EVALUATING THE IMPACT OF A PHARMACIST IN OPTIMIZING INFLAMMATORY BOWEL DISEASE TREATMENT

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Background

Inflammatory Bowel Disease (IBD) is a complex chronic disease that requires life-long medical management. The American College of Gastroenterology (ACG) recommends treating patients with IBD based on disease location, severity, complications, and prognosis in an individualized approach. While mild cases of IBD can be managed with less costly, conventional therapies, such as 5-aminosalicylates, corticosteroids, and immunomodulators, more severe cases often require the use of advanced therapies, such as biologics and small molecule therapies.

Risankizumab-rzaa is a humanized monoclonal antibody targeting interleukin-23 which was approved in June 2022 for the treatment of adults with moderately to severely active Crohn's Disease. Since its initial FDA approval for treating Crohn's Disease, Risankizumab-rzaa has been FDA approved for the treatment of Ulcerative Colitis. Risankizumab joins a handful of advanced therapies that are approved for treatment of IBD. Despite significant growth in treatment options, there are many barriers that prevent patients from benefitting from these advancements.

Barriers to therapy include:

- Prior Authorization Requirements
- Step Therapy
- Formulary Exceptions
- Site of Care Requirements
- Cost

Role of a Clinical Specialty Pharmacist:

- Facilitate access of high cost, high touch medications
- Provide patient education
- Monitor safety, adherence, and efficacy of specialty medications
- Provide up to date drug information and recommendations to healthcare team

Methodology

This study was designed as a retrospective chart review of patients initiated on Risankizumab-rzaa for the treatment of moderately to severely active Crohn's Disease. Eligible patients included those who were 19 years and older with a diagnosis of moderately to severely active Crohn's disease who were to be initiated on Risankizumab-rzaa between June 2022 to June 2024.

Charts were reviewed for the following:

- Prior authorization required
- Appeal required
- Second-level appeal required
- Peer to peer required
- Final determination of request
- Date of medication request
- Date of medication approval

Primary Outcomes
Percent of standard Risankizumab-rzaa IV induction approved
Percent of standard Risankizumab-rzaa SQ approved
Percent of dose-escalated Risankizumab-rzaa approved
Average time to approval (days)
Secondary Outcomes
Percent of patients requiring dose escalation
Percent of requests requiring additional authorization steps
Percent of patients in which re-induction was required
Time from medication initiation to dose escalation

Results

This project is currently in progress. Initial findings show that between June 2022 and June 2024 106 patients were started on Risankizumab-rzaa for the treatment of moderately to severely active Cohn's Disease. 25 patients required dose escalation from standard Risankizumab 360 mg every 8 weeks dosing. Dose escalations were defined as any dose or frequency change greater than 360 mg SQ every 8 week. 1 patient required dose escalation to every 6 week dosing and 24 patients required dose escalation to every 4 weeks. 2 patients required re-induction.

Conclusion

A large portion of IBD patients are referred to UAB for management of very severe, refractory disease. Having tried and fail several conventional therapies and standard biologic therapies prior to establishing care at UAB, limited treatment options are available for many patients. Therapy options often require the use of dose escalated therapies, dual therapies, and off label medications in an effort to manage patients' disease through the use of medication. With this comes many barriers to medication access in the form of high co-pays and red tape from payers.

The clinical specialty pharmacists at UAB play a huge role in breaking these barriers down and allowing providers the ability to optimize therapy prior to surgical intervention. The authors of this study anticipate that the results will highlight the essential role of a clinical pharmacist in the management in inflammatory bowel disease in insuring patient access to medication.

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