

## Inflammantory Bowel Disease Registry Overview

The Exponent Outcomes Inflammatory Bowel Disease (IBD) Registry is a 15 year observational hybrid disease state and health services registry focused on patients suffering from IBD. It collects IBD disease state and treatment data gathered during routine patient care. By participating you will help shape and guide the standard of care for future IBD 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 IBD. 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 IBD.

The registry will collect data on the progression and treatment of patients' IBD. The data set includes the Patient Global Assessment (PGA), the Investigator Global Assessment (IGA), patient quality of life, patient physical function, the Harvey-Bradshaw Index (HBI) or Partial Mayo Scoring Index for Ulcerative Colitis Activity (PMSI), and standard labs in the management of IBD. The full data set is included in the study protocol and also available upon request.

## Inclusion and Exclusion Criteria

### Inclusion

1. Patient is 18 years or older.
2. Patient is diagnosed with IBD 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 IBD biologics or JAK inhibitors or is starting IBD biologic or JAK inhibitor therapy.
6. IBD 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

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|---|--|
| 1. Amjevita (Adalimumab-atto): SC Injection | 8. Omvoh: SC Injection                               |
| 2. Cimzia (Certolizumab): SC Injection      | 9. Rinvoq (Upadacitinib): Oral                       |
| 3. Hadlima (adalimumab): SC Injection       | 10. Simponi / Simponi Aria (Golimumab): SC Injection |
| 4. Hulio (adalimumab): SC Injection         | 11. Skyrizi (Risankizumab): SC Injection             |
| 5. Humira (Adalimumab): SC Injection        | 12. Stelara (Ustekinumab): SC Injection              |
| 6. Idacio (adalimumab): SC Injection        | 13. Xeljanz (Tofacitinib): Oral                      |
| 7. Jyseleca (Filgotinib): Oral              |  |

### Current Study Pharmacies

- Accredo Specialty
- BioPlus
- CVS Specialty
- Curant Health
- ESI
- Optum Specialty
- Walgreens Specialty