



Chronic Condition Registry
Inflammatory Bowel Disease

Exponent Outcomes

Who We Are

- Exponent Outcomes partners with healthcare providers to improve the long-term health outcomes of patients with chronic conditions.
- We focus on maximizing the value of care by tracking how access to cost-effective treatments impacts both patient outcomes and healthcare savings.

What We Do

- Collaborate with medical practices to gather data on chronic disease management.
- Provide actionable insights to healthcare stakeholders, including Medicare, Medicaid, insurance plans, and professional medical societies, through data-driven reports.
- We do not test any new devices or medications.

Exponent Outcomes

Why Join Our Program?

- Contribute to research to deliver better outcomes to chronic disease patients.
- Enhance your practice's revenue stream.

When You Join

- **Collaborative Role:** Participate as a principal investigator, actively contributing to cutting-edge research and care optimization.
- **Simplified Participation:** Our IRB-approved registry program is designed to track chronic conditions with minimal impact on your practice's time and resources.
- **No Change to Patient Treatment:** No modifications in patient care is required to participate in our registries.

Inflammatory Bowel Disease Registry Overview

- The Exponent Outcomes Inflammatory Bowel Disease (IBD) Registry is an IRB approved 15-year observational hybrid disease state and health services registry focused on patients suffering from IBD.
- Collects IBD disease state and treatment data gathered during routine patient care.
- Participating patients require two Case Report Form (CRF) submissions per year.
- The registry accepts patients currently receiving treatment as well as patients newly beginning treatment.
- New patients will be admitted throughout the duration of the study.
- By participating in the registry, patients will be offered access, at no charge, to the following services:
 - Behavioral Health Support
 - Pharmacy Medication Services Review (PMSR)
 - Prior Authorization Assistance (PAA)
 - Copay Assistance

Patient Services

- **Behavioral Health Support:** Optional service for identifying and managing depression and anxiety often associated with chronic conditions. Support frequency is tailored to meet individual patients' preferences and needs.
- **Pharmacy Medication Services Review (PMSR):** Comprehensive pharmacist evaluation of prescription and over-the-counter medications to identify and resolve potential medical issues.
- **Prior Authorization Assistance (PAA):** Expert guidance to navigate and complete prior authorizations, addressing barriers to accessing prescribed medications.
- **Copay Assistance:** Depending on the selected study pharmacy, the Study Sponsor can cover up to 100% of the patient's medication copay.

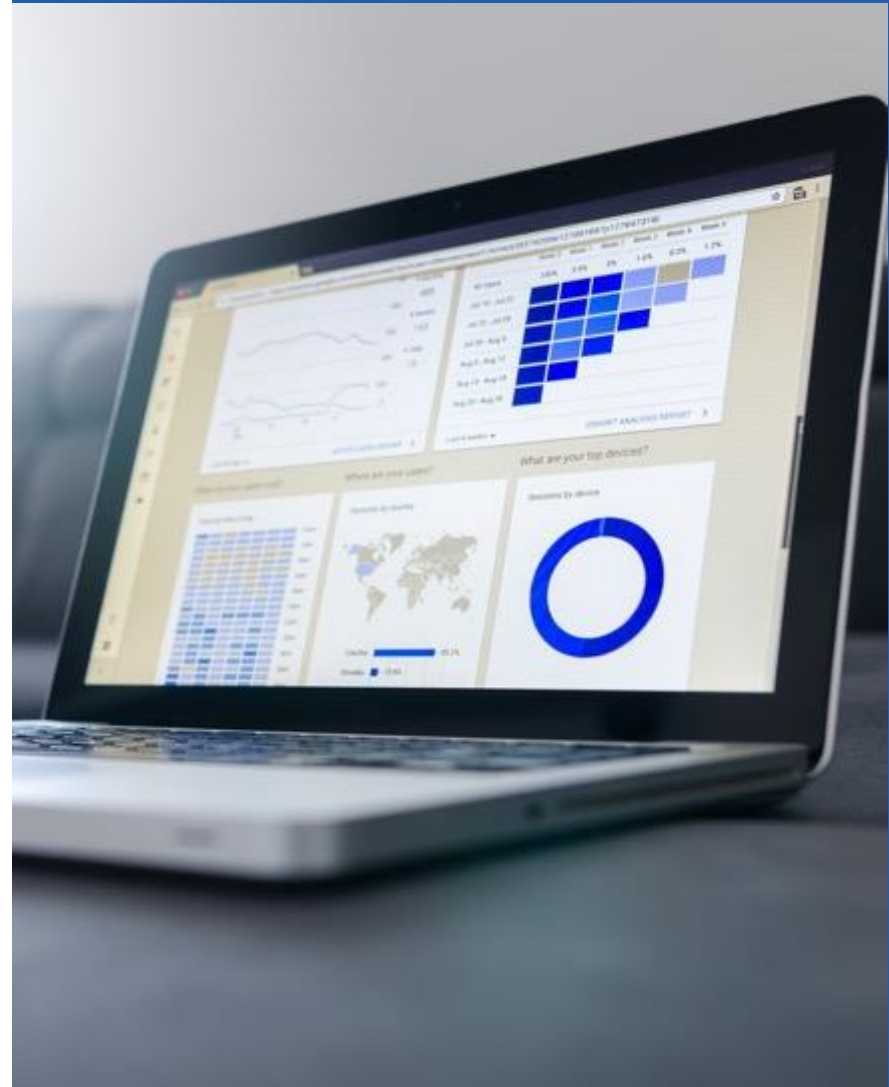
Data Collected

- **Informed by Comprehensive Research:** Data collection is based on an extensive analysis of leading IBD systematic reviews and meta-analyses, ensuring alignment with the most relevant metrics for observational research and clinical care.
- **No Additional Data Collection Required:** Leverages information already gathered during routine patient care, simplifying participation.
- **Streamlined Submission Process:** Most data can be provided through a medication list and a recent visit note.



Inclusion Criteria

- Patient is 18 years or older.
- Patient is diagnosed with any form of IBD and being treated with biologics or JAK inhibitors.
- IBD biologics and JAK inhibitors must be acquired through a study pharmacy.



Inclusion Criteria (Continued)

Included Medications (Non-Exhaustive)

- Amjevita (Adalimumab-atto): SC Injection
- Cimzia (Certolizumab): SC Injection
- Hadlima (adalimumab): SC Injection
- Huilio (adalimumab): SC Injection
- Humira (Adalimumab): SC Injection
- Idacio (adalimumab): SC Injection
- Jyseleca (Filgotnib): Oral
- Omvoh (mirikizumab-mrkz): SC Injection
- Rinvoq (Upadacitinib): Oral
- Simponi / Simponi Aria (Golimumab): SC Injection
- Skyrizi (Risankizumab): SC Injection
- Stelara (Ustekinumab): SC Injection
- Xeljanz (Tofacitinib): Oral

Study Pharmacies

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



Benefits to Patient

1. Access to Premium Services at No Cost:

- Pharmacy Medication Services Review (PMSR)
- Prior Authorization Assistance (PAA)
- Behavioral Health Support
- Copay Assistance

2. Participation Incentives:

- \$25 gift card upon enrollment
- Additional \$25 gift card for each Patient-Reported Outcome submission (up to two per year)

Practice Participation

- 1. IRB Registration:** The primary investigator and research coordinators are registered with the IRB via an amendment, fully managed and funded by Exponent Outcomes.
- 2. Patient Identification and Enrollment:** Identify eligible patients who meet the study's inclusion criteria and obtain their informed consent. Exponent Outcomes will assist in identification.
- 3. Case Report Form Submission:** Submit two Case Report Forms per subject annually. Most data is already collected during routine care and can be satisfied by providing a medication list and a recent visit note.

Patient Participation

- 1. Complete Enrollment Paperwork:** Fill out the initial Patient Reported Outcomes survey, provide informed consent, and sign additional consent forms, including for electronic communication.
- 2. Submit Patient Reported Outcomes Forms:** Complete two Patient Reported Outcomes forms annually. The first is included as part of the enrollment paperwork.
- 3. Attend Telehealth Appointment:** Participate in one 15-minute telehealth appointment per year to review available services and assess anxiety and depression scores.

Projected Practice Revenue

- 1. Up to \$1,000 per Subject Annually:** With two CRFs submitted per year, your practice can earn up to \$1,000 per enrolled subject at 500 per Case Report Form (CRF).
- 2. Broad Inclusion Criteria:** The inclusive criteria likely apply to over 50% of your practice's patient population, making participation accessible for a large number of subjects.
- 3. Potential Revenue for 100 Subjects:** Enrolling 100 subjects could generate up to \$100,000 annually from completed CRFs.

Next Steps

- **Sign NDA**
- **Submit Site Qualification Application**
- **Schedule Follow-Up Call** to address questions and provide additional details

