS) codes. Qualifying exposure dispensing dates are defined as the first exposure episode during the query period that meets all requested criteria, specified below. See Appendix B for a full list of drug names and codes used to define IL-1/-6 inhibitors in this request.

Cohort Eligibility Criteria: Those included in the cohorts were required to be continuously enrolled in plans with medical and drug coverage for at least 183 days prior to their first qualifying dispensing, during which gaps in coverage of up to 45 days were allowed. The adult cohort included members who were 17 to less than 65 years of age and had a diagnosis of AOSD. The pediatric cohort included members who were six months to less than 17 years of age and had a diagnosis of SJIA. Eligible members could not have evidence of PAH or ILD events in any available enrollment history prior to the first qualifying dispensing event. Please see Appendix C for a list of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) AOSD and SJIA diagnosis codes used to define the cohorts, and see Appendix D for a list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and ICD-10-CM codes used as exclusion criteria in defining first qualifying dispensings.

Health Care Characteristics of Interest: Prior glucocorticoid agent and pain medication use were assessed throughout patient’s entire available enrollment history until the day prior to first qualifying IL-1/-6 inhibitor dispensing. Diagnoses of PAH, ILD, and MAS were identified from the day after first qualifying IL-1/-6 dispensing until the patient’s disenrollment or Data Partner end date. See Appendix E for HCPCS and Current Procedural Terminology, Fourth Edition (CPT-4) codes, and the generic and brand drug names used to define glucocorticoid agents and pain medications, and Appendix F for ICD-10-CM diagnosis codes used to define PAH, ILD, and MAS.

Please see Appendices G (adult population) and H (pediatric population) for the specifications of parameters used in the analyses for this request.

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

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.
| Appendix A | Dates of Available Data for Each Data Partner (DP) as of Request End Date (March 31, 2018) |
| Appendix B | List of Generic and Brand Drug Names and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Interleukin (IL)-1/-6 Inhibitor Exposure in this Request |
| Appendix C | List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define the Adult and Pediatric Cohorts in this Request |
| 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 as Exclusion Criteria in Defining First Qualifying Dispensings |
| Appendix F | List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Health Care Characteristics of Interest in this Request |
| Appendix G | Specifications Defining Parameters for the Adult Cohort Used in this Request |
| Appendix H | Specifications Defining Parameters for the Pediatric Cohort Used in this Request |
Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Tool*

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

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

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

- **Ambulatory Visit (AV)** - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED)** - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP)** - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS)** - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA)** - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

**Cohort Definition (drug/exposure)** - indicates how the cohort will be defined: (1): Cohort includes only the first valid treatment episode during the query period; (2): Cohort includes all valid treatment episodes during the query period; (3): 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 MP algorithm: (0): Counts all occurrences of an HOI during an exposure episode; (1): de-duplicates occurrences of the same HOI code and code type on the same day; (2): de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

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

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

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

*not all terms may be used in this report*
Table 1. Characterization Table for the First QualifyingDispensing of Interleukin (IL)-1/-6 Inhibitors among Adult Members with Adult-Onset Still’s Disease (AOSD) in the Sentinel Distributed Database (SDD) between October 1, 2015 and March 31, 2018

<table>
<thead>
<tr>
<th>IL-1/-6 inhibitor use among adult members with AOSD, no evidence of PAH or ILD prior to IL-1/-6 dispensing</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of episodes</td>
<td>222</td>
</tr>
<tr>
<td>Number of unique patients</td>
<td>222</td>
</tr>
<tr>
<td>Eligible Members</td>
<td>1,265</td>
</tr>
<tr>
<td>Eligible Member Years</td>
<td>984.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>42</td>
<td>11.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: 17-64</td>
<td>222</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>139</td>
</tr>
<tr>
<td>Gender (Male)</td>
<td>83</td>
</tr>
<tr>
<td>Year (2015)</td>
<td>61</td>
</tr>
<tr>
<td>Year (2016)</td>
<td>93</td>
</tr>
<tr>
<td>Year (2017)</td>
<td>68</td>
</tr>
<tr>
<td>Year (2018)</td>
<td>0</td>
</tr>
</tbody>
</table>

Recorded history of:

<table>
<thead>
<tr>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucocorticoid Use</td>
<td>192</td>
</tr>
<tr>
<td>Pain Medication Use</td>
<td>143</td>
</tr>
</tbody>
</table>

Diagnosis following dispensing:

<table>
<thead>
<tr>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary Arterial Hypertension (PAH)</td>
<td>7</td>
</tr>
<tr>
<td>Interstitial Lung Disease (ILD)</td>
<td>2</td>
</tr>
<tr>
<td>Macrophage Activation Syndrome (MAS)</td>
<td>13</td>
</tr>
</tbody>
</table>

Health service utilization intensity in the prior 183 days:

<table>
<thead>
<tr>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of ambulatory encounters (AV)</td>
<td>12.3</td>
</tr>
<tr>
<td>Mean number of emergency room encounters (ED)</td>
<td>0.5</td>
</tr>
<tr>
<td>Mean number of inpatient hospital encounters (IP)</td>
<td>0.4</td>
</tr>
<tr>
<td>Mean number of non-acute institutional encounters (IS)</td>
<td>0</td>
</tr>
<tr>
<td>Mean number of other ambulatory encounters (OA)</td>
<td>3.5</td>
</tr>
</tbody>
</table>

---

1 Eligible Members and Member Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.
### IL-1/-6 inhibitor use among pediatric members with SJIA, no evidence of PAH or ILD prior to IL-1/-6 dispensing

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of episodes</td>
<td>194</td>
</tr>
<tr>
<td>Number of unique patients</td>
<td>194</td>
</tr>
<tr>
<td>Eligible Members(^1)</td>
<td>897</td>
</tr>
<tr>
<td>Eligible Member Years(^1)</td>
<td>670.4</td>
</tr>
</tbody>
</table>

#### Characteristic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>9.3</td>
<td>4.8</td>
</tr>
</tbody>
</table>

#### Recorded history of:

<table>
<thead>
<tr>
<th>Recorded history of</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucocorticoid Use</td>
<td>144</td>
<td>74.2%</td>
</tr>
<tr>
<td>Pain Medication Use</td>
<td>135</td>
<td>69.6%</td>
</tr>
</tbody>
</table>

#### Diagnosis following dispensing:

<table>
<thead>
<tr>
<th>Diagnosis following dispensing</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary Arterial Hypertension (PAH)</td>
<td>1</td>
<td>0.5%</td>
</tr>
<tr>
<td>Interstitial Lung Disease (ILD)</td>
<td>4</td>
<td>2.1%</td>
</tr>
<tr>
<td>Macrophage Activation Syndrome (MAS)</td>
<td>20</td>
<td>10.3%</td>
</tr>
</tbody>
</table>

#### Health service utilization intensity in the prior 183 days:

<table>
<thead>
<tr>
<th>Health service utilization intensity in the prior 183 days</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of ambulatory encounters (AV)</td>
<td>12.1</td>
<td>11.5</td>
</tr>
<tr>
<td>Mean number of emergency room encounters (ED)</td>
<td>0.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Mean number of inpatient hospital encounters (IP)</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Mean number of non-acute institutional encounters (IS)</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Mean number of other ambulatory encounters (OA)</td>
<td>3.8</td>
<td>12.6</td>
</tr>
</tbody>
</table>

\(^1\) Eligible Members and Member Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.
## Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request End Date (March 31, 2018)

<table>
<thead>
<tr>
<th>Data Partner ID</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP01</td>
<td>01/01/2000</td>
<td>03/31/2018</td>
</tr>
<tr>
<td>DP02</td>
<td>01/01/2005</td>
<td>09/30/2017</td>
</tr>
<tr>
<td>DP03</td>
<td>01/01/2008</td>
<td>06/30/2017</td>
</tr>
<tr>
<td>DP04</td>
<td>01/01/2008</td>
<td>11/30/2017</td>
</tr>
<tr>
<td>DP05</td>
<td>01/01/2000</td>
<td>06/30/2017</td>
</tr>
<tr>
<td>DP06</td>
<td>01/01/2006</td>
<td>12/31/2017</td>
</tr>
<tr>
<td>DP07</td>
<td>01/01/2000</td>
<td>08/31/2017</td>
</tr>
<tr>
<td>DP08</td>
<td>01/01/2000</td>
<td>10/31/2017</td>
</tr>
<tr>
<td>DP09</td>
<td>06/01/2007</td>
<td>10/31/2017</td>
</tr>
<tr>
<td>DP10</td>
<td>01/01/2000</td>
<td>12/31/2017</td>
</tr>
<tr>
<td>DP11</td>
<td>01/01/2004</td>
<td>01/31/2018</td>
</tr>
<tr>
<td>DP12</td>
<td>01/01/2000</td>
<td>01/31/2017</td>
</tr>
<tr>
<td>DP13</td>
<td>01/01/2000</td>
<td>12/31/2016</td>
</tr>
<tr>
<td>DP14</td>
<td>01/01/2000</td>
<td>03/31/2016</td>
</tr>
<tr>
<td>DP15</td>
<td>01/01/2012</td>
<td>06/30/2017</td>
</tr>
</tbody>
</table>

\(^1\)Start 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 Date and End Dates are calculated by individual tables, the overall End Date is the minimum of all the table End Dates.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Code Type</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Code Type</th>
<th>Code</th>
<th>Code Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anakinra</td>
<td>NDC</td>
<td>ANAKINRA</td>
<td>Kineret</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canakinumab</td>
<td>NDC</td>
<td>CANAKINUMAB/PF</td>
<td>Ilaris (PF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCPCS</td>
<td>J0638</td>
<td>PX</td>
<td>Injection, canakinumab, 1 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rilonacept</td>
<td>NDC</td>
<td>RILONACEPT</td>
<td>Arcalyst</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCPCS</td>
<td>J2793</td>
<td>PX</td>
<td>Injection, rilonacept, 1 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sarilumab</td>
<td>NDC</td>
<td>SARILUMAB</td>
<td>Kevzara</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>NDC</td>
<td>TOCILIZUMAB</td>
<td>Actemra</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCPCS</td>
<td>C9264</td>
<td>PX</td>
<td>Injection, tocilizumab, 1 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCPCS</td>
<td>J3262</td>
<td>PX</td>
<td>Injection, tocilizumab, 1 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix C. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define the Adult and Pediatric Cohorts in this Request

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Code Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>M06.1</td>
<td>Adult-onset Still's disease</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.2</td>
<td>Juvenile rheumatoid arthritis with systemic onset</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.20</td>
<td>Juvenile rheumatoid arthritis with systemic onset, unspecified site</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.21</td>
<td>Juvenile rheumatoid arthritis with systemic onset, shoulder</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.211</td>
<td>Juvenile rheumatoid arthritis with systemic onset, right shoulder</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.212</td>
<td>Juvenile rheumatoid arthritis with systemic onset, left shoulder</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.219</td>
<td>Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.22</td>
<td>Juvenile rheumatoid arthritis with systemic onset, elbow</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.221</td>
<td>Juvenile rheumatoid arthritis with systemic onset, right elbow</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.222</td>
<td>Juvenile rheumatoid arthritis with systemic onset, left elbow</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.229</td>
<td>Juvenile rheumatoid arthritis with systemic onset, unspecified elbow</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.23</td>
<td>Juvenile rheumatoid arthritis with systemic onset, wrist</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.231</td>
<td>Juvenile rheumatoid arthritis with systemic onset, right wrist</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.232</td>
<td>Juvenile rheumatoid arthritis with systemic onset, left wrist</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.239</td>
<td>Juvenile rheumatoid arthritis with systemic onset, unspecified wrist</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.24</td>
<td>Juvenile rheumatoid arthritis with systemic onset, hand</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.241</td>
<td>Juvenile rheumatoid arthritis with systemic onset, right hand</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.242</td>
<td>Juvenile rheumatoid arthritis with systemic onset, left hand</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.249</td>
<td>Juvenile rheumatoid arthritis with systemic onset, unspecified hand</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.25</td>
<td>Juvenile rheumatoid arthritis with systemic onset, hip</td>
<td>ICD-10-CM</td>
</tr>
<tr>
<td>M08.251</td>
<td>Juvenile rheumatoid arthritis with systemic onset, right hip</td>
<td>ICD-10-CM</td>
</tr>
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<td>M08.29</td>
<td>Juvenile rheumatoid arthritis with systemic onset, multiple sites</td>
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### 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 as Exclusion Criteria in Defining First Qualifying Dispensings

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### 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 as Exclusion Criteria in Defining First Qualifying Dispensings

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<td>Lymphangioleiomyomatosis</td>
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<td>Adult pulmonary Langerhans cell histiocytosis</td>
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<td>Surfactant mutations of the lung</td>
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CDER_MPL1R_WP101

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# Appendix F. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Health Care Characteristics of Interest in this Request

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## Macrophage Activation Syndrome

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### Exposure
- **Query period:** October 1, 2015 - March 31, 2018
- **Coverage:** Medical and drug coverage
- **Enrollment required:** 183 days
- **Enrollment gap:** 45 days
- **Age groups:** 17 to <65 years

### Inclusion Criteria

#### Criteria evaluation window relative to index

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<th>Covariate evaluation window relative to index</th>
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#### AOSD Inclusion
- **Any**

#### Pain medication use
- **Any**

#### Glucocorticoid use
- **Any**

### Baseline Covariates

#### Encounter case setting
- **Group:**
  - AOSD
  - PAH
  - ILD
  - MA

#### Encounter setting
- **Group:**
  - Baseline

### Medical Care Utilization

#### Evaluation window relative to index
- **Inpatient hospital stays:**
- **Non-acute institutional stays:**
- **Emergency department visits:**
- **Ambulatory visits:**
- **Other ambulatory visits:**

---

**Appendix G. Specifications Defining Parameters for the Adult Cohort Used in this Request**

This request used the Cohort Identification and Descriptive Analysis (CIDA) tool version 5.4.4 to calculate the proportion of pulmonary arterial hypertension, interstitial lung disease, and macrophage activation syndrome diagnoses among an adult population with adult onset Still’s disease after exposure to interleukin inhibitors in the Sentinel Distributed Database (SDD).

---


National Drug Codes (NDCs) are checked against First Data Bank’s “National Drug Data File (NDDF®) Plus.”
## Appendix H. Specifications Defining Parameters for the Pediatric Cohort Used in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) tool version 5.4.4 to calculate the proportion of pulmonary arterial hypertension, interstitial lung disease, and macrophage activation syndrome diagnoses among a pediatric population with systemic juvenile idiopathic arthritis after exposure to interleukin inhibitors in the Sentinel Distributed Database (SDD).

### Exposure

- **Query period:** October 1, 2015 - March 31, 2018
- **Coverage:** Medical and drug coverage
- **Enrollment required:** 183 days
- **Enrollment gap:** 45 days
- **Age groups:** 6 months to <17 years

### Scenario

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### Medical Care Utilization