Inflammatory Bowel Diseases
Clinical Primer and Care Pathway Tool Kit
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Jointly provided by

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INTRODUCTION

This primer and toolkit features general clinical considerations on the appropriate diagnosis, assessment, and treatment of Crohn’s disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD), as well as payer-specific insights on the economic burden and specialty drug management initiatives. Perspectives from a series of 8 regional roundtables involving 20 payer representatives and 39 IBD specialist providers, representing nearly 300,000 covered lives, are also shared, with recommendations for future collaborative interventions to improve patient access, care quality, and cost management in the treatment of IBD.

Let them talk!
A moderator drew out attendees and encouraged participation leading to exchanges such as:

Provider: So you can go back to your office and advocate for us to get that [FC testing] covered?

Payer: I will, absolutely.

297,878
Approximate number of IBD patients managed/cared for by attendees

Key Input From Providers
- Quarterly collaboration meetings with local IBD providers and representations from a different payer company to share clinical updates and discuss any access to care issues
- When patients switch plans, payers should recognize the agents they’re on and be okay with that
- More data is needed on why there is a denial
- Payers could help by being more involved with educating providers

Key Input From Payers
- Disease specific severity data is needed on populations not individual patients to help with predictors of severity.
- The Foundation can help facilitate IBD guidelines dissemination to payers in conjunction with providers.
- Collaboration is needed to establish treatment algorithms.
- Better care pathways based on current guidelines are needed.
- IBD involves more variables than other disease states where diagnosis and treatment tend to be black and white.
- GI is just one of many specialties that payers cover so need to consider allocation of resources

Problem: Lack of communication between patient care providers and health plan decision makers hindering optimal care for IBD patients

Solution: Bring together providers from leading IBD Centers and managed care decision makers from the plans covering the same patients with regional roundtable discussions

Stimulate discussion with presentations:
- Clinical and Economic Review of IBD
- Payer Benefit Management Strategies for IBD
- IBD Patient Access to Appropriate Care
- Care Pathways and Interdisciplinary Disease

A testimonial that gets to the heart of what this initiative accomplished:

I just wanted to thank you all again for doing this event. I just had a patient who had lymphocytic colitis stabilized on a therapy but changed insurances to another health plan. The re-authorization was denied since it is in the guidelines. I discussed it with a GI peer reviewer but got nowhere and this patient was now late on his infusion. Normally I would be stuck but in this case I emailed pharmacy director from the meeting who then reached out to higher ups at the health plan to whom I was able to explain the situation and extenuating circumstance and the fact that he is delayed. After starting a discussion it only took 48 hours and now he is approved and getting his drug. Being able to speak to the insurance company and have that higher level discussion made the world of a difference and was only possible since you did the roundtable meeting.
Pathophysiology and Symptomology

- Inflammatory bowel disease (IBD) is an idiopathic disease caused by a dysregulated immune response to host intestinal microflora.

- There are two major types of IBD:
  - Ulcerative colitis (UC) is limited to inflammation of the colonic mucosa
    - The inflammation associated with UC can cause ulceration, edema, bleeding, and fluid and electrolyte loss.
  - Crohn's disease (CD) inflammation can affect any segment of the gastrointestinal tract from the mouth to the anus.
    - CD involves “skip lesions” and is transmural.

- Inflammatory mediators have been identified in IBD, and considerable evidence suggests that these mediators play an important role in the pathologic and clinical characteristics of these disorders.

- Cytokines, which are released by macrophages in response to various antigenic stimuli, bind to different receptors and produce autocrine, paracrine, and endocrine effects.
  - Cytokines differentiate lymphocytes into different types of T cells.
    - Helper T cells, type 1 (Th-1), are associated principally with CD.
    - Th-2 cells are associated principally with UC.

- This immune response disrupts the intestinal mucosa and leads to a chronic inflammatory process.

- IBD features a genetic predisposition, and patients with this condition are more prone to the development of malignancy.
Healthy Microenvironment versus IBD Microenvironment³

DISEASE OVERVIEW
• Symptoms associated with IBD can vary significantly across individual patients, making the condition very difficult to diagnose and potentially resulting in delays in treatment

### Symptomology of IBD\(^4,5,6\)

<table>
<thead>
<tr>
<th></th>
<th>Ulcerative colitis</th>
<th>Crohn’s disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>47%</td>
<td>77%</td>
</tr>
<tr>
<td>Anemia</td>
<td>40%</td>
<td>27%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>38%</td>
<td>29%</td>
</tr>
<tr>
<td>Bleeding</td>
<td>80%</td>
<td>22%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>90%</td>
<td>73%</td>
</tr>
<tr>
<td>Fever</td>
<td>1%</td>
<td>35%</td>
</tr>
<tr>
<td>Fistulae</td>
<td>0%</td>
<td>16%</td>
</tr>
<tr>
<td>Iridocyclitis, uveitis</td>
<td>11%</td>
<td>10%</td>
</tr>
<tr>
<td>Weight loss</td>
<td>5%</td>
<td>54%</td>
</tr>
</tbody>
</table>
**Epidemiology**

- IBD affects up to 3.1M Americans and is exhibiting increasing prevalence in the US and other industrialized nations\(^7\).
- 70,000 new cases are diagnosed every year in the United States, most prominently in younger adults (aged 15-30 years), creating higher impact on commercial plan populations\(^7,8\).

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**Trends in Age-and Sex-Adjust Incident Rate of Crohn’s Disease (CD) and Ulcerative Colitis (UC)**

*Olmsted County, Minnesota, 1970-2011*

![Graph showing trends in age-and sex-adjust incident rate of Crohn’s Disease (CD) and Ulcerative Colitis (UC) from 1970-2011.](image-url)
Clinical Burden

- IBD flares/complications and atherothrombotic events account for approximately half of IBD-related hospitalizations, totaling >200,000 per year nationally
- After 30 years of disease, up to one-third of patients with UC will require surgery
- Approximately 70% of patients with CD eventually require surgery, and 30% of these patients will experience recurrence within 3 years
Economic Burden

- Compounding the economic impact of IBD is the relatively young age at onset, the chronic nature of the disease, and significant morbidity in severe cases, which often account for 80% of total costs.
- The total annual financial burden of IBD in the United States was estimated to be as high as $32 billion in 2014, but total costs may significantly exceed these earlier estimates.\(^7\)
- On a per-annual basis, patients with IBD incur a greater than 3-fold higher direct cost of care compared with non-IBD controls ($22,987 vs $6956 per-member per-year paid claims) and more than twice the out-of-pocket costs ($2213 vs $979 per-year reported costs), with all-cause IBD costs rising after 2013.\(^12\)

Total Direct Annual Costs per Patient (PMPY; IBD and non-IBD Controls)\(^{12}\)
• The advent of biologic therapy has resulted in a shift of costs away from surgery and hospitalization to prescription drugs.

Longitudinal Trends in All-Cause Costs of IBD\textsuperscript{12}
• The cost effectiveness of biologic therapy has been established in IBD, assuming pharmacotherapy optimally prescribed in clinically appropriate scenarios

• Costs can climb even higher in patients whose disease is not optimally managed
  ○ In a retrospective claims analysis of 13,005 CD and 19,878 UC patients:\(^{14,15}\)
    □ Markers of suboptimal therapy were defined as follows:
      - discontinuation or switch (except for corticosteroid)
      - dose escalation, augmentation, inadequate loading (biologics)
      - prolonged corticosteroid use (>3 months)
      - surgery or hospitalization
    □ 80% had ≥ 1 suboptimal treatment marker
    □ Total costs were higher with suboptimal therapy:
      - CD—$18,736 vs. $10,878
      - UC—$12,679 vs. $9,653
Payer and Provider Perspectives

Key Takeaways

• IBD affects 1.6M – 3.1M Americans and is exhibiting increasing prevalence in the US and other industrialized nations

• Compounding the economic impact of IBD is the relatively young age at onset, the chronic nature of the disease, and significant morbidity in severe cases, which often account for 80% of total costs

• The advent of biologic therapy has resulted in a shift of costs away from surgery and hospitalization to prescription drugs

• The cost effectiveness of biologic therapy has been established in IBD, assuming pharmacotherapy optimally prescribed in clinically appropriate scenarios

“What I see as a problem is the undervaluing of what it takes to care for these patients.”

-Gastroenterology Provider

“We’re not seeing as many hospital admissions for IBD nowadays; the treatments are better.”

-Regional Payer
ACCURATE AND TIMELY DIAGNOSIS

Misdiagnosis

- Optimal IBD management has been historically encumbered by underdiagnosis and misdiagnosis
- A UK study showed 10% of patients with IBD were misdiagnosed with irritable bowel syndrome (IBS)\(^6\)
- A 2017 survey of 4,000 patients with IBD in the US revealed that accurate IBD diagnoses may be even more difficult to attain than previously thought\(^7\)
  - Overall, 62% of respondents needed ≥5 office visits before receiving an accurate diagnosis

Diagnostic Modalities

- IBD diagnosis requires a comprehensive inventory of clinical findings

Radiographic/Imaging Screening and Assessment Standards\(^8,9\)

- Traditional upper endoscopy and colonoscopy with biopsy represent the standard for IBD diagnosis
- Capsule endoscopy, as well as other forms of radiologic exams or diagnostic imaging, may also be used to evaluate segments of the intestines and/or areas outside the bowel that cannot be reached by traditional endoscopy
  - These forms of imaging are often costly and may be denied by insurers, including some of the following:
    - X-ray
    - Ultrasound
    - Computed tomography (CT)
    - Magnetic resonance imaging (MRI)
Laboratory Analyses and Assays\textsuperscript{18,19}

- Screening tests for intestinal inflammation should be included in the work up of all new patients presenting with diarrhea and pain.
- Inflammation may be detected through a number of laboratory analyses involving blood cells and proteins in the blood or stool.
- Blood biomarkers include CRP and ESR, while stool biomarkers include calprotectin and lactoferrin.
- Specialized serology tests can be used to confirm a diagnosis of CD, distinguish CD from UC, or vice versa.
  - Biomarkers such as pANCA, ASCA, CBir1, and OmpC may be included in serology tests and are present in approximately 80% of patients with IBD.

<table>
<thead>
<tr>
<th>Screening Tests</th>
<th>Laboratory Analyses</th>
<th>Decision Making</th>
</tr>
</thead>
</table>
| • Screening tests for intestinal inflammation should be included in the workup of all new patients presenting with diarrhea and pain. | • Inflammation may be detected through a number of laboratory analyses involving blood cells and proteins in the blood or stool.  
  - These tests are often denied by insurers | • In addition to diagnosis, such laboratory analyses may further elucidate disease characteristics and most likely clinical course, thereby guiding therapeutic decision making. |
Selectivity of Serologic Markers

<table>
<thead>
<tr>
<th>Serologic markers/antibodies</th>
<th>Positive Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANCAAs Anti-neutrophil cytoplasmic antibodies (cANCA), sANCA, pANCA)</td>
<td>2%-28% CD 20%-85% UC</td>
</tr>
<tr>
<td>ASCA Anti-saccharomyces cerevisiae antibodies</td>
<td>29%-69% CD 5%-15% UC</td>
</tr>
<tr>
<td>Anti-OmpC Antibodies to outer membrane porin</td>
<td>24%-50% CD 5%-11% UC</td>
</tr>
<tr>
<td>Anti-CBir1 Flagellin related antigen</td>
<td>50% CD 5%-11% UC</td>
</tr>
<tr>
<td>Anti-I2 Pseudomonas flavescens-associated</td>
<td>20%-50% CD 2%-10% UC</td>
</tr>
<tr>
<td>Flagellin A4-Fla2 and Fla-X antibodies</td>
<td>Newly identified</td>
</tr>
<tr>
<td>Antilaminaribioside carbohydrate IgG (ALCA)</td>
<td>About 57% CD</td>
</tr>
<tr>
<td>Antichitobioside carbohydrate IgA (ACCA)</td>
<td>Antiglycan antibody</td>
</tr>
<tr>
<td>Anti-synthetic mannoside antibodies (ASMA or AMCA)</td>
<td>Antiglycan antibody</td>
</tr>
<tr>
<td>Pancreatic antibodies</td>
<td>Pancreatic secretion</td>
</tr>
<tr>
<td>Serum p53 antibodies</td>
<td></td>
</tr>
</tbody>
</table>

- Fecal calprotectin (FC) and fecal lactoferrin (FL) are useful screening tests for IBD
  - According to a meta-analysis of diagnostic accuracy studies:
    - In adults, the pooled sensitivity and pooled specificity of FC was 0.93 and 0.96
    - In children/teenagers the pooled sensitivity and pooled specificity of FC was 0.92 and 0.76
    - Screening by measuring FC levels would result in 67% and 35% reductions in the number of adults and children/teenagers requiring endoscopy, respectively
    - The downside of this screening strategy was delayed diagnosis in 6% of adults and 8% of children/teenagers due to a false negative test result
- FC is likewise cost-effective due to the avoidance of unnecessary endoscopy
  - A decision analytic tree yielded the following:
    - In adults, FC screening saved $417/patient but delayed diagnosis for 2.2/32 patients with IBD among 100 screened patients
    - In children, FC screening saved $300/patient but delayed diagnosis for 4.8/61 patients with IBD among 100 screened patients
    - If endoscopic biopsy analysis remained the standard for diagnosis, direct endoscopic evaluation would cost an additional $18,955 in adults and $6250 in children to avoid 1 false-negative result from FC screening
    - Compared with the FC cutoff level of 100 μg/g, the cutoff level of 50 μg/g cost an additional $55 and $43 for adults and children, respectively, but yielded 2.4 and 6.1 additional accurate diagnoses of IBD per 100 screened adults and children, respectively
Payer and Provider Perspectives

Key Takeaways

• The optimal management of IBD has been historically encumbered by underdiagnosis and misdiagnosis, both of which can lead to increasing morbidity and healthcare resource utilization

• A comprehensive workup involving a myriad of clinical findings is necessary to diagnose and effectively manage these diseases

• Coverage for various laboratory and imaging assessments can help to ensure that IBD is diagnosed in an accurate and timely manner prior to initiating appropriate management strategies

“There’s a lot of overlap between IBD and IBS; it’s complicated. It’s easy to miss.”

-Gastroenterology Provider

“We should be covering FC testing.”

-Regional Payer
General Treatment Considerations

- IBD treatment should be based on the following:
  - Symptoms/disease severity
  - Comorbidities
  - Goal of remission

**IBD Treatment Approaches**

- Surgery
- Biologics & Small Molecules
  - Infliximab
  - Adalimumab
  - Certolizumab
  - Golimumab
  - Vedolizumab
  - Natalizumab
  - Ustekinumab
- Immunosuppressants (tacrolimus, azathioprine, etc.)
- Steroids (prednisone, budesonide, etc.)
- 5-ASA
- Antibiotics
- Tofacitinib
- Nutritional support
- Probiotics
Care Pathways and Decision Support Tools

- Clinical pathways aim to reduce treatment variability while allowing individualized care

Goal of Clinical Pathways Initiatives

- Care pathways provide clinical decision support via consideration of various patient-specific factors

Treat to Target

- Disease Severity and/or Presentation
- Comorbidities
- First, Second, and Third-line Therapy Choices
- Alternative Therapy Choices
• Existing evidence-based treatment guidelines serve as the foundation for clinical pathways initiatives

• Clinical guidelines for IBD are available from multiple organizations, and the American Gastroenterological Association (AGA) and the Crohn's & Colitis Foundation, among others, have developed care pathways using the available evidence
AGA Care Pathway for Ulcerative Colitis: Overview

1. Make Diagnosis and Assess Inflammatory Status
2. Assess Comorbidities and Disease- and Therapy-Related Complications
3. Stratify According to Colectomy Risk
4. Inductive and Maintenance Therapy (Low Risk)
5. Identify Patient Requiring Hospitalization
6. Therapy for High-Risk, Outpatient Not in Remission
7. Inductive and Maintenance Therapy (High Risk, Inpatient)
AGA Clinical Decision Support Tool for Crohn’s Disease: Overview

1. Assess inflammatory status
2. Assess comorbidities and disease and therapy-related complications
3. Assess current and prior disease burden
4. Identify as low-risk patient
   - Perform initial treatment (low risk)
   - Perform treatment for patient in remission (low risk)
   - Perform treatment for patient not in remission (low risk)
5. Identify as moderate/high-risk patient
   - Perform initial treatment (mod/high risk)
   - Perform treatment for patient not in remission (mod/high risk)
Payer and Provider Perspectives

Key Takeaways

- IBD care interventions should be based on individual patient symptoms/disease severity, comorbidities, and the goal of remission, with a myriad of pharmacologic agents to choose from in designing a customized treatment plan.
- Care pathways aim to reduce treatment variation while maintaining individualized care for patients with chronic disease.
- Evidence-based treatment guidelines serve as the foundation for most published care pathways, including the AGA’s care pathways and clinical decision support tools.

“The drugs we have now are game changers because of remission. If you can get a patient there, you change everything.”
-Gastroenterology Provider

“Which agent is being used has become the biggest issue.”
-Gastroenterology Provider

“The biggest savings are going to be in the outliers, the patients that aren’t going to follow the algorithm.”
-Gastroenterology Provider

“Agreeing on what the outcomes are and being able to measure them is very hard.”
-Regional Payer
Current Trends in Specialty Drug Management

- The specialty drug trend is outpacing traditional agents and currently accounts for nearly half of all pharmaceutical spending

**Specialty Drug Trend Forecast**

- Inflammatory conditions such as IBD represent a significant driver of the specialty trend and, as a result, remain the focus of payer management initiatives

**Specialty Drug Trend by Class**

- The number of patients with autoimmune diseases being treated per year is up 63% since 2013, representing 6 million patients

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PAYER INTERVENTIONS FOR IBD MANAGEMENT

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Patients Being Treated for Autoimmune Disease with Specialty Drugs in the US, 2013-2018

5-Year CAGRs Overall: 8.1%

- 2% All Other Indications
- 9.4% Ankylosing Spondylitis
- 20.4% Ulcerative Colitis
- 11.7% Crohn’s Disease
- 15.3% Psoriatic Arthritis
- 15.5% Psoriasis
- 3.7% Rheumatoid Arthritis

Source: IQVIA Real World Evidence, Longitudinal Prescription Data, Jan 2019
Current Payer Approaches to IBD Management

- Specialty drugs across all disease states are subject to various payer management initiatives:
  - Utilization management
    - Prior authorization (PA)
    - Step therapy/step edits
    - Quantity limits
  - Benefit Design
    - Formulary positioning/exclusion
    - Contracting
    - Site of care/channel management
    - Cost-sharing

- Prior authorization is among the most common and simple utilization management initiatives but involves a potentially lengthy process that can impede access to care and cause frustration among stakeholders:
  - Delays from pre-authorization can further lead to worsening patient outcomes, potentially preventing the patient from receiving appropriate treatment and resulting in disease progression and lost time from work and/or school.

Prior Authorization Process and Goal

- Prior authorization can likewise increase administrative burden on the provider.

- In terms of benefit design, restrictive or exclusive formularies present a barrier to access for members with inflammatory conditions.

<table>
<thead>
<tr>
<th>36%</th>
<th>Proportion of physicians with staff who work exclusively on PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>Average PAs per physician per week</td>
</tr>
<tr>
<td>14.9</td>
<td>Average number of hours per week spent by prescribers on PA</td>
</tr>
<tr>
<td>779 million</td>
<td>Total number of hours prescribers spend each year on PA</td>
</tr>
<tr>
<td>$83,000</td>
<td>Annual average per-prescriber cost of interacting with payers</td>
</tr>
<tr>
<td>$83.4 billion</td>
<td>Estimated annual cost of prescribers' interactions with payers</td>
</tr>
</tbody>
</table>
PAYER INTERVENTIONS FOR IBD MANAGEMENT

Formulary Exclusion Classes

- Increasing member cost-share also represents a barrier to quality care, with high-deductible health plans (HDHPs) on the rise
  - The prevalence of HDHPs increased from 28% in 2016 to 33% in 2017
- Copay assistance mitigates a noteworthy component of patient cost burden, but accumulator adjustment programs can reintroduce financial barriers to access

Finding the right sequence of therapies in a complex chronic disease such as IBD can be a challenge

- Treatment adherence can result in improved Quality of Life and decreased health care utilization

Patients with IBD often rely on copay assistance programs to mitigate the financial burden of cost sharing

- A significant proportion of patients now only have high-deductible plan options
- Copay assistance programs are offered by manufacturers of specialty drug products

Copay Accumulator Programs interfere with a vital lifeline for patients with chronic conditions necessitating specialty drugs

- Accumulator adjustment and copay allowance maximization negate the benefits of copay assistance programs and reintroduce financial barriers to care
Contracting Considerations

- The current norm in contracting for inflammatory conditions features discounts based on volume, which may in turn drive formulary structure.
- Anti-TNF agents comprise the largest rebate guarantee category (i.e., 50% of what payers are contractually obligated to pay health care purchasers/employers).
- One particular challenge with the present contracting system is that payers have indication-based formularies but not indication-based contracting; this issue needs to be addressed in order to provide earlier access to effective drugs.
- Newer, value-based models are experiencing increased uptake, but are not without specific barriers related to best price and a lack of objective/measurable outcome on which to base contracts.

Traditional vs. Value-Based Contracting

## Traditional Contracting

- **Flat, Volume or Share-Based**
  - Concessions depend on volume or share

## Value-Based Contracting

- **Indication-Based**
  - Rebate specific to an indication
- **Regimen-Based**
  - Rebate paid when two products used in combination
- **“Outcomes-” Based**
  - Concessions depend on how well the drug works for a patient/cohort

### Increasing Data & Complexity

- TNF inhibitors represented 65% of pharmacy-related costs for CD between 2011 and 2013, but 59.5% of pharmacy costs were attributed to adalimumab and infliximab alone.

All of these aforementioned management initiatives can have an adverse effect on patient access to treatment and may result in non-medical switching of therapies.

- Non-medical switching in chronic disease can result in the re-emergence of symptoms and may disrupt continuity of care.
- Although drug costs can be reduced by selecting lower-cost medications, switching tends to lead to higher total costs.
Average Increases in Non–Drug Spending Due to Non–Medical Switching Across All Medications

<table>
<thead>
<tr>
<th>Condition</th>
<th>No Switch</th>
<th>Switch to Lower-Cost Rx</th>
<th>Multiple Switches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>$975</td>
<td>$1,035</td>
<td>$1,425</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>$2,859</td>
<td>$4,141</td>
<td>$4,886</td>
</tr>
<tr>
<td>COPD</td>
<td>$1,307</td>
<td>$2,316</td>
<td>$3,171</td>
</tr>
<tr>
<td>Crohn's disease</td>
<td>$2,072</td>
<td>$4,499</td>
<td>$4,890</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>$1,829</td>
<td>$1,977</td>
<td>$2,042</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>$1,766</td>
<td>$4,362</td>
<td>$2,625</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>$1,467</td>
<td>$1,997</td>
<td>$1,540</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>$588</td>
<td>$648</td>
<td>$671</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>$1,474</td>
<td>$1,894</td>
<td>$1,714</td>
</tr>
</tbody>
</table>
Specialty Pharmacy Management Programs

- Payers often employ specialty pharmacy programs to manage patients with chronic conditions requiring specialty therapies given the complexity of these diseases, necessitating pharmacy feedback for providers, and the cost of the drug products

Goals of a Specialty Pharmacy Management Program

1. Equalize benefits between pharmacy and medical to avoid members choosing the administration site based on their coverage
2. Optimize cost management by receiving the lowest unit cost from dispensing pharmacies and receive any available rebates from manufacturers
3. Ensure appropriate use by employing clinical guidelines and criteria, prior authorization, and formulary programs
4. Improve clinical management by assessing and intervening on adherence and persistency, patient care services, therapy and case management, and demonstrating improved outcomes
5. Expertly craft the contract to account for changes in the industry, including generic biologics
Plan Algorithms and Care Pathways

- Care pathways initiatives have gained traction in oncology, the therapeutic area where they originated, but expansion into other disease categories is underway.
- According to a survey of 21 payers, providers, and vendors, in the next 5 years, care pathways development is expected to increase in both oncology (85%) and other therapeutic areas (65%).
- Payers view evidence-based care pathways as being valuable for the following reasons:
  - Improved integration of clinical guideline-based care
  - Reduced variation in care
  - Improved cost management
  - Reduced administrative resources necessary for claims review/denial/appeal
  - Attractive candidates for care pathway development include disease states with any of the following characteristics:
    - High cost of treatment or utilization
    - High prevalence
    - Availability of multiple branded therapies
    - Heterogeneity in treatment patterns
- Collaborative networks, care pathways, and standardized treatment algorithms may represent avenues for wide-scale implementation of quality improvement in IBD management.
Payer and Provider Perspectives

Key Takeaways

- Specialty drugs are driving the overall trend right now, causing heightened awareness and management efforts on the part of payers.
- Drugs for inflammatory conditions, including IBD, have been the focus of many of these efforts, with volume-based contracting and rebates already firmly in place.
- Increased patient cost-share and restrictive formularies are gaining traction, but payers must remain cognizant of the impact of management initiatives on patient access and resultant outcomes.

“I have a team setup to deal with [the prior authorization process]. I don’t know that a general gastroenterologist would be able to take the time.”

-Gastroenterology Provider

“The drugs we have had for a decade work really well. Anything we introduce now, how much better can it be? That’s why we have to evaluate this space.”

-Regional Payer
The Crohn's & Colitis Foundation sponsored a series of 8 regional roundtables among payer stakeholders and IBD specialist providers in 2018 and 2019 to enhance disease awareness and facilitate collaboration between health plan decision makers and clinical thought leaders. Pertinent findings from these meetings are subsequently presented, embodying the management of nearly 300,000 patients with IBD either cared for or covered by the 59 clinician and payer representatives in attendance, respectively. This activity was supported by an independent educational grant from Takeda Pharmaceuticals U.S.A., Inc.

Payers and providers cited the following as top priorities for improving care quality in IBD:
1. Increased communication channels between IBD providers and managed care decision makers
2. Pharmacy benefit designs allowing for a personalized treatment approach among patients with IBD
3. Integration of available IBD care pathways from professional organizations into plan infrastructure
4. Designating qualified IBD providers and/or their centers with a “Gold Card” approach to managing patients with IBD

As a means of facilitating collaboration in IBD management, health care stakeholders had a number of recommendations...

Payers recommended the following:
1. Regional collaboration to align treatment pathways
2. A mechanism to share evidence-based data to support earlier treatment with biologics for more severe patients
3. Reduce administrative burden for both the plan and providers
4. Collaborative efforts to integrate evidence-based guidelines into plan-wide algorithms
5. Meetings such as the aforementioned regional roundtables to foster a proactive working relationship
6. Education of diagnosed members and linking rural providers to IBD specialists for guidance on the most appropriate treatment pathways for their patients
7. Heightened awareness of each other’s goals to reduce communication barriers

Providers offered the following recommendations:
1. A regional meeting between clinicians and payers on a semi-annual or annual basis
2. Collaboration and communication to help payers understand the complexity of IBD management
3. Meeting with representatives from a different payer organization on a quarterly basis to provide updates in area and to discuss any issues with access to care
4. Establish centers of excellence
5. Provide objective evidence of success/failure and rational and efficient step therapy
6. Payer education of policies and initiatives to members of the foundation and other physicians
7. Increase transparency regarding authorizations and pricing
REFERENCES


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