

Chronic Rheumatoid Arthritis Registry Overview

The Exponent Outcomes Chronic Inflammatory Arthritides (CIA) Registry is an CIA approved 15 year observational hybrid disease state and health services registry focused on patients suffering from CIA. It collects CIA disease state and treatment data gathered during routine patient care. By participating you will help gather data to shape and guide the standard of care for future CIA patients and your practice will be reimbursed out of the study budget for your contribution.

Participating patients require only two Case Report Form (CRF) submissions per year and the majority of the needed data can be satisfied solely by providing a copy of a recent Health & Physical (H&P) and a current medication list. We estimate each submission will take 10 minutes or less. The registry has rolling admission and new patients will be admitted throughout the duration. We accept patients currently receiving treatment as well as patients newly beginning treatment.

By participating in the registry patients will be offered access to Pharmacy Medication Services Review (PMSR), Prior Authorization Assistance (PAA), Behavioral Health Support, and co-pay assistance. These services will be provided by Exponent Outcomes and the registry sponsor, StayWell Health Center of Connecticut, at no cost to your patients and require nothing of you or your staff. If these services are already provided by your practice, they can continue to be provided as is without change. Patients are not required to use the services offered.

Registry Overview

The purpose of this registry is to evaluate the impact patients' access to PMSR, PAA, and Behavioral Health Support has on their clinical outcomes, the patient reported outcomes, and the overall healthcare costs when provided in conjunction with biologics and Janus Kinase (JAK) inhibitors to treat CIA. Access to these services has been studied in patient populations and has been shown to result in improved clinical outcomes, patient reported outcomes, and reduced overall costs, but this has not been studied in patients suffering from CIA.

The registry will collect the 21-point core data set recommended by The European League Against Rheumatism (EULAR) for observational research and clinical care. The data set includes the Patient Global Assessment (PGA), the Investigator Global Assessment (IGA), patient quality of life, patient physical function, joint counts, and standard labs in the management of CIA. The full data set is included in the study protocol and also available upon request.



Inclusion and Exclusion Criteria

Inclusion

- 1. Patient is 5 years or older.
- 2. Patient is diagnosed with CIA and being treated with biologics or JAK inhibitors. (Non-exhaustive list below)
- 3. Patient must be provided access to PMSR and PAA. (Provided by Exponent Outcomes at no cost to the patient.)
- 4. Patient must be provided access to Behavioral Health Support services. (Provided by Study Sponsor at no cost to the patient.)
- 5. Patient must be already treated with CIA biologics or JAK inhibitors or is starting CIA biologic or JAK inhibitor therapy.
- 6. CIA biologics and JAK inhibitors must be acquired through the study's central pharmacies to fulfill the objectives of the study. (List of current study pharmacies below, will be amended as required).

Exclusion

- 1. Inability to give informed consent either directly or via legal guardian.
- 2. Inability to participate in data collection via phone, survey, or in-person interview.

Medication List

- 1. Actemra (Tocilizumab): SC Injection
- 2. Amjevita (Adalimumab-atto): SC Injection
- 3. Cimzia (Certolizumab): SC Injection
- 4. Cosentyx (Secukinumab): SC Injection
- 5. Hadlima (adalimumab): SC Injection
- 6. Huilio (adalimumab): SC Injection
- 7. Humira (Adalimumab): SC Injection
- 8. Idacio (adalimumab): SC Injection

Current Study Pharmacies

- Accredo Specialty
- BioPlus
- CVS Specialty
- Curant Health

- 9. Ilaris (Canakinumab): SC Injection
- 10. Rinvoq (Upadacitinib): Oral
- 11. Rituxan Hycela (Rituximab): SC Injection
- 12. Simponi / Simponi Aria (Golimumab): SC Injection
- 13. Skyrizi (Risankizumab): SC Injection
- 14. Stelara (Ustekinumab): SC Injection
- 15. Xeljanz (Tofacitinib): Oral
 - ESI
 - Optum Specialty
 - Walgreens Specialty