



# Stepping in for Patients with Inflammatory Bowel Disease

**APRIL**  
**21**

**Dinner Meeting: 6:00 PM – 8:00 PM**

Moscone West Convention Center  
Room 3014-3016  
San Francisco, CA

Supported by an educational grant from  
Takeda Pharmaceuticals U.S.A., Inc.

**CME**  
**Outfitters**  
CONTINUING MEDICAL EDUCATION





# Learning Objective 1

Integrate the complexities of disease progression to facilitate decision making for patients with inflammatory bowel disease.



## Learning Objective 2

Utilize a proactive, personalized approach weighing risk/benefit and cost when making decisions for patients with inflammatory bowel disease.





## Learning Objective 3

Differentiate between mechanisms of action of therapies and how those differences translate to clinical decision-making in patients with inflammatory bowel disease.



# Audience Response



How have you been involved in treatment for IBD?

- A. Medication eligibility determination for patients
- B. Review treatment algorithms and therapies
- C. Formulary decision-making
- D. Medication counseling
- E. Coordination treatment with specialty pharmacy, PBM, or health plan

# Audience Response



Other than cost, what is the primary challenge you face when managing patients with IBD?

- A. Lack of established guidelines and algorithms
- B. Knowing when to initiate, stop, or switch therapies
- C. Safety and tolerability of current therapies
- D. Differentiation of therapies



# Complexities of IBD Progression

Lawrence R. Kosinski,  
MD, MBA, AGAF, FACG



# IBD Disease Progression and Treatment Strategy

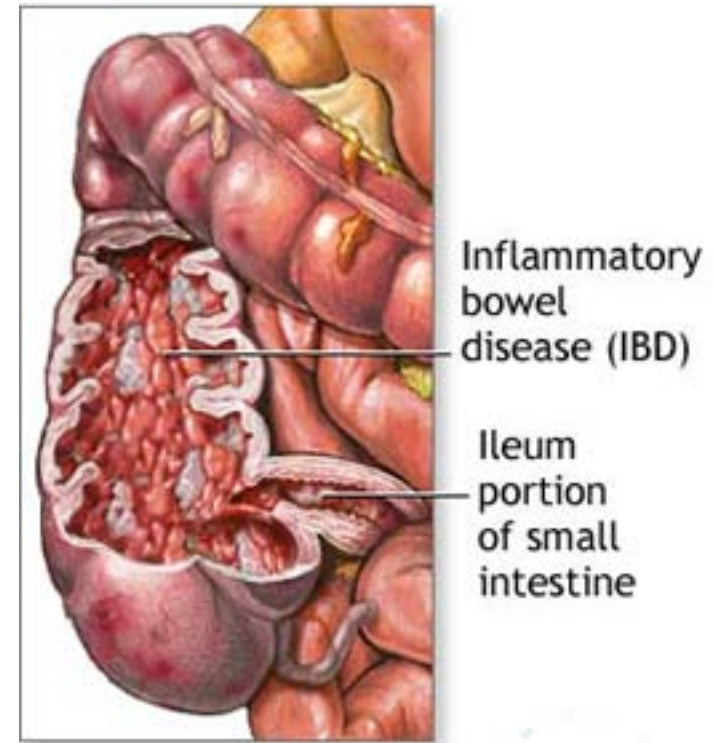


- Treatment by location phenotype
- Top down vs. bottom up strategies
- Risk assessment strategies
- Clinical Decision Support (CDS) tools

# Location of Disease Phenotypes

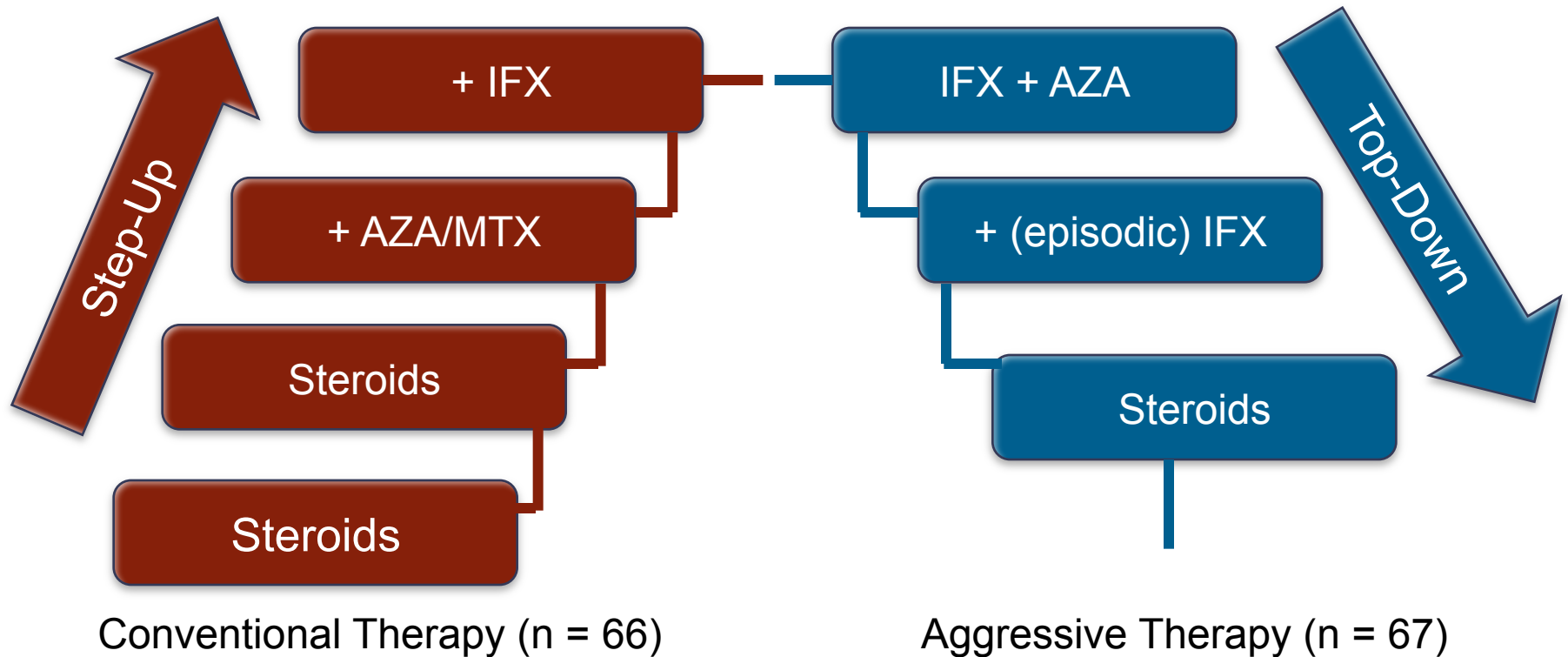


- Crohn's disease (CD)
  - Terminal Ileum
  - Diffuse small bowel disease
  - Colonic Disease
  - Small and large bowel disease
  - Perianal Disease
  - Other
- Ulcerative colitis (UC)
  - Pancolitis
  - Left-sided colitis
  - Proctosigmoiditis
  - Proctitis



# Early Aggressive Biologic Therapy vs. Conventional Management in CD

Newly-diagnosed Crohn's disease (n = 133)\*  
No previous anti-TNF, antimetabolite, or steroids



\*Within 4 years

D'Haens G, et al. *Lancet*. 2008;371(9613): 660-667.



# AGA Crohn's Disease (CD) Care Pathway



- Risk assessment
  - Disease burden
  - Inflammation
  - Comorbidities
- Induction of remission
- Maintenance of remission
- CDS tools

American Gastrological Association (AGA). AGA Website. <http://campaigns.gastro.org/algorithms/IBDCarePathway/>. Published 2014. Accessed March 26, 2016.

# AGA Clinical Pathway for Crohn's Disease: Characterizing Risk



<b>Low Risk</b>		<b>High Risk</b>
● > 30 years	Age of diagnosis	● < 30 years
● Limited	Anatomic involvement	● Extensive
● No	Perianal and/or severe rectal disease	● Yes
● Superficial	Ulcers	● Deep
● No	Prior surgical resection	● Yes
● No	Structuring and/or penetrating behavior	● Yes

# Risk Assessment in CD

## Step 1

### Disease Burden Risk Assessment

	Low Risk	High Risk
Age at Diagnosis:	<input type="radio"/> Over 30	<input checked="" type="radio"/> Under 30
Anatomic Involvement:	<input checked="" type="radio"/> Limited	<input type="radio"/> Extensive
Perianal Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Severe Rectal Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Deep Ulcers:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Strictureing:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Penetrating Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes

Overall Risk:

Low

## Step 2

### Inflammation Burden Risk Assessment

Symptoms	Lab Abnormalities
<input type="checkbox"/> Fever	<input type="checkbox"/> Low Hb
<input checked="" type="checkbox"/> Abdominal Pain	<input type="checkbox"/> Leukocytosis
<input type="checkbox"/> GI Bleeding	<input type="checkbox"/> Elevated CRP
<input type="checkbox"/> Localized Tenderness	<input checked="" type="checkbox"/> Decreased Albumin
<input type="checkbox"/> Weight Loss	<input type="checkbox"/> Elevated ESR
<input checked="" type="checkbox"/> Joint Pains	<input type="checkbox"/> Elevated FCP
<input type="checkbox"/> Cutaneous Signs	

Overall Risk:

High

## Step 3

### Comorbidity Burden Risk Assessment

Comorbidity
<input type="checkbox"/> Infections <i>Examples: C Diff, CMV</i>
<input type="checkbox"/> Strictureing/Remodeling <i>Examples: Abnormal Imaging, Obstructive Symptoms, Weight Loss</i>
<input type="checkbox"/> Symptoms from Prior Surgery <i>Examples: Bile Acid Diarrhea, Bacterial Overgrowth, Steatorrhea</i>
<input type="checkbox"/> Adverse Medical Reaction <i>Examples: Recent addition of new drug; drug holiday</i>
<input type="checkbox"/> Abnormal Abscess/Fistula <i>Examples: Pain, Fistula, Drainage, Fever</i>
<input type="checkbox"/> Perianal Abscess/Fistula <i>Examples: Pain, Fistula, Drainage, Fever</i>

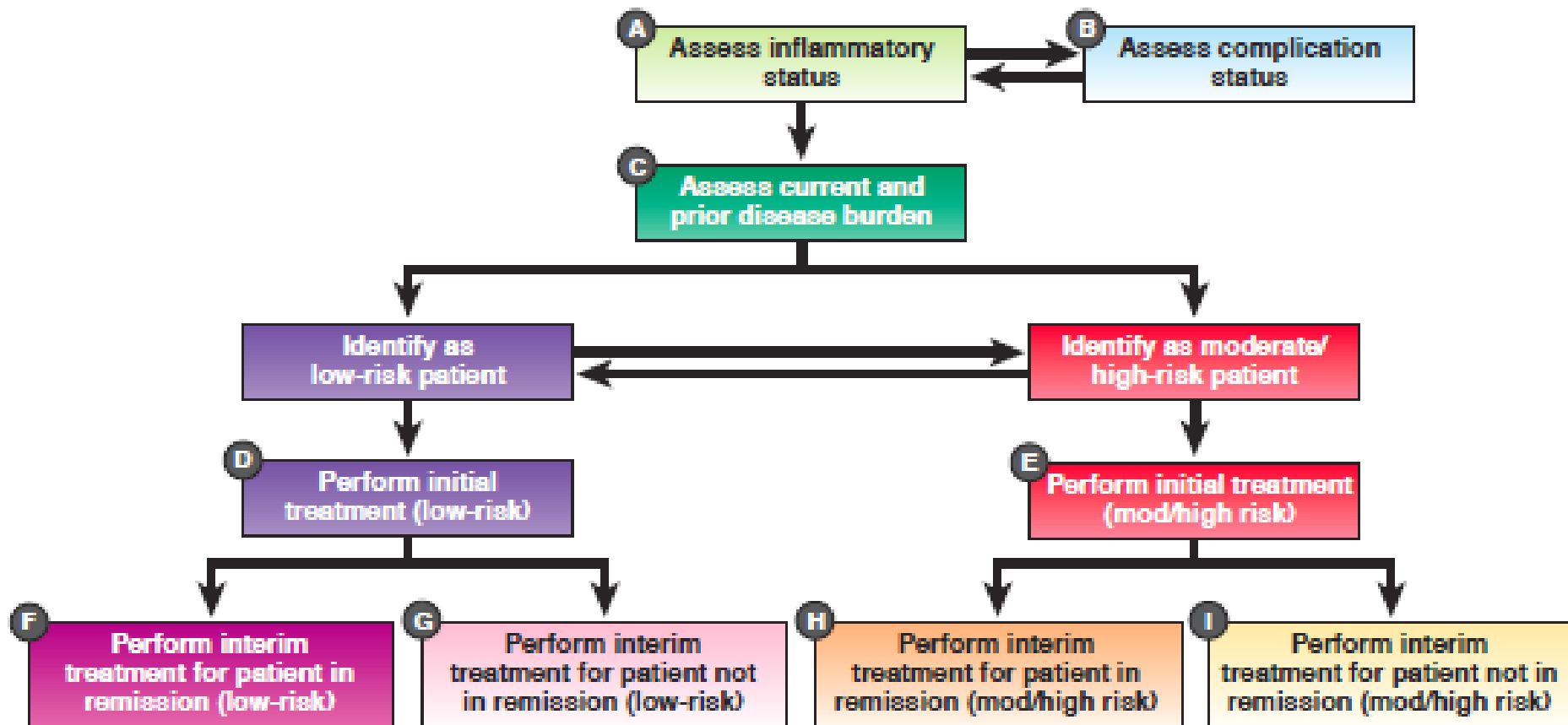
Overall Risk:

Low

American Gastrological Association (AGA). AGA Website.  
<http://campaigns.gastro.org/algorithms/IBDCarePathway/>. Published 2014.  
 Accessed March 26, 2016.



# AGA CDCP – Pathway Based on Risk



American Gastrological Association (AGA). AGA Website. <http://campaigns.gastro.org/algorithms/IBDCarePathway/>. Published 2014. Accessed March 26, 2016.

# Maintenance of Remission in CD

Remission

Steroid induced

Anti-TNF induced

Anti-TNF =  
thiopurine induced

Immunomodulator  
(thiopurine or MTX)  
over no  
immunomodulator

OR

Anti-TNF =/- thiopurine over  
no anti-TNF  
*Recommendation 9*  
SR HQE

SR = strong recommendation, WR = weak recommendation, MQE = moderate-quality evidence, HQE = high-quality evidence  
American Gastrological Association (AGA). AGA Website. <http://campaigns.gastro.org/algorithms/IBDCarePathway/>. Published 2014. Accessed March 26, 2016.

# Physician Engagement CDS Tool

**Crohn's Disease CDS Tool**

**Extent of Disease** PQRS Since: 2004  
 Small Intestine:  Ileitis  Diffuse  Ileitis  
 Colon:  Colitis  Ileocolitis  
 Other Locations ICD  
 Ext Manifestations: K50.00  
 Other Manifestations:

**Project Sonar Risk Assessments**  
 Disease Burden Assess **Low**  
 Inflammation Assess **High**  
 Comorbidities Assess **High**  
 Date Assessed: Today 01/17/2015

**Therapy Options**  
 Initial Therapy **Therapy**  
 Remission Therapy **Therapy**  
 Exacerbation Therapy **Therapy**

**Studies:**  
 Project Sonar  
 BCBS Project Sonar  
 IGG CD Infl Burden Risk

**Most Recent Sonar Score** 40

**Testing**  
 Test Name Date Result  
 Chest X Ray  
 Quantiferon Gold 2014  
 PPD PQRS 2014  
 Dexascan PQRS

**Inflammation Burden Risk Assessment**  
 Symptoms:  Fever,  Abdominal Pain,  GI Bleeding,  Localized Tenderness,  Weight Loss,  Joint Pains,  Cutaneous Signs  
 Lab Abnormalities:  Low Hb,  Leukocytosis,  Elevated CRP,  Decreased Albumin,  Elevated ESR,  Elevated FCP  
 Score: 3

**Disease Burden Risk Assessment**  
 Low Risk High Risk  
 Age at Diagnosis:  Over 30  Under 30  
 Anatomic Involvement:  Limited  Extensive  
 Perianal Disease:  No  Yes  
 Severe Rectal Disease:  No  Yes  
 Ulcers:  Superficial  Deep  
 Structuring:  No  Yes  
 Penetrating Disease:  No  Yes  
 Score: 4 High

**Biologic Use** Initiate New Biologic

Biologic Name	Status	Start Date	Drug Level	Antibody	End Date	Reason for Change
infliximab	Current	01/01/2015	Therapeutic	Negative	//	
adalimumab	Discontinued	05/01/2014	Sub-Therapeutic	Positive High	12/31/2015	Loss of Efficacy

**Aminosalicylates/5-ASA**  No  Yes PQRS Date: //

**Immunizations** Most Recent Year

Vacc Status	Created Vac	Immunization	Seq Nbr
Completed	11/23/2012	hep A (adult)	1
Completed	11/23/2012	flu (split) (6-35 mos)	1
Completed	10/11/2011	Twinrix	2
Completed	08/20/2015	hepatitis B vaccine, adult dosage	

**Labs:** Add Labs

**Albumin, CRP, Hemoglobin Dec**  
 Line graph showing trends from 05/30/14 to 09/30/14.  
 Legend: Albumin\_dec (blue), CRP\_Dec (orange), Hemoglobin (green)  
 Data points (approximate):  
 05/30/14: Albumin 7.000, CRP 0.700, Hemoglobin 14.000  
 04/23/14: Albumin 3.900, CRP 3.900, Hemoglobin 12.000  
 04/10/14: Albumin 3.600, CRP 3.600, Hemoglobin 12.000  
 03/1/14: Albumin 3.000, CRP 3.000, Hemoglobin 12.000  
 02/27/14: Albumin 4.000, CRP 4.000, Hemoglobin 13.000  
 09/30/14: Albumin 12.000, CRP 12.000, Hemoglobin 12.000

**Comorbidity Burden Risk Assessment**  
 Comorbidity Examples  
 Infections C DM, OMV  
 Stricture/Renodding Abnormal Imaging, Obstructive Symptoms, Weight Loss  
 Symptoms from Prior Surgery Ble Acid Diarrhea, Bacterial Overgrowth, Steatorrhea  
 Adverse Medical Reaction Recent addition of new drug; drug holiday  
 Abdominal Access/Fistula Pain, Fistula, Drainage, Fever  
 Perianal Access /Fistula Pain, Fistula, Drainage, Fever  
 Score: 3

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website. [http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016.



# AGA Ulcerative Colitis (UC) Care Pathway



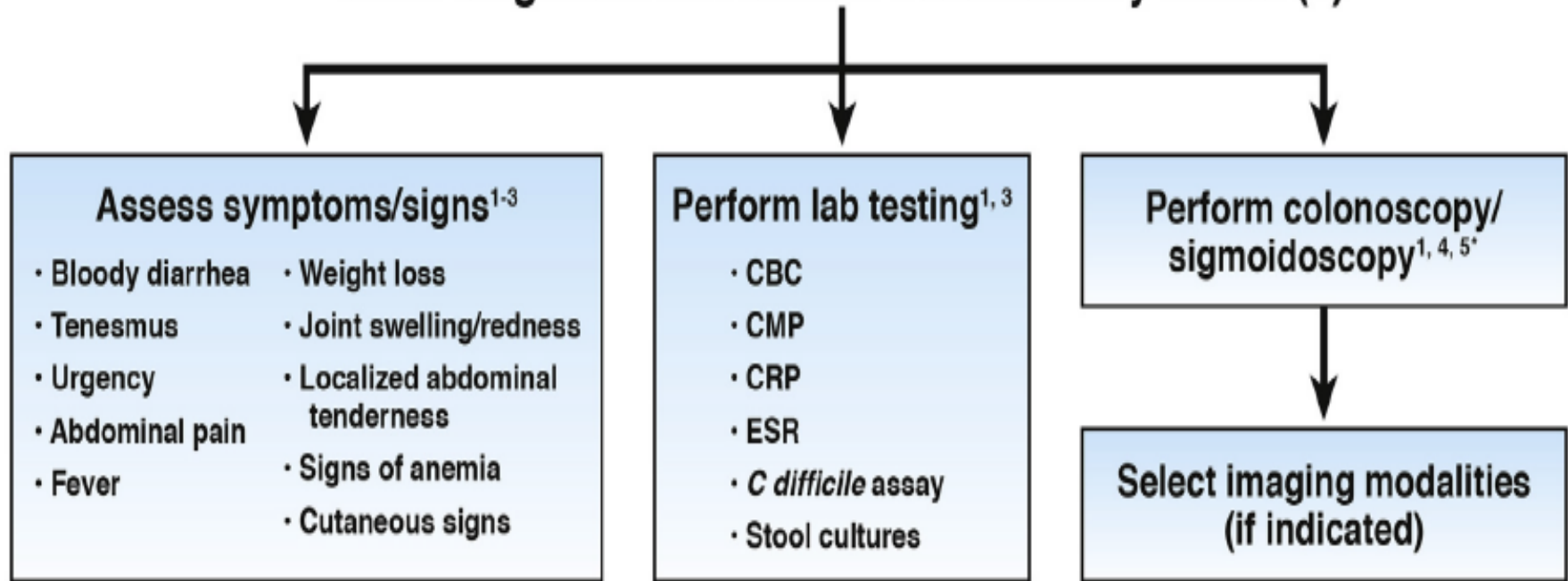
- Risk assessment of UC
  - Inflammation
  - Co-morbidities
  - Colectomy risk
- Initial therapy
- Exacerbation treatment options
- CDS tool

American Gastrological Association (AGA). AGA Website.  
<http://campaigns.gastro.org/algorithms/UlcerativeColitis/>. Published 2015.  
Accessed March 26, 2016.

# Risk Assessment in UC



## Make diagnosis and assess inflammatory status (1)



\* In patients with severe colitis, flexible sigmoidoscopy is safer and preferred over colonoscopy<sup>4, 5</sup>

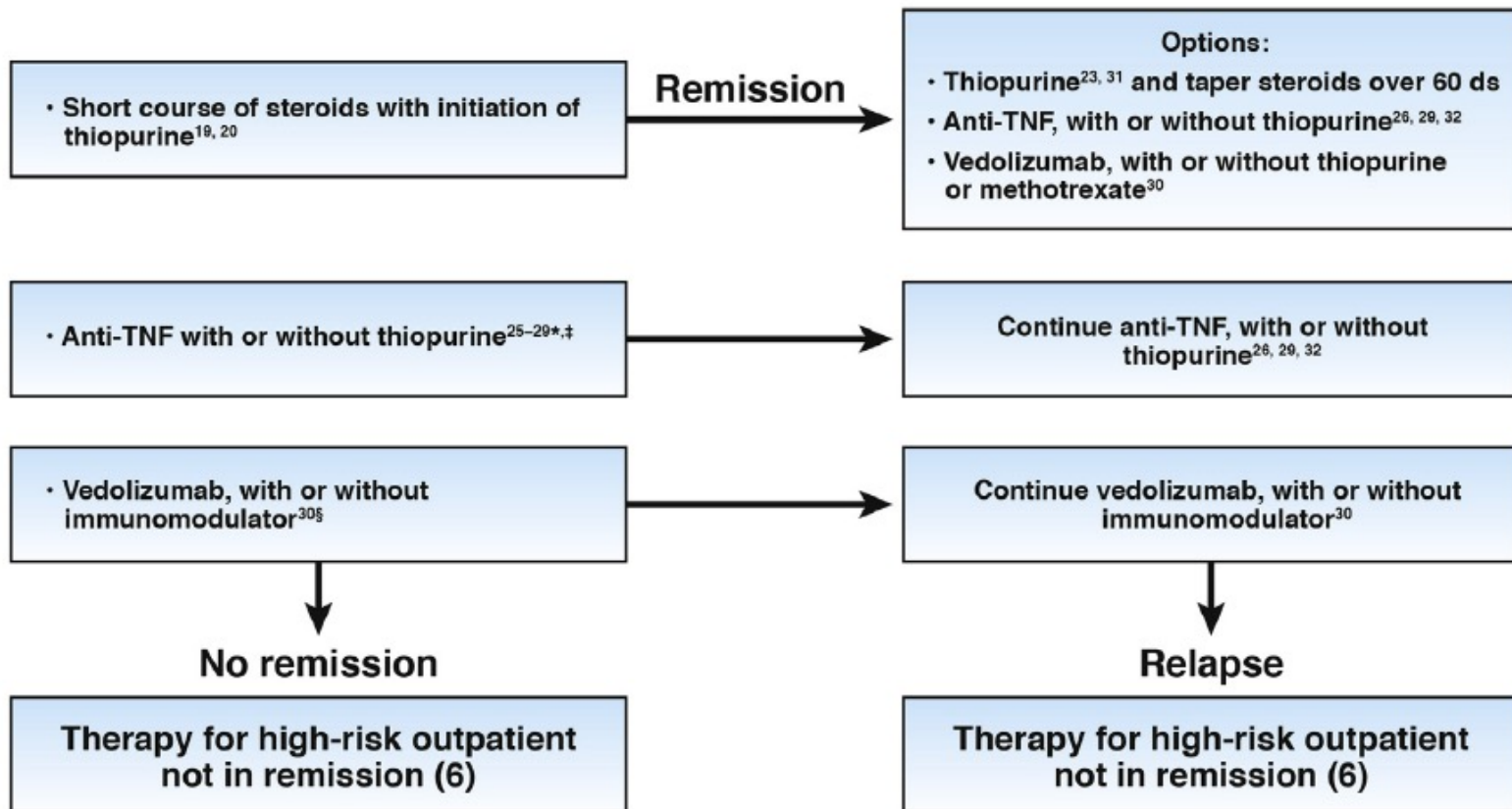
American Gastrological Association (AGA). AGA Website.  
<http://campaigns.gastro.org/algorithms/UlcerativeColitis/>. Published 2015.  
Accessed March 26, 2016.

# Initial Therapy in High Risk UC Patients

## Inductive and maintenance therapy (high-risk, outpatient) (5)

### Induction therapy

### Maintenance therapy



# Validation of AGA Pathway Risk Assessment Metrics vs. Cost in CD

**Study Objective:** Assess the predictive value of the 26 individual CDCP metrics vs. baseline CD related medical costs of participating Project Sonar patients (N = 282)

**CD Related Healthcare Costs:** CD related medical costs were identified from each pts 2014 BCBS medical claims with ICD-9-CM 555.X or select ICD-9-CM symptom codes

Patients total medical costs were linked to their 26 individual AGA CDCP measures

Costs were divided into three groups: low (min-9th percentile), middle (10th to 89th percentile) and high (90th percentile – max)

**Conclusions:** 4/26 CDCP risk factors were found to be significant drivers of CD related medical costs. Crohn's patients with joint pain, decreased albumin, infections, and/or structuring may be at risk for both clinical failure and increased Crohn's related medical costs.

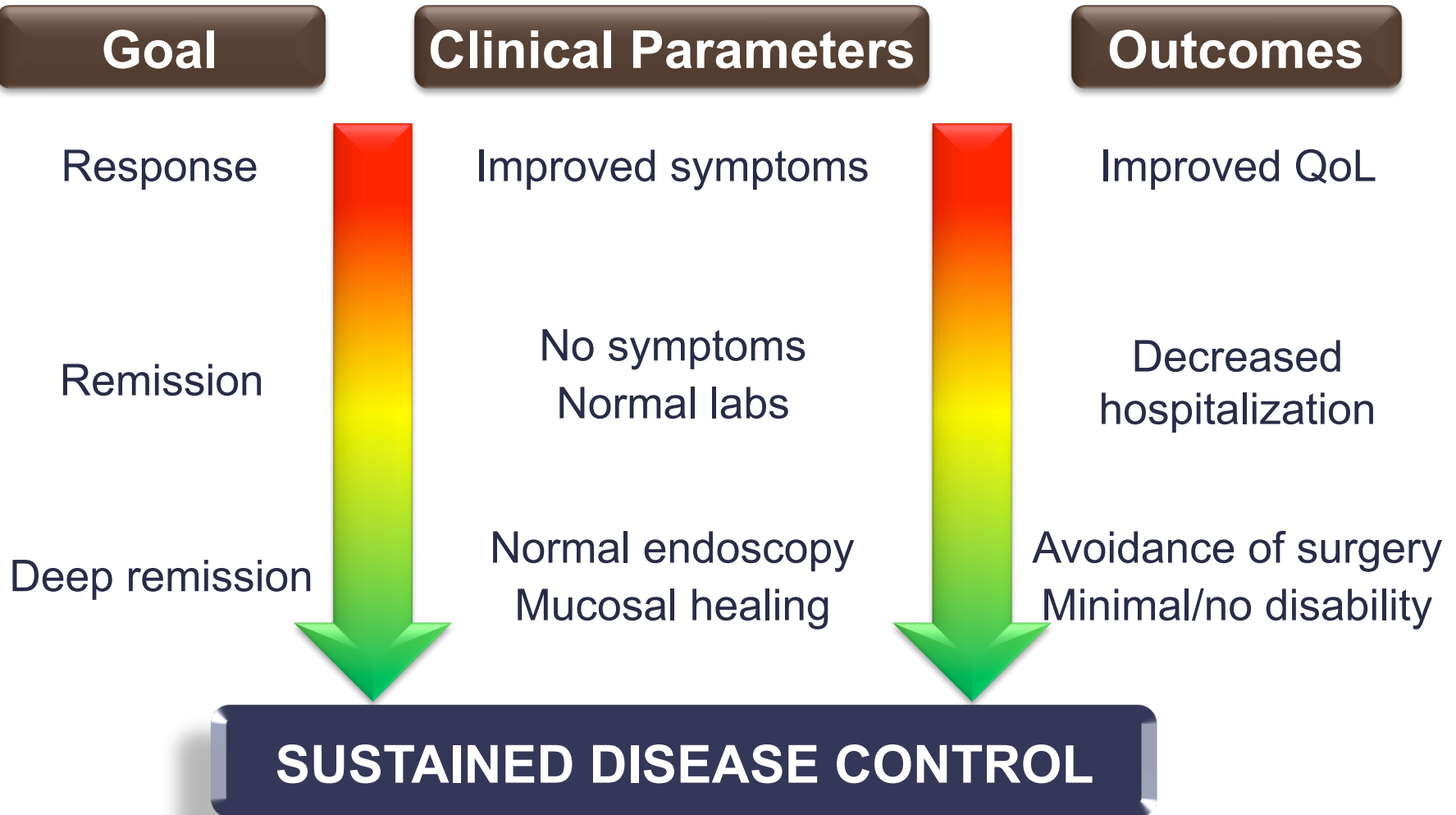




# IBD Therapies: Risk, Benefit, Mechanism of Action

Miguel Regueiro, MD,  
AGAF, FACG, FACP

# Movement to Objective Measures of Control and Chronic Care Model of IBD



# Therapeutic Agents



- **ASA compounds**
  - Sulfasalazine
  - Oral 5-ASA formulations
  - Rectal 5-ASA
- **Glucocorticosteroids**
  - Systemic steroids
  - Topically acting steroids
- **Antibiotics\***
  - Metronidazole\*
  - Quinolones\*
- **Immunosuppressives**
  - Azathioprine or 6-mercaptopurine/TPMT
  - Methotrexate
- **Biological therapies**  
**PPD/HBV**
  - Infliximab
  - Adalimumab
  - Certolizumab pegol
  - Golimumab
  - Natalizumab (JCV Ab)
  - Vedolizumab
- **Nutritional therapies**
  - Elemental and polymeric formulas
  - Pre- and probiotics
- **Symptomatic agents**
  - Anti-diarrheals
  - Anti-spasmodics

\*FDA-Approved for infections; not FDA-approved for UC/CD

Adapted from Rutgeerts PJ. *Rev Gastroenterol Disord.* 2004;4(suppl 3):S3-S9. PMID: 15580150.

# 5-Aminosalicylates (5-ASAs)

	Name	Indications	Adverse Events	MOA
Oral Agents			<ul style="list-style-type: none"> <li>• Common &gt; 10%               <ul style="list-style-type: none"> <li>• Headache</li> <li>• Malaise</li> <li>• Cramps</li> <li>• Gas</li> </ul> </li> <li>• Uncommon 1%-10%               <ul style="list-style-type: none"> <li>• Hair loss</li> <li>• Skin rash</li> <li>• Worsening colitis</li> </ul> </li> <li>• Rare &lt; 1%               <ul style="list-style-type: none"> <li>• Pneumonitis</li> <li>• Pericarditis</li> <li>• Pancreatitis</li> <li>• Interstitial nephritis</li> </ul> </li> <li>• 20% are allergic to sulfa</li> </ul>	Interfere with the production of arachidonic acid by affecting thromboxane and lipoxygenase synthesis pathways
Sulfasalazine	Azulfidine	Primarily UC		
Mesalamine	Asacol, Pentasa, Lialda, Apriso	Primarily UC		
Balsalazide	Colazol	Primarily UC		
Olsalazine	Dipentum	Primarily UC		
Rectal Formulations				
Mesalamine suppository	Canasa	Ulcerative proctitis and left-sided UC		
Mesalamine enema	Rowasa			



# Corticosteroids

	Indications	Short-term Adverse Events	Long-term Adverse Events	MOA
Glucocorticosteroids (systemic)				
Prednisone	UC and CD Induction of remission, not maintenance	<ul style="list-style-type: none"> <li>• Acne</li> <li>• Insomnia</li> <li>• Fluid retention</li> <li>• Weight gain</li> <li>• Emotional lability</li> <li>• Blurred vision (fluid accumulation in lens of eye)</li> </ul>	<ul style="list-style-type: none"> <li>• Bones               <ul style="list-style-type: none"> <li>• Osteoporosis: 10-50%</li> <li>• Osteonecrosis/ avascular necrosis: 5%</li> </ul> </li> <li>• Myopathy: 7%</li> <li>• Eye               <ul style="list-style-type: none"> <li>• Glaucoma</li> <li>• Cataracts: 22%</li> </ul> </li> <li>• Infection: 10-20%</li> <li>• DM: 2.3 RR compared to general pop</li> <li>• HTN: up to 20%</li> <li>• Psychosis: 3-5%</li> </ul>	<p>Potent anti-inflammatory and immunosuppressive agents</p> <p>Inhibit production of arachidonic acid, alter leukocyte function, and ↓ the expression of pro-inflammatory cytokines, e.g. IL-1, IL-2, IL-4, IL-5, IL-6, IL-8, and interferon gamma</p>
Solumedrol (Medrol)				
Prednisolone				
Hydocortisone (IV, PO, suppository/foam, enema)				
Rapidly metabolized steroid (nonsystemic)				
Budesonide (Entocort, Uceris)	UC and CD Induction of remission, not maintenance			

DM = diabetes mellitus, RR = relative risk, HTN = hypertension

Package Inserts: [Drugs@FDA.gov](mailto:Drugs@FDA.gov).

# Bacterial “Modifying” Agents\*

	Use	Adverse Events	MOA
Ciprofloxacin* (Cipro)	Perianal fistula, pouchitis, bacterial overgrowth  Possibly effective as primary agents in some patients	<ul style="list-style-type: none"> <li>• Tendon complication, rare; &lt; 1%</li> <li>• ↑ risk of tendon complications:                             <ul style="list-style-type: none"> <li>• If over 60 years of age</li> <li>• If taking corticosteroids</li> <li>• Kidney, heart of lung transplant</li> </ul> </li> </ul>	MOA primary antibacterial effect, but possible anti- inflammatory properties
Metronidazole* (Flagyl)		<ul style="list-style-type: none"> <li>• Disulfiram reaction with alcohol</li> <li>• Metallic taste/”hairy tongue”</li> <li>• Peripheral neuropathy</li> </ul>	
Rifaximin* (Xifaxan)		<ul style="list-style-type: none"> <li>• Nausea, vomiting, dizziness, swelling</li> </ul>	
Probiotics		<ul style="list-style-type: none"> <li>• Gas, bloating</li> </ul>	
Prebiotics		<ul style="list-style-type: none"> <li>• Gas, bloating</li> </ul>	

- Side effects common to all antibiotics – diarrhea, nausea, vomiting, allergic reaction (fever/hives)
- Any IBD patient on antibiotics who develops diarrhea, think *Clostridium difficile!*

\*FDA-approved for infections; not FDA-approved for CD or UC; Package Inserts. [Drugs@FDA.gov](mailto:Drugs@FDA.gov).

# Immunomodulators

	Indication	Adverse Events	MOA
Oral	CD > UC	<ul style="list-style-type: none"> <li>• <b>Dose-dependent</b> (5%, non-allergic): bone marrow suppression, hepatitis</li> <li>• <b>Dose independent</b> (10-15%, allergic/ idiosyncratic): fever, rash, arthralgias, fatigue, diarrhea, pancreatitis (pain w/in 2 wk)</li> <li>• <b>Viral processes:</b> EBV, lymphoma, HPV, shingles</li> </ul>	Metabolized to 6-TGN that inhibit ribonucleotide synthesis, exhibit antiproliferative effects on activated lymphocytes (suppression of T cell function and natural killer cell activity)
6-mercaptopurine (6-MP) Azathioprine (Imuran)			
IM/SQ/Oral	CD	<ul style="list-style-type: none"> <li>• Hepatotoxicity, myelosuppression, interstitial pneumonitis, oligospermia, stomatitis, alopecia</li> <li>• Teratogenic (Cat. X)</li> </ul>	Inhibits dihydrofolate reductase and purine synthesis ↓ production of IL-1, IL-2, leukotriene B4, may induce T cell apoptosis
Methotrexate (Trexall)			
IV/Oral	UC	<ul style="list-style-type: none"> <li>• Paresthesias, hypertrichosis, tremor, hypertension, nausea, gingival hyperplasia, vomiting, headaches, nephrotoxicity, seizures</li> <li>• Opportunistic infection: Pneumocystis pneumonia (prophylaxis)</li> </ul>	Inhibits proliferation & activation of T helper cells by interfering with IL-2 production. ↓ recruitment of cytotoxic T cells and inhibits production of IL-3, IL-4, TNF-alpha, and interferon gamma
Cyclosporine			

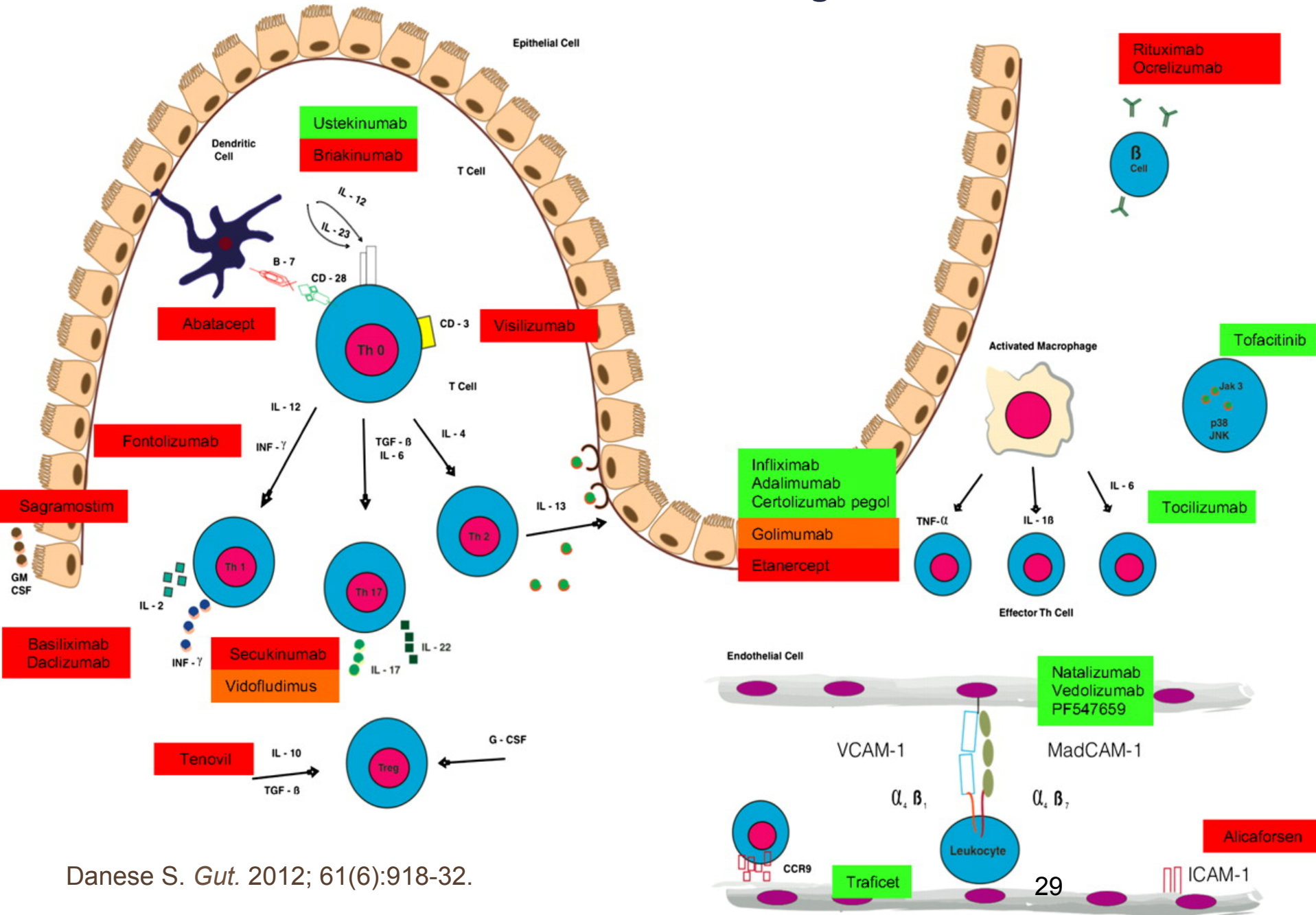
EBV = Epstein Barr Virus

Package Inserts. [Drugs@FDA.gov](mailto:Drugs@FDA.gov).

# FDA-Approved Biologics for IBD

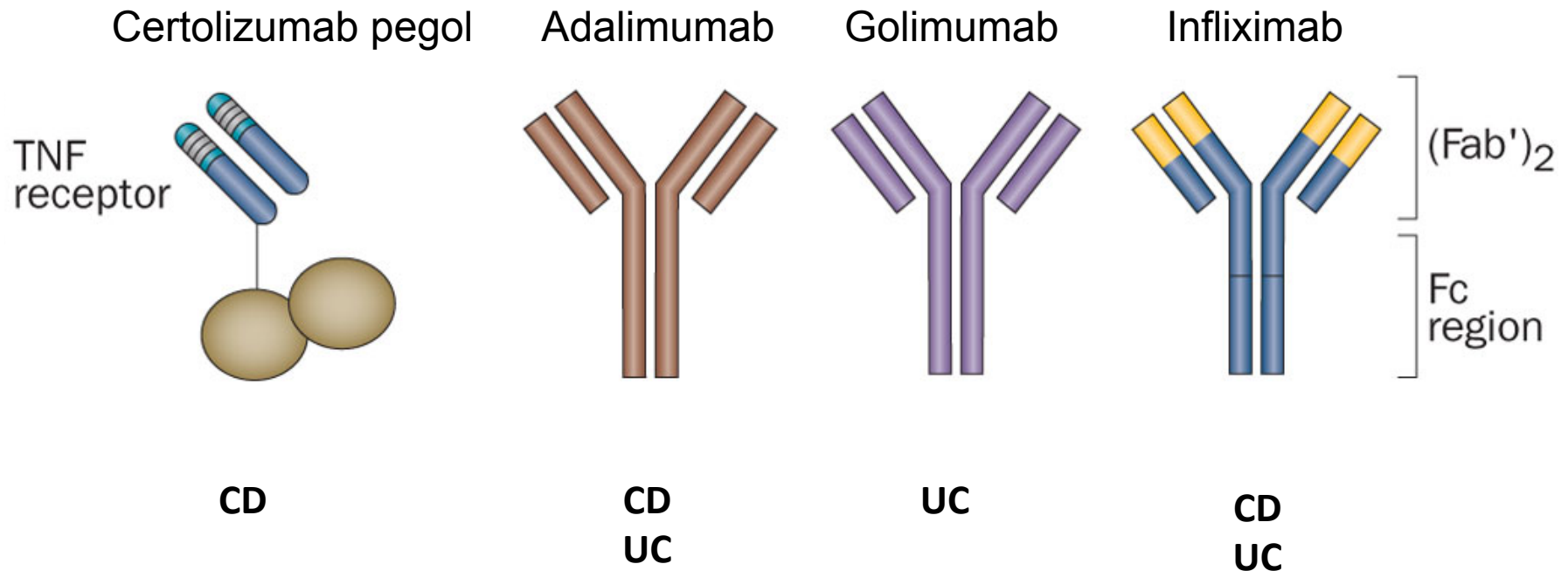
	Indications	Adverse Events
<b>Anti-TNF Agents</b>		
Infliximab (Remicade)	CD, UC	Serious infections...including TB, bacterial sepsis, invasive fungal, and other opportunistic infections; Lymphoma and other malignancies...have been reported in children and adolescent patients treated with TNF blockers; See BOXED WARNING
Adalimumab (Humira)	CD, UC	
Certolizumab (Cimzia)	CD	
Golimumab (Simponi)	UC	
<b>A4<math>\beta</math>7 Integrin Antagonists</b>		
Natalizumab (Tysabri)	CD	Headache, fatigue, infusion rxn, UTI, arthralgia, depression pain in extremity, rash, gastroenteritis, vaginitis. Increased risk of PML
Vedolizumab (Entyvio)	CD, UC	Nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, pain in extremities

# MOA of IBD Meds: Green = Successful, Orange = Potential, Red = Failed

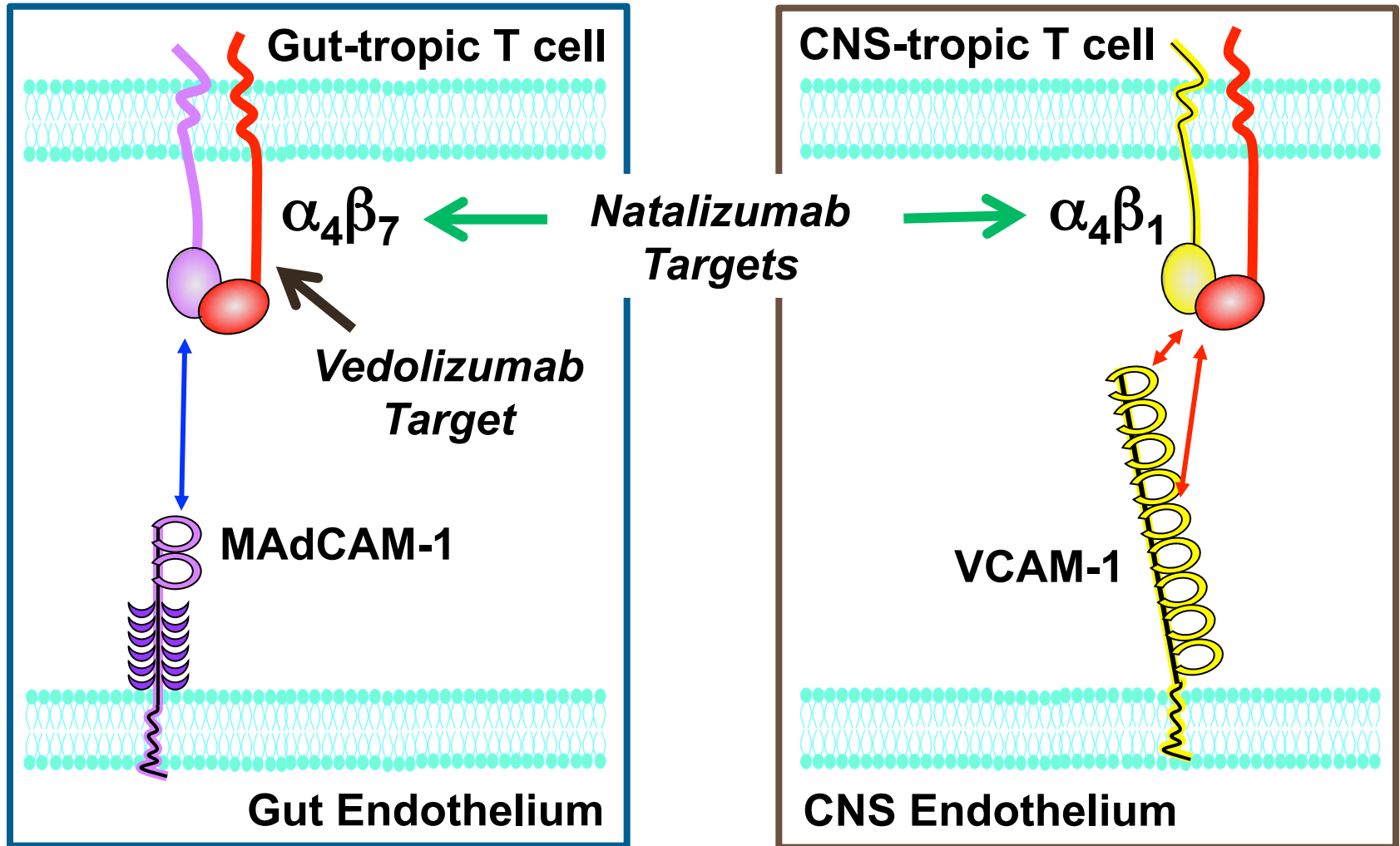




# Anti-TNF Therapies for Inflammatory Bowel Disease



# Anti- $\alpha_4$ Integrins and Their Ligands Block Tissue-tropic Lymphocyte Migration



von Andrian UH, Mackay CR. *N Eng J Med* 2000;343(14):1020-1034. PMID: 11018170.

von Andrian UH, Engelhardt B *N Eng J Med* 2003;348;(1):68-72. PMID: 12510047.

# Pipeline Agents



- \*Ustekimumab (human mab)
  - Pursuing indication in CD
- \*Tofacitinib (kinase inhibitor)
  - Pursuing indication in UC

\* Not currently FDA-approved for CD or UC

# How Do You Position Biologics for IBD?



- Patient: Goals and engagement of the patient
- Indications and Guidelines: FDA labeling and treatment guidelines
- Efficacy: No comparative efficacy studies, difficult to compare across trials
- Demographics: Gender, age, weight, pregnancy
- Adherence and formulation
- Severity of disease: inpatient vs. outpatient
- Subtypes of disease: fistula, postop, EIMs
- Pharmacokinetics, drug levels, antibodies
- Safety: Active or prior infection/malignancy
- Need for concomitant immunosuppression

# Positioning Biologics in IBD

	Indication	Severe, Extensive Fistula, Inpatient	Safety (Thiopurine would increase risk)	Need for Concom IMM	Pregnancy	Ability to measure Drug level and abs	Adherence	Extra-Intestinal Manifest
IFX	UC/CD	++ ↓albumin ↑CRP	+	Yes	+	+	IV monitored	++ Rheum Derm Peds Postop
ADA	UC/CD	+/-	+	Yes	+	+	SQ self	++ Rheum Derm Peds Postop
CTZ	CD	+/-	+	Yes	++	-	SQ self	+
GOL	UC	+/-	+	Yes	+	-	SQ self	+
NATA	CD	+/-	+ - if JCV	Yes	?+	-	IV monitored	-
VEDO	UC/CD	+/-	++ >50y?	Yes	?+	-	IV monitored	- ?PSC

Package inserts. [Drugs@FDA.gov](mailto:Drugs@FDA.gov).





## Cost

There are no comparative efficacy studies, and no cost comparison studies to guide clinicians.

# Cost of Non-Biologics



- Mesalamine - \$500/month (maintenance treatment)
- Mesalamine HD - \$1087/6 week induction course
- Mesalamine DR 400mg - \$897/6 week induction course or \$427/month maintenance dose
- Other mesalamine - \$567 - \$1134/month induction or \$567/month maintenance dose
- Other mesalamine - \$2698 for 8 week induction
- Sulfasalazine - \$50-70/month\*
- Balsalazide - \$250-\$400 for 8-12 weeks induction course\*
- Olsalazine - \$1868/month\*

Micromedex Website. <http://micromedex.com/products/product-suites/clinical-knowledge/redbook>. Published 2016. Accessed April 12, 2016.

# Cost of Non-Biologics



## Corticosteroids

- Budesonide EC - \$1900 for 8 week induction; \$633/month for maintenance x 3 months
- Other budesonide - \$3870 for 8 week induction

## DMARDS/Immunomodulators

- Mercaptopurine - \$115/month (based on 70kg adult)\*
- Azathioprine - \$40-55/month (based on 70kg adult)\*
- Methotrexate - \$50/month\*

\*Generic prices are estimates

Micromedex Website. <http://micromedex.com/products/product-suites/clinical-knowledge/redbook>. Published 2016. Accessed April 12, 2016.

# Wholesale Cost of Biologics



- Infliximab: ~\$1900 per 100 mg (5-10 mg/kg dose) - \$5000 – 10,000 every 8 weeks (depending on weight/dose)
  - Example: 65 kg patient @ 5 mg/kg would get 325 mg
- Vedolizumab: ~\$5800 every 8 weeks
- Adalimumab: ~\$2500 per dose - \$4500/month
- Certolizumab: ~\$5100 per dose - \$4000/month
- Natalizumab: ~\$300 per dose - \$5300/month
- Golimumab: ~\$3100 per dose - \$4500/month

Price does not include infusion (administration)

Micromedex Website. <http://micromedex.com/products/product-suites/clinical-knowledge/redbook>. Published 2016. Accessed April 12, 2016.

# Cost of Colectomy



- Laparoscopic-assisted colectomy with ileal pouch-anal anastomosis (IPAA)
  - \$43,000 (colectomy with temporary ileostomy)
  - \$45,000 (creation of ileoanal pouch)
  - \$30,000 (ileostomy closure/reconnection)
  - \$45,000 small bowel resection w/anastomosis
  - Average daily hospital stay: \$2500
  - Significant quality of life burden





# Overview of the IBD Medical Home

A New Model for 360°  
Subspecialty Patient  
Centered Care

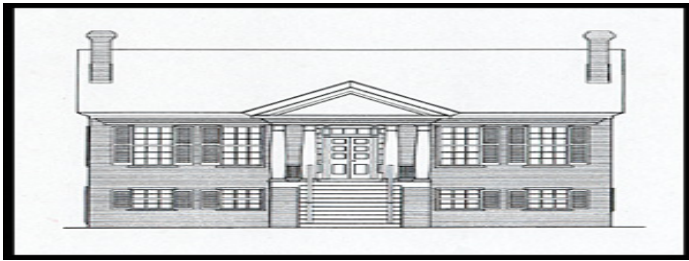


# What is a Patient Centered Medical Home?

## The History



- Primary care model the last decade (initial PCMH)
  - Prominent component of health care reform law
  - Endorsed by the ACP, AAFP, AAP, AMA



- Combines primary care with systematic improvement of a patient population
  - Personal physician providing first contact and continuous care
  - Use of chronic disease registries
  - Implementation of information technology
  - New operations for communication between MDs and patients

# Two Key Ingredients in Considering a Specialty Home



1. A population of patients whose principal care is from a specialist
2. Partnership with a health plan around that disease state
  - Chronic disease (spanning at least 5 years)
  - Decreasing utilization = return on investment



**...BUT the “secret sauce” in a specialty Medical Home or any chronic disease model that we were initially missing.....**

# Mental Health Specialists





# UPMC Health Plan Perspective on an IBD Home

First meeting about  
medical home in 2012



# Medical Home Utilization



## What Types of Service do these Members Utilize?

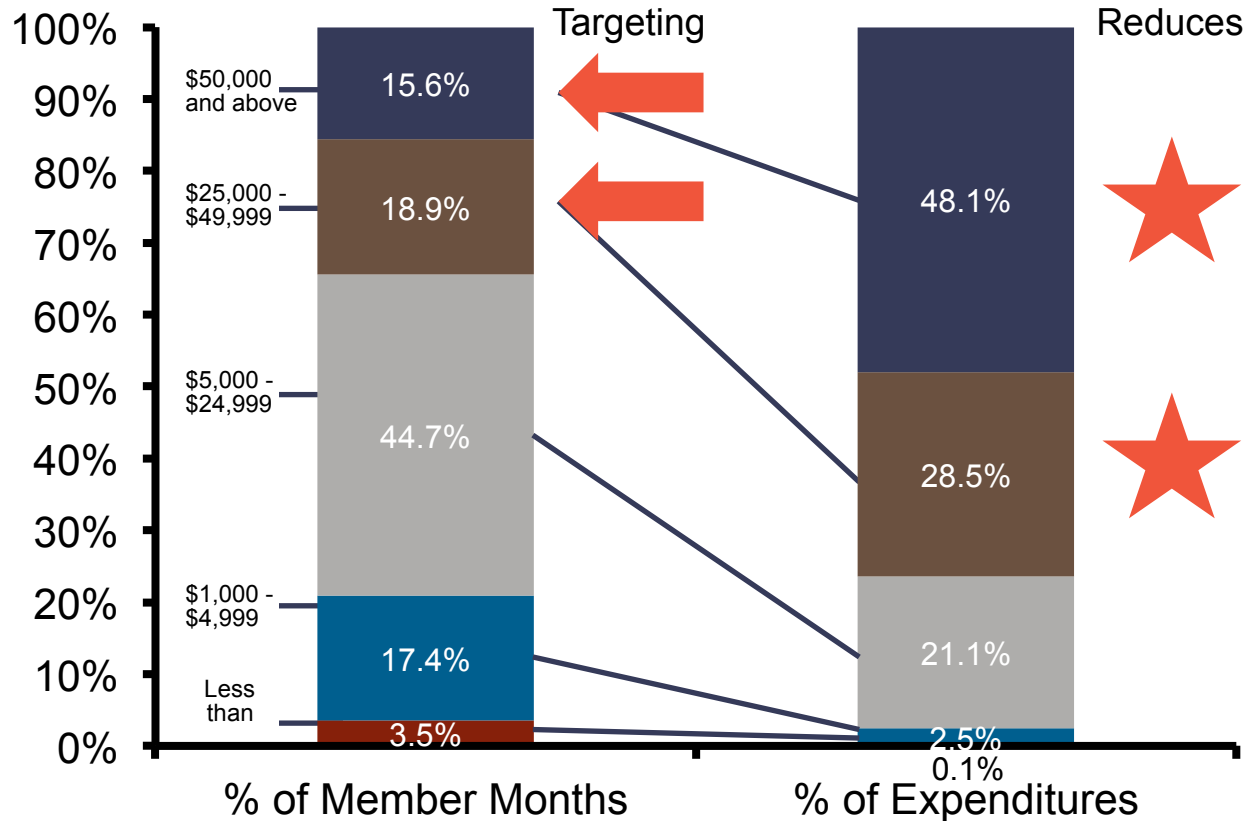
Rank	Financial Service Type	Total PMPM	% of Total Claim Expenditure	Units/ 1,000	Unique Members with at least 1 Claim	% of Members in population with at 1 least 1 claim
1	Pharmacy	\$616.13	31.6%	32,591	2,190	92.2%
2	Injectable Drugs	\$370.18	19.5%	4,549	1,126	47.4%
3	IP Medical Surgical	\$306.48	16.2%	408	523	22.0%
4	Specialist	\$130.21	6.9%	10,553	2,226	93.7%
5	Outpatient Surgery	\$71.08	3.8%	924	1,238	52.1%
6	Emergency Room	\$67.94	3.6%	1,389	1,119	47.1%
7	Lab Services	\$58.84	3.1%	5,785	2,197	92.5%
8	PCP	\$40.26	2.1%	5,577	2,013	84.7%
9	Observations	\$35.04	1.8%	200	292	12.3%
10	High Tech Radiology	\$34.25	1.8%	478	975	41.0%

Regueiro M., et al. Accepted, *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care.



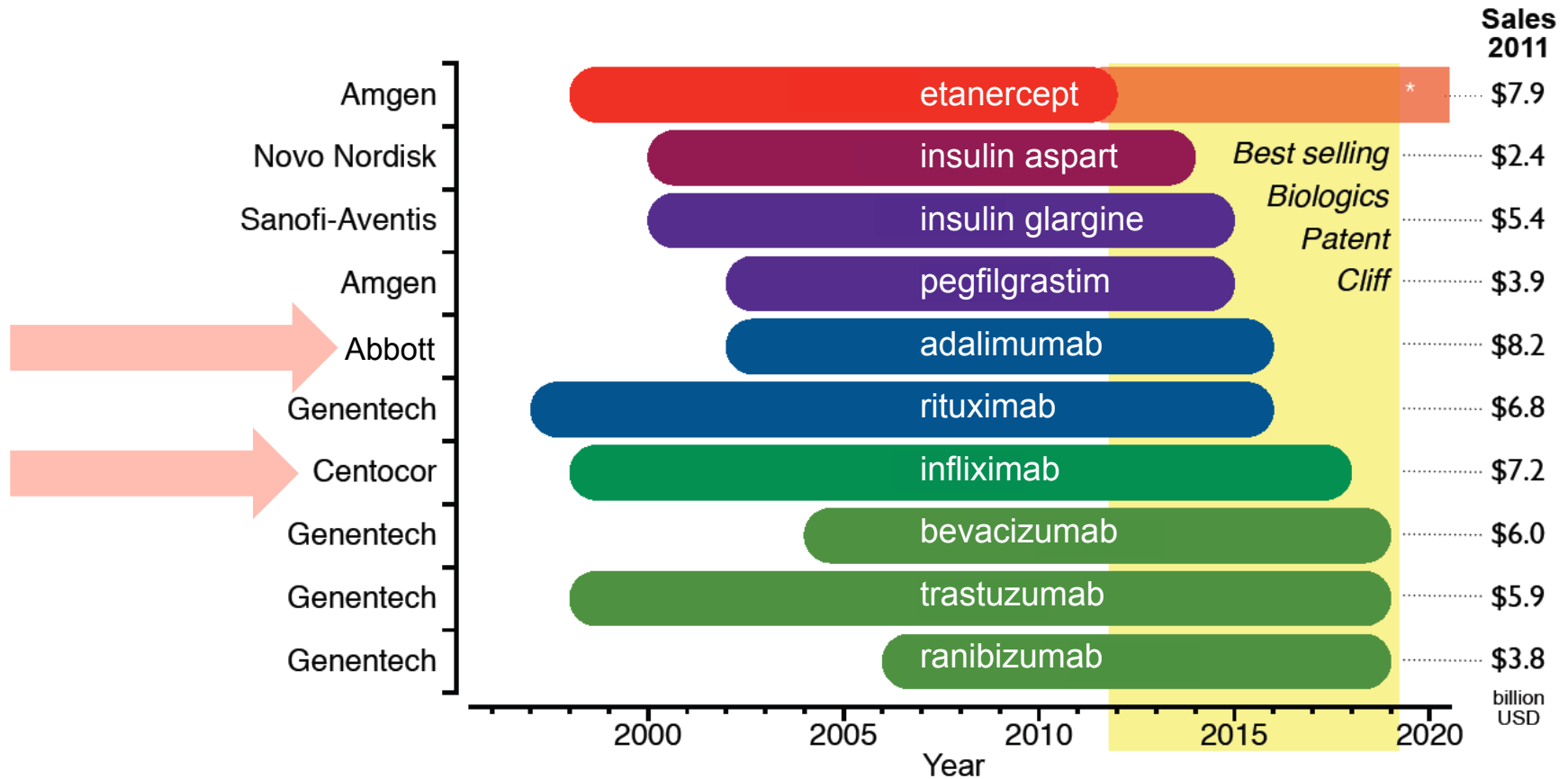
# “Super-utilizer Patients” Drive Unplanned Care and Cost

Distribution of Total Medical and Pharmacy Payments by Proportion of Member Population



Regueiro M., et al. Accepted. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care.

# Discussion Around Biologics and Biosimilars: Impact on the IBD Medical Home



Regueiro M., et al. Accepted, *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care.

# First Biosimilar Receives US FDA Approval in IBD



- Food and Drug Administration approved biosimilar for infliximab on April 5, 2016
  - Infliximab-dyyb
- Approved for rheumatoid arthritis, ulcerative colitis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease (adult and pediatric)
- Launch is possible in late 2016
- Price is pending

Food and Drug Administration (FDA). FDA Website. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494227.htm>. Published April 5, 2016. Accessed April 6, 2016.

# How Does UPMC Decide Who to Include in Medical Home?



- UPMC HP Insurance with Crohn's or UC
- 16 to 50 years of age
- >25% of spend in the past year on IBD

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.



# UPMC IBD Medical Home Patient Example

# Despite No Active Crohn's, He Visits the ER Frequently – 14 Times Over a 6 Week Period

Chart Review

Filters Preview Refresh Select All Deselect All

68 records match filters, more records to load

Filters: Hide Add'l Visits










To save time, not all records have been loaded and sorted. [Load](#)

	Date	Type	△	Dept Specialty
	08/08/2015	ER Report		None
	08/08/2015	ER Report		None
	08/04/2015	ER Report		None
	07/30/2015	ER Report		None
	07/28/2015	ER Report		None
	07/28/2015	ER Report		None
	07/19/2015	ER Report		None
	07/12/2015	ER Report		None
	07/12/2015	ER Report		None
	07/05/2015	ER Report		None
	06/28/2015	ER Report		None
	06/28/2015	ER Report		None
	06/27/2015	ER Report		None
	06/27/2015	ER Report		None

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.



# 9 Visits to ER Led to Admission to the Hospital 1 Hospitalization and Pt Developed *Cdiff*

	08/08/2015	Hospital-Encounter	None
	08/04/2015	Hospital-Encounter	None
	07/30/2015	Hospital-Encounter	None
	07/28/2015	Hospital-Encounter	None
	07/19/2015	Hospital-Encounter	None
	07/12/2015	Hospital-Encounter	None
	07/05/2015	Hospital-Encounter	None
	06/28/2015	Hospital-Encounter	None
	06/27/2015	Hospital-Encounter	None

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.

# 19 CT Scans and Many Other Radiographic Tests In One Year

Result ... ▾	Order Date	Test	
	8/17/2015	08/17/2015	XRAY ABDOMEN 1 VIEW
	8/7/2015	08/07/2015	XRAY ABDOMEN 1 VIEW
	7/19/2015	07/18/2015	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	6/23/2015	06/22/2015	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	5/11/2015	05/11/2015	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	5/11/2015	05/10/2015	XRAY ABDOMEN 1 VIEW
	5/10/2015	05/10/2015	CT HEAD WITHOUT CONTRAST
	5/10/2015	05/10/2015	XRAY CHEST 2 VIEWS
	4/21/2015	04/20/2015	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	4/20/2015	04/20/2015	US RETROPERITONEAL COMPLETE
	4/7/2015	04/07/2015	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	4/7/2015	04/07/2015	XRAY CHEST ONE VIEW
	3/29/2015	03/29/2015	XRAY CHEST 2 VIEWS
	2/15/2015	02/15/2015	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	1/23/2015	01/15/2015	DXA AXIAL SKELETAL 1 OR MORE SITES
	1/23/2015	01/20/2015	US RETROPERITONEAL COMPLETE
	1/5/2015	01/05/2015	XRAY ABDOMEN 1 VIEW
	12/30/2014	12/30/2014	XRAY ABDOMEN 2 VIEWS
	12/25/2014	12/22/2014	CT SPINE THORACIC WITHOUT CONTRAST ED PATIENT PROF ONLY
	12/25/2014	12/22/2014	CT CHEST WITHOUT CONTRAST
	12/23/2014	12/23/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	12/22/2014	12/22/2014	CT SPINE LUMBAR WITHOUT CONTRAST ED PATIENT PROF ONLY
	12/22/2014	12/22/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	12/22/2014	12/22/2014	CT CERVICAL SPINE WITHOUT CONTRAST
	12/22/2014	12/22/2014	CT HEAD WITHOUT CONTRAST
	12/18/2014	12/18/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	12/15/2014	12/14/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	12/14/2014	12/14/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	11/26/2014	11/26/2014	UROGRAPHY RETROGRADE WITH OR WITHOUT KUB
	11/5/2014	11/05/2014	XRAY ABDOMEN 1 VIEW
	11/3/2014	11/03/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST
	10/21/2014	10/20/2014	XRAY ABDOMEN 2 VIEWS
	10/16/2014	10/15/2014	XRAY CHEST 2 VIEWS
	10/15/2014	10/15/2014	CT ABDOMEN AND PELVIS WITHOUT CONTRAST

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.

# Enrolled in the Total Care IBD Medical Home Program On July 23 – In The Past Month, No ER Visits, No CT Scans



	08/31/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	08/27/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	08/24/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	08/17/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	08/13/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	08/13/2015	Office Visit	Plastic Surgery	Acarturk, Tahsin Oguz, MD
	08/10/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	08/06/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	07/27/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD
	07/23/2015	Office Visit	Gastroenterology	Regueiro, Miguel, MD

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care, In press.

# Cost of Patients in the 1st Year PRIOR to Enrollment



<b>Total</b>	<b>\$3,685,064</b>
<b>Med Cost</b>	<b>\$1,348,142</b>
<b>PMPM</b>	<b>\$2,910</b>

PMPM = per member per month

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.

# Moving from Subspecialty Centers to Subspecialty Homes

## What is the Difference?



- **Traditional IBD center** – collaboration with hospital/medical center
  - Often built around the healthcare team
  - Gastroenterologists as consultants and referred patients by providers
  - RVU based, volume proposition for payment
  - Institutional support from downstream revenue
    - surgery, pathology, radiology, infusions

# Moving from Subspecialty Centers to Subspecialty Homes

## What is the Difference?



- **IBD Patient Centered Medical Home** – collaboration with insurance company
  - Puts patient at the center of the care model
  - GI's as principal care providers and “referred” patients by payer – population based approach
  - Value based – quality, preventative medicine, telemedicine, mental health care, etc.
  - Insurance/Payer support to improve value and reduce cost – shared savings or global payment models





# Role of Psychiatrist in IBD Medical Home

**Eva Szigethy, MD, PhD**  
University of Pittsburgh  
Pittsburgh, PA

# Role of Psychiatrist in IBD Medical Home



- Optimize team-based treatment plan
- Support patient's self-efficacy in disease management
- Address co-morbid psychiatric conditions
- Manage chronic pain

# IBD Medical Home: Team-based, Patient-Centered, Coordinated Care

**GI  
Doctor**



**Psychiatrist**

**Nurses and  
Nurse  
Practitioner**

**Social  
Worker**

**Dietitian**

# Why? Anxiety and Depression



- Anxiety and depression is more common in patients with IBD compared to other diseases or the general population.<sup>1-6</sup>
- Anxiety symptoms in IBD patients associated with reduced medical adherence, increased risk of surgery, and lower quality of life.<sup>7-10</sup>
- Depressive symptoms in IBD patients associated with inflammation, pain, and poorer response to IBD treatment in most but not all studies.<sup>11-15</sup>

1. Burke et al., *JAACAP*, 1989; 2. Addolorato et al., *Scand J Gastro*, 1997; 3. Fuller-Thomson & Sulman, *Inflam Bow Dis*, 2006; 2015; 4. Reigada et al., *J Ped Gastro Nutr*, 2004; 5. Loftus et al., *Am J Gastro*, 2011 6. Kappelman et al., *Clin Gastro Hep*, 2013; 7. Graff et al., *Inflam Bow Dis*, 2009; 8. Gray et al., *J Pediatr Psychol*, 2012; 9. Greenley et al., *J Pediatr Psychol*, 2010; 10. Nahon et al., *Inflam Bow Dis*, 2012; 11. Mittermaier et al., *Psychosom Med*, 2004; 12. Persoons et al., *Alim Pharm Ther*, 2005; 13. Szigethy et al., *J Ped Gastro Nutr*, 2014; 14. Farrokhyar et al., *Inflam Bow Dis*, 2006; 15. Mickocka-Walus et al., *Inflam Bow Dis*, 2007, 2015.

# Cost of Untreated Depression



- Cost of major depressive disorder in US- \$210.5 billion in 2010<sup>1</sup>
- 38% of total costs attributed to depression itself<sup>1</sup>
- Physical and mental comorbidities account for largest portion of economic burden of depression<sup>1</sup>
- For every \$1 spent on major depression direct treatment cost, \$2.57 spent on direct costs of treating comorbidities<sup>1</sup>
- IBD patients with depression less likely to adhere to medical care plans<sup>2</sup>

1. Greenberg P. Scientific American Website. <http://blogs.scientificamerican.com/mind-guest-blog/the-growing-economic-burden-of-depression-in-the-u-s/e>. Published 2015. Accessed March 28, 2016.
2. Mikocka-Walus A, et al. *Clin Gastroenterol Hepatol*. 2016;25. pii: S1542-3565(16)00047-1.

# Why? Chronic Pain



- Chronic pain is common in IBD patients and can be present in the presence and absence of active IBD in both children and adults <sup>1-5</sup>
- Approximately 25% of IBD patients are on chronic opioid medications which have no evidence of efficacy and potential side effects including worsening pain, increased risk of infection, and death <sup>9-12</sup>

<sup>1</sup> Keohane et al., *Am J Gastro*, 2010; <sup>2</sup> Long & Drossman, *Am J Gastro*, 2010; <sup>3</sup> Halpin & Ford, *Am J Gastro*, 2012; <sup>4</sup> Farrokhar et al., *Inflam Bow Dis*, 2006; <sup>5</sup> Crandall et al., *J Ped Gastro Nutr*, 2007; <sup>9</sup> Hanson et al., *Inflam Bow Dis*, 2009; <sup>10</sup> Long et al., *Inflam Bow Dis*, 2012; <sup>11</sup> Buckley et al., *Clin Gastro Hep*, 2014; <sup>12</sup> Lichenstein et al., *Am J Gastro*, 2012; Edwards 2001; Cross 2005; Hanson 2009; Long 2011; Szigethy 2014



# Psychiatrist in IBD Medical Home



Treat whole person beyond inflammation  
and biologics



# Optimize Medical Team's Treatment Plan

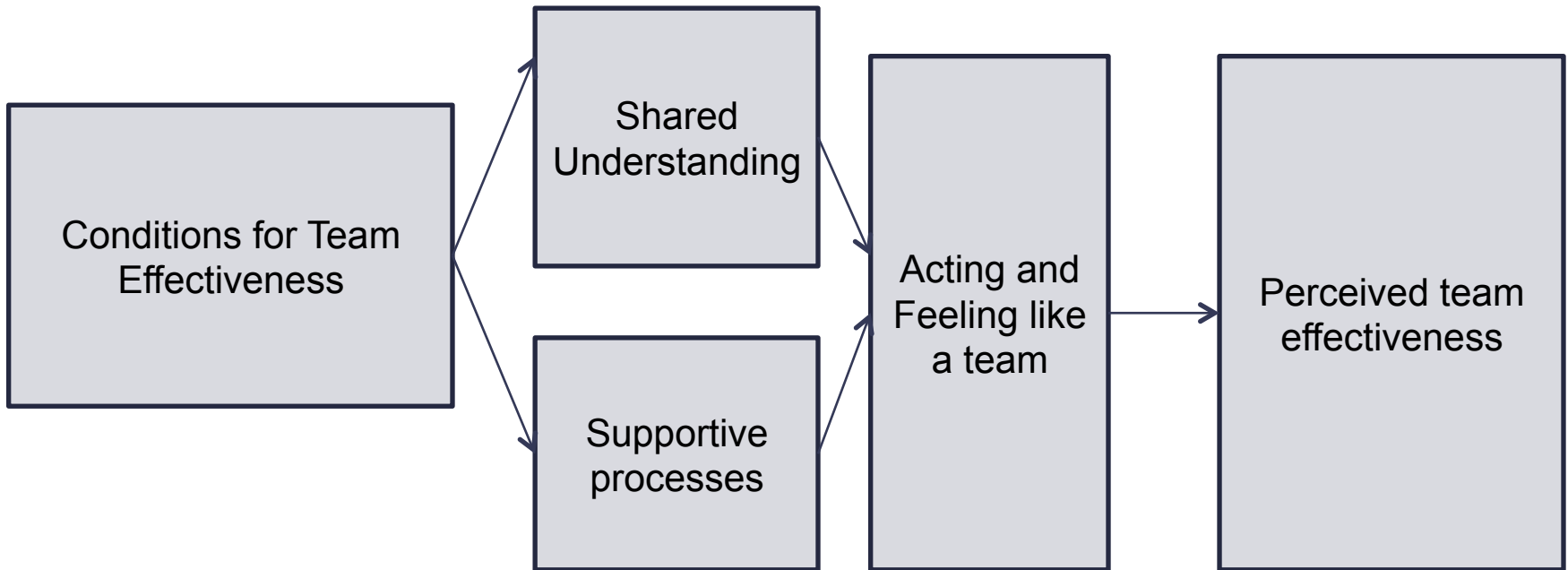


- Team cross-training- behavioral and medical
- Motivational interviewing training of staff
- Focus on team process

# Importance of Interprofessional Care Team



“Team-based care is key tenet to transforming primary care practices into primary care medical homes”



Song H, et al. Development and validation of the primary care team dynamics survey.<http://www.thefreelibrary.com/Development+and+validation+of+the+primary+care+team+dynamics+survey.-a0418089506>. Published June 1, 2015. Accessed April 2, 2016.

# Support Patient's Self-Efficacy in Disease Management



- Patient obstacles to disease self-management
  - Knowledge gaps
  - Poor adjustment
  - Anxiety
  - Skills deficits
  - Depression/low motivation
  - Stress/chaos

# Self-Management is a Skill



- Recognizing/responding to changes in disease
- Strengthening medical decision-making skill
- Optimizing relationships with care providers
- Using medications effectively
- Incorporating good nutrition and exercise
- Preparing for emergencies/unexpected events
- Managing stress/emotions NOT necessary to meet criteria for psychiatric disorder to benefit

# Self Management in IBD Patients

Problem	Skill Deficit	Self- Management Tool
Refusing to start a biologic	<ul style="list-style-type: none"> <li>• Limited knowledge</li> <li>• Denial about disease severity</li> <li>• Fear of needles/ injections</li> </ul>	<ul style="list-style-type: none"> <li>• Education by provider</li> <li>• Peer support specialists</li> <li>• Behavioral techniques</li> </ul>
Low insight into psychosocial factors affecting disease status	<ul style="list-style-type: none"> <li>• Stigma around mental health</li> </ul>	<ul style="list-style-type: none"> <li>• Education about brain-gut connection in IBD</li> </ul>
Poor pain control	<ul style="list-style-type: none"> <li>• Pain catastrophizing or amplification</li> </ul>	<ul style="list-style-type: none"> <li>• Relaxation skills</li> <li>• Distracting activities</li> </ul>
Avoid returning to work	<ul style="list-style-type: none"> <li>• Difficulty tolerating discomfort when not at home</li> </ul>	<ul style="list-style-type: none"> <li>• Relaxation</li> <li>• Distress tolerance skills</li> <li>• Foster acceptance</li> <li>• “Pacing”- exposure hierarchy</li> </ul>



# Address Comorbid Psychiatric Conditions



- Most cases of anxiety or depression can be treated successfully with psychosocial interventions such as cognitive behavioral therapy and mindfulness techniques<sup>1-5, 14,15</sup>
- Suicidal ideation and behavior is treatable if detected as part of psychosocial screening<sup>6,7</sup>
- Although no randomized trials exist in IBD patients, serotonin re-uptake inhibitors (SSRIs), tricyclic antidepressants (TCA) and serotonin-noradrenergic reuptake inhibitors (SNRIs) have the most support for reducing anxiety and depression used together with psychotherapy<sup>8-11</sup>
- Immunosuppressant therapy may also reduce depression<sup>12,13</sup>

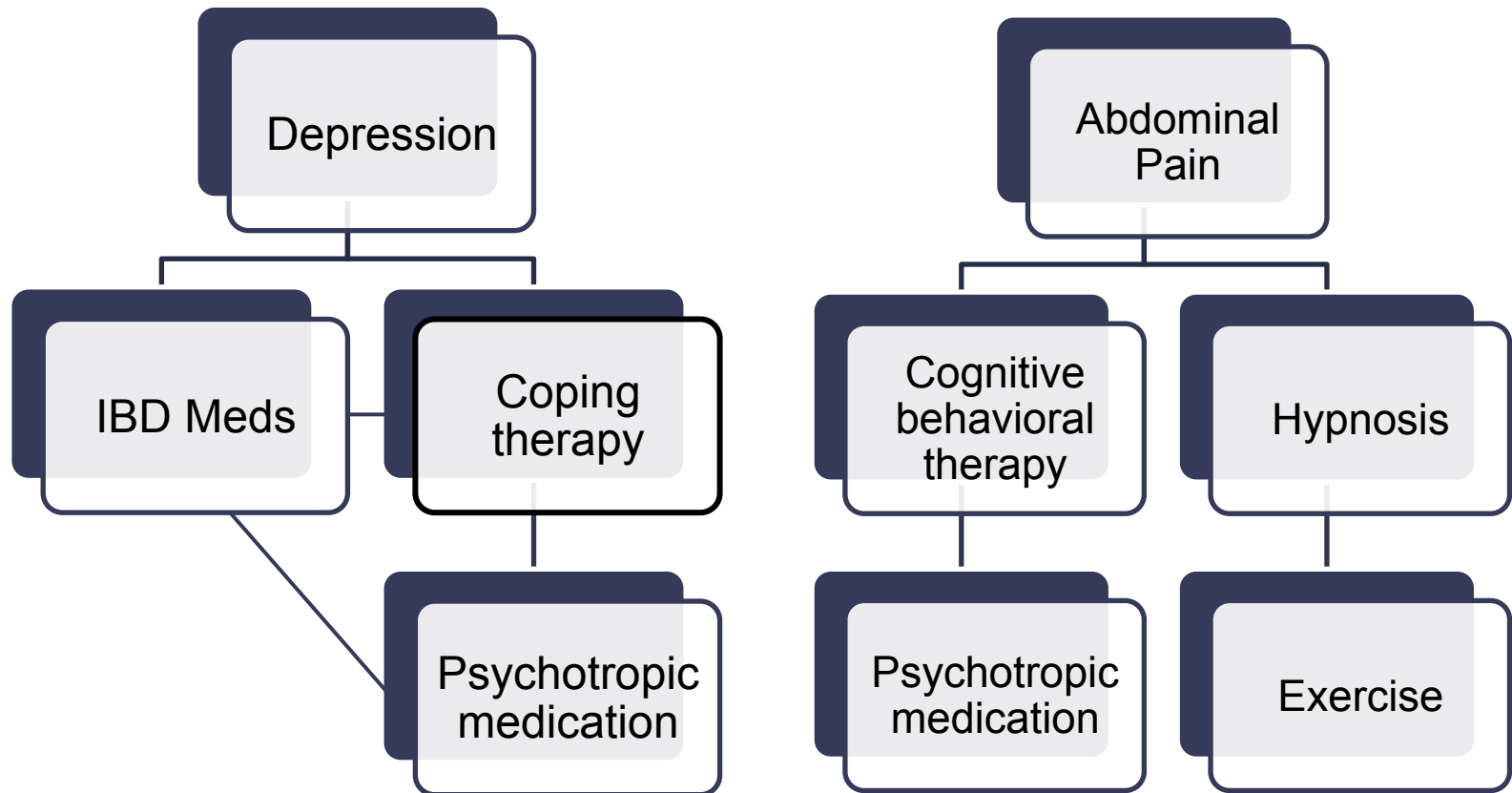
1 Knowles et al., *Inflam Bow Dis*, 2013; 2 McCombie et al., *J Crohns Colitis*, 2013; 3 Goodhand et al., *Expert Rev Gastro Hep*; 2009; 4 Szigethy et al., *Inflam Bow Dis*, 2015; 5 Szigethy et al., *JAACAP*, 2014; 6 Gradus et al., *Inflam Bow Dis*, 2010; 7 Mikocka-Walus et al., *J Psychosom Res*, 2012; 8 Goodhand et al., *Inflam Bow Dis*, 2012; 9 Rush et al., *NEJM*, 2006; 10 Kane et al., *Gastro*, 2003; 11 Iskandar et al., *J Clin Gastro*, 2014; 12 Horst et al., *Dig Dis Sci*, 2015; 13 Raison et al., *JAMA Psychiatry*, 2013; 14. Neilson, 2015; 15 McCombie, 2013.

# Manage Chronic Pain

- Psychosocial Treatment
  - Psychosocial interventions such as hypnosis, cognitive behavioral therapy and mindfulness techniques, have the most support for pain management.<sup>1-3</sup>
- Non-opioid pain medications<sup>4-6</sup>
  - TCAs and SNRIs have the most empirical support for treating abdominal pain.
  - Medications used for neuropathic pain such as mood stabilizers and glutaminergic agents have some support.
  - Treatment of chronic pain is a longer-term process and is best achieved with a strong doctor-patient relationship and an interdisciplinary team approach.<sup>7</sup>
  - Opioid detoxification recommended for chronic narcotic use for abdominal pain.<sup>8-10</sup>
  - Cost of prescription medications in US in 2013 for chronic pain was \$17.8 billion<sup>11</sup>

<sup>1</sup>Palsson & Whitehead, *Clin Gastro Hep*, 2013; <sup>2</sup>Henrich et al., *J Psychosom Res*, 2014; <sup>3</sup>Berrill, *J Crohns Colitis*, 2014; <sup>4</sup>Drossman, *Am J Gastro*, 2009; <sup>5</sup>Ford et al., *Am J Gastro*, 2014; <sup>6</sup>Srinath et al., *Inflam Bowel Dis*, 2014; <sup>7</sup>Drossman, *Am J Gastro*, 2013; <sup>8</sup>Kurlander & Drossman, *Nature Rev Gastro* <sup>11</sup>Rafia, 2014

# Personalized Psychosocial Management Pathways



Courtesy: Szigethy E.

# Value = Quality/Cost



## Improving quality

- High behavioral response rate to treatment
- Increased medical adherence
- Increased pain control and decreased narcotic use
- Increased quality of life and productivity

## Reducing costs

- Reduced unplanned care (ER visits and hospitalizations)
- Using behavioral therapy first then generic psychotropics and those on formulary
- Coordinated care more efficient and scalable



# Project Sonar

A Care Management  
Platform for Chronic  
Disease

# Cost of Care Analysis

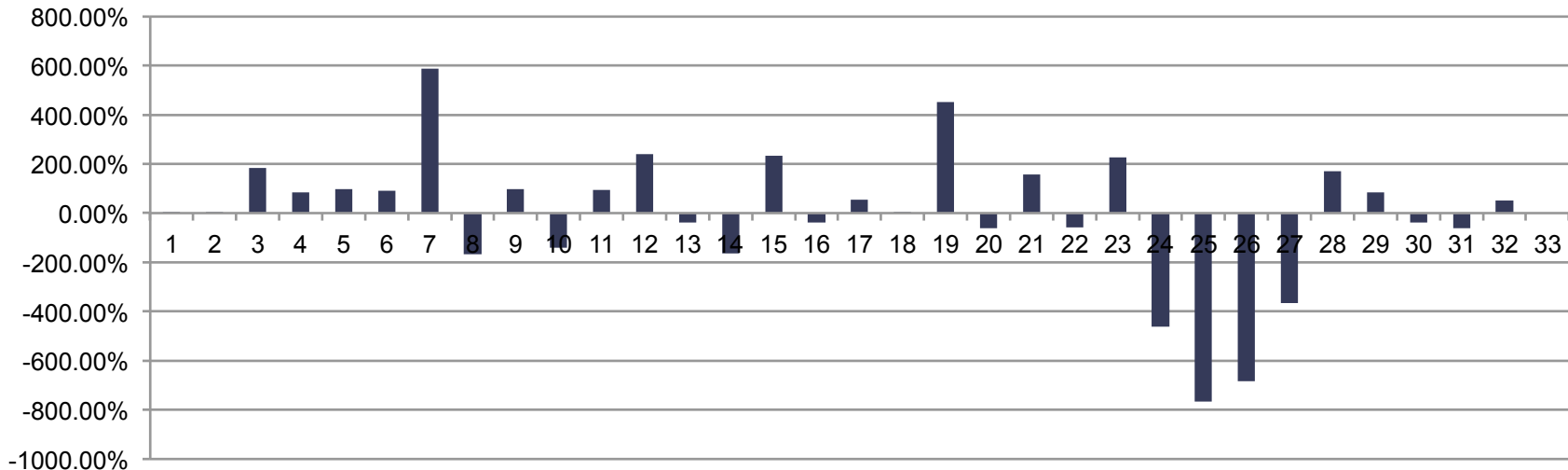
- Database of 21,000 patients
- Two years of experience
  - \$240M in annual expenses for Crohn's disease
  - \$11,000 per patient per year
- > 50% of all expenses paid are for hospital services
  - Likely to be primarily complication related
  - Fastest growth area of expense
- Biologics are 10% of total expenditures
- Gastroenterologists receive 10% of all professional payments and only 3.5% of total payments
  - But we manage the illness and complications
  - Is there an opportunity to improve care at the provider level?
  - A potential for a shared savings program

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.

[http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016



# Hospital Admissions



- Overall hospitalization rate = 17%
- Hospitalization rate for patients on a biologic = 12%
- Hospitalization rate for patients receiving office infusions of biologics <5%
- Less than 1/3 of admitted patients were seen by a physician in the 30 days prior to admission

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.

[http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016

# Project Sonar

- One of the first intensive medical homes (IMH) for a specialty group in US
  - Partnership between IGG and Blue Cross Blue Shield Illinois
  - Deployed for use in patients with CD
- Major components of an IMH
  - Team-based care of a population
    - Nurse care manager (NCM) team
    - Committed team of physicians
  - Guideline driven care model
    - AGA Crohn's Disease Care Pathway
    - Clinical Decision Support (CDS) Tools integrated into the IGG EMR
  - Patient engagement tools
    - Structured data “pings” to assess symptomatology using patient portal
    - Identify opportunities for early interventions
    - Reduce potentially avoidable ER, IP utilization
  - Powerful data analytics

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.

[http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016

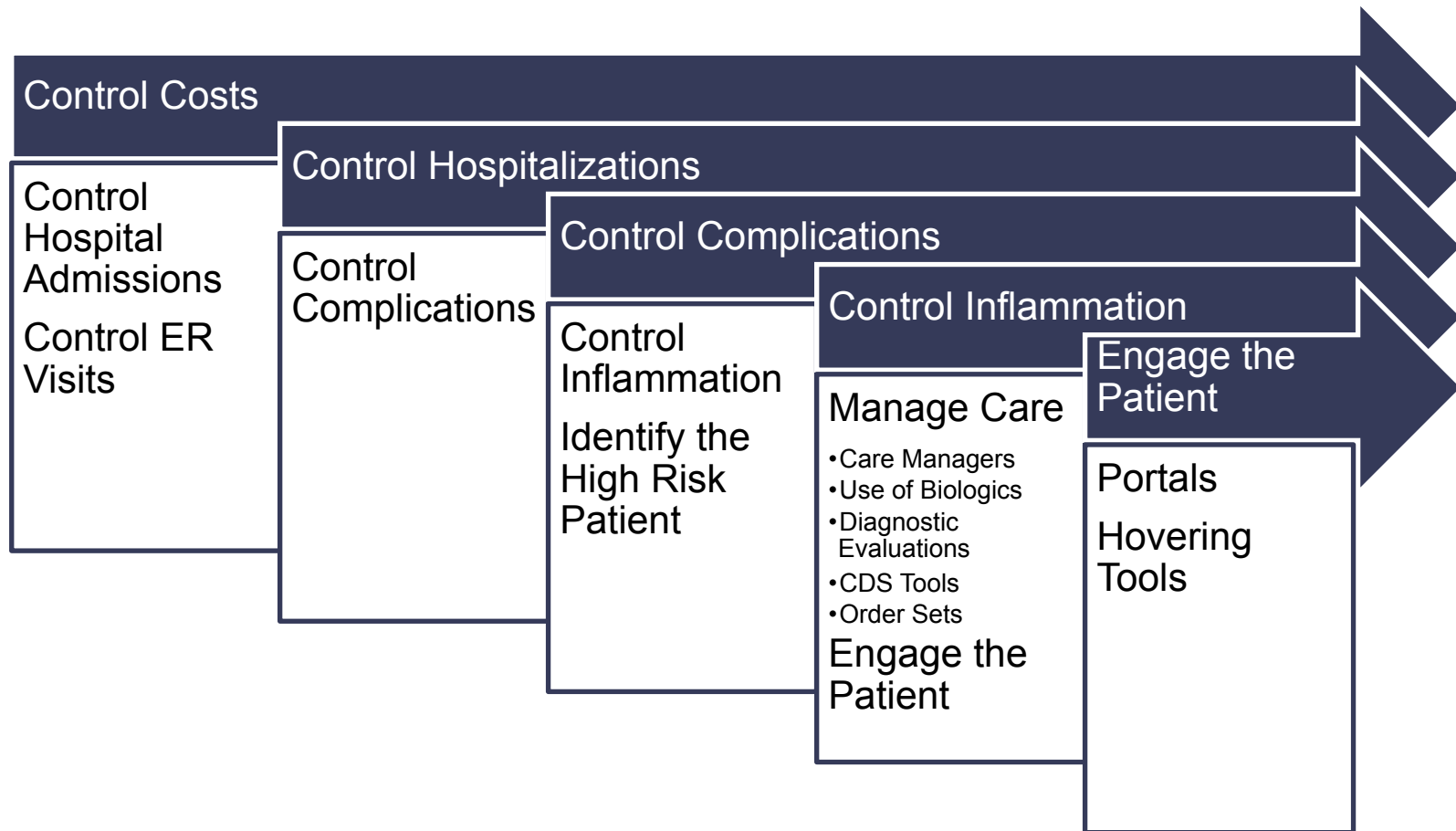
# BCBS IL IMH Business Model

- Super visit payment
- Supplemental payment PMPM to be used to establish clinical infrastructure – team-based care
  - Nurse care manager
  - Physician champion
- BCBS IL provides SonarMD Patient Engagement Platform
  - Provided at no cost to the medical practice
  - Limited implementation fee to be paid by medical practice
- Performance measurements
  - BCBS IL will add patients to your attributed list twice a year
  - Provider may add patients to the attributed list as appropriate

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.  
[http://sonarmd.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonarmd.com/files/7314/5497/1982/Sonar_Article.pdf).

Published Fall 2015. Accessed April 15, 2016

# AGA Crohn's Disease Care Pathways Project



Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.

[http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016

# Proprietary CDS Tools Tie it All Together

**IGG HPI CDS Crohns**

## Crohn's Disease CDS Tool

**Extent of Disease** PQRS

Small Intestine:  TI Only  Diffuse Since: 2004

Colon:  Pancolitis  Ileocolitis ICD

Other Locations

External Manifestations: PQRS

Under your care for at least one year  Yes  No PQRS

**Medications**

**Steroid Use** PQRS

Patient managed with corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days during this period  Yes  No

Steroid Sparing Drug in use: NM PQRS

Budesonide  Yes  No

**Immunomodulator Use**  None  Imuran/6MP  MTX PQRS

**Current Biologic Use** certolizumab Initiate PQRS

**Previous Biologic Use** Remicade (infliximab) PQRS

Reason for change: Infusion Reaction PQRS

Last AntiTNF Antibody Date: // Result

**Aminosalicylates/5-ASA**  No  Yes PQRS

**Immunizations and Other Tests**

Most Recent Year

Influenza PQRS 2015  Chest X Ray

Pneumovac PQRS  Quantiferon Gold 2014

HAV  PPD PQRS 2014

HBV PQRS  Dexascan PQRS

Results:

**Project Sonar Risk Assessments**

**Disease Burden** Assess Low

**Inflammation** Assess High

**Comorbidities** Assess High

**Date Assessed:** Today 01/17/2016

**Sonar Score:**

Date	Sonar Score
01/14/15	36.000
12/15/14	48.000
11/6/14	114.000

**Therapy Options**

Initial Therapy Therapy

Remission Therapy Therapy

Exacerbation Therapy Therapy

**Studies:**

Project Sonar

BCBS Project Sonar

Research

**IGG CD Dis Burden Risk**

**Disease Burden Risk Assessment**

	Low Risk	High Risk
Age at Diagnosis:	<input checked="" type="radio"/> Over 30	<input type="radio"/> Under 30
Anatomic Involvement:	<input checked="" type="radio"/> Limited	<input type="radio"/> Extensive
Perianal Disease:	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Severe Rectal Disease:	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Ulcers:	<input type="radio"/> Superficial	<input checked="" type="radio"/> Deep
Structuring:	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Penetrating Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes

Calculate Score 4 High

**IGG CD Infl Burden Risk**

**Inflammation Burden Risk Assessment**

**Symptoms**

Fever

Abdominal Pain

GI Bleeding

Localized Tenderness

Weight Loss

Joint Pains

Cutaneous Signs

**Lab Abnormalities**

Low Hb

Leucocytosis

Elevated CRP

Decreased Albumin

Elevated ESR

Elevated FCP

Calculate Score 3

**Comorbidity Burden Risk Assessment**

**Comorbidity**

Infections

Structuring/Renodding

Symptoms from Prior Surgery

Adverse Medical Reaction

Abdominal Access/Fistula

Perianal Access/Fistula

**Examples**

C DM, DMV

Abnormal Imaging, Obstructive Symptoms, Weight Loss

Bile Acid Diarrhea, Bacterial Overgrowth, Steatorrhea

Recent addition of new drug/drug holiday

Pain, Fistula, Drainage, Fever

Pain, Fistula, Drainage, Fever

Calculate Score 3

**Labs:**

Date	Albumin	CRP	Hemoglobin
05/30/14	7.000	0.700	14.000
04/14/14	3.500	2.000	12.000
03/17/14	3.500	2.000	12.000
04/23/14	3.500	2.000	12.000
04/10/14	3.500	2.000	12.000

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website. [http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016.



# Project Sonar

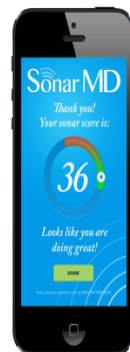
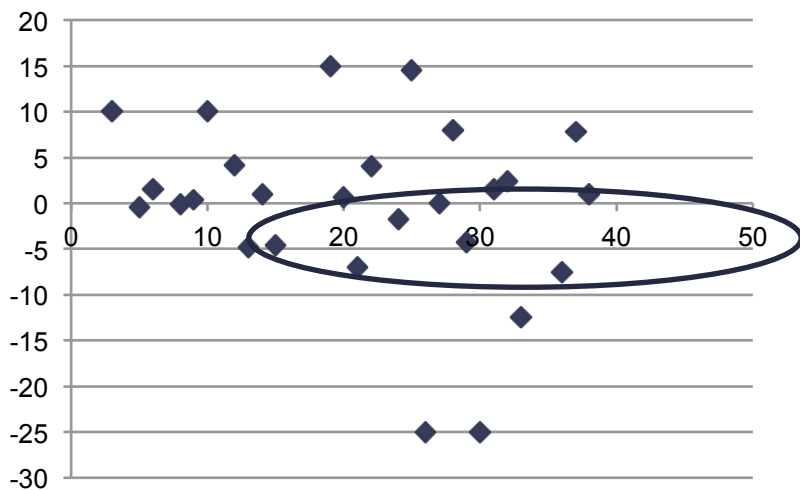
Patient Engagement  
and Hovering Tool



# Web-based Patient Engagement Tools



## Sonar Score Slope



Name	DOB	Sex	Last Ping	IMI	Stage	Score	Notes	History	Edit
Shawn White	03/01/1966 (26)	M	24/06/2015	✓	6.54	6.54			
Shawn White	03/01/1966 (26)	M	24/06/2015				Notes: MRI: 09/23/15-617 MRI: open disc at level, compressive soft tissue disc at level, narrow disc esp. video		
Shawn White	03/01/1966 (26)	M	24/06/2015		0.12	0.12			
Shawn White	03/01/1966 (26)	M	24/06/2015	✓	0.83	0.83			
Shawn White	03/01/1966 (26)	M	24/06/2015	✓	-9.22	-9.22			
Shawn White	03/01/1966 (26)	M	24/06/2015		2.26	2.26			
Shawn White	03/01/1966 (26)	M	24/06/2015		-3.58	-3.58			
Shawn White	03/01/1966 (26)	M	24/06/2015	✓	-4.00	-4.00			
Shawn White	03/01/1966 (26)	M	24/06/2015	✓	16.53	16.53			

$$CDAI = \text{Sum}((2S)+(5P)+(7G)+(20\text{Sum}(c) +(30D))$$

Algorithm for automated responses drives behavior

What patients tell you (subjective) is different from what really happens (objective)  
reporting Portal Response Rate 27% Application Response Rate 66%

# BCBS Intensive Medical Home Program Details



## Attribution Period

- The payer attributes your patients to you
- They will be your existing patients that are under this payer for at least 12 months

## Enrollment Period

- A Supervisit must be performed on each attributed patient during this period
  - This is a nurse visit coded with an “S-code” and billable
  - You can combine a provider E&M Visit at the same time
- Perform a risk assessment using the SonarMD Platform
- Establish a treatment plan based on the risk assessment using the AGA Crohn’s Disease Care Pathway

## Performance Period




- Each patient must be “touched” on a monthly basis – Sonar Pings qualify
- Hospitalizations must be closely monitored
- ER Visits must be tracked

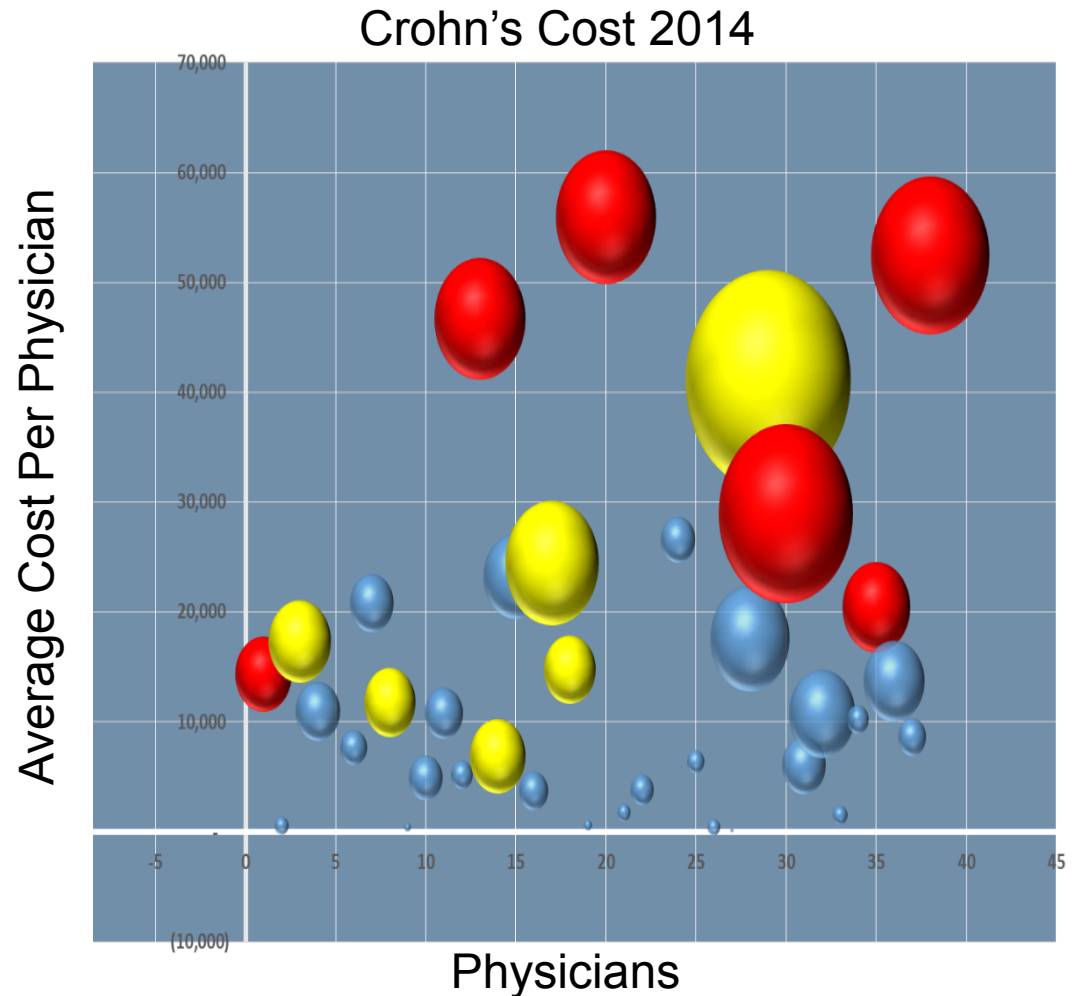
Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.

[http://sonarmd.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonarmd.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016

# Cost/Patient by Physician

## Legend of effects

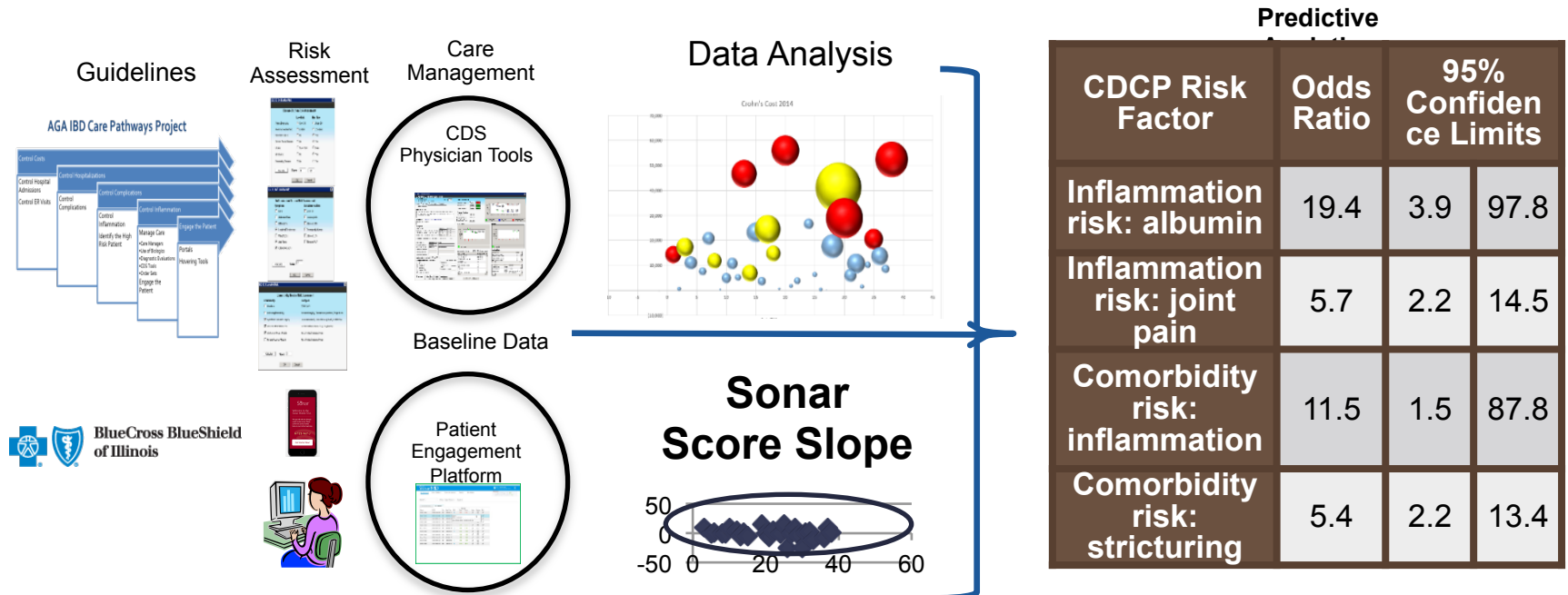
-  Hospitalization
-  HOPD Infusions
-  No specific driver



Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website.

[http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016.

# Putting it All Together



**Project Sonar Financial Summary - Claims from Dec 1, 2014 - Sept 30, 2015**

	Total Crohn's Payments	Average Per Patient Payment	Total Normalized Crohn's Payments	Normalization Difference	Inpatient Payments	Emergency Room Payments	Infusable Biologics	Injectable Biologics
Pre-Period	\$ 2,118,308.65	\$ 13,936.24	\$ 1,932,069.37	\$ (186,239.28)	\$ 210,967.47	\$ 52,363.19	\$ 892,443.30	\$ 560,980.84
Study Period	\$ 1,884,758.63	\$ 12,399.73	\$ 1,741,326.02	\$ (143,432.62)	\$ 90,410.85	\$ 24,465.00	\$ 972,485.87	\$ 423,561.72
Difference	\$ (233,550.02)	\$ (1,536.51)	\$ (190,743.36)	\$ 42,806.66	\$ (120,556.62)	\$ (27,898.19)	\$ 80,042.57	\$ (137,419.12)
Percentage Difference	-11.03%	-11.03%	-9.87%	-22.98%	-57.14%	-53.28%	8.97%	-24.50%

Kosinski L. Project Sonar: A Solution for Change. Project Sonar Website. [http://sonar.md.com/files/7314/5497/1982/Sonar\\_Article.pdf](http://sonar.md.com/files/7314/5497/1982/Sonar_Article.pdf). Published Fall 2015. Accessed April 15, 2016.

# Clinical Connections



- Project Sonar is a successful example of population health
  - Hospitalization rate cut by more than 50%
  - Cost of care decreased > 20% based upon lower utilization
  - Improved patient satisfaction
  - Generated more revenue for our practice
- Why were we successful?
  - Providers practicing according to guidelines
    - Using CDS Tools
    - Team-based care model
    - Appropriate use of risk assessments
  - We engage the patients
    - Every patient is proactively “touched” once a month
    - We intervene before they even realize that they are in need of care

# Audience Response



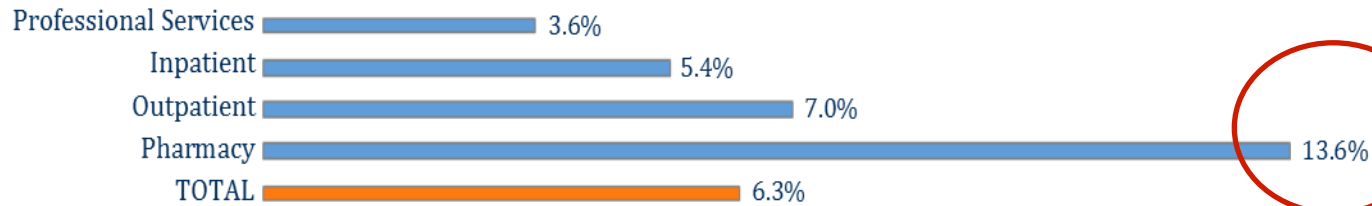
Which is an effective way to control costs in patients with IBD?

- A. Formulary and utilization management
- B. Collaboration with providers
- C. Target patients using data analytic strategies
- D. All of the above



# Pharmacy Costs Trending Higher

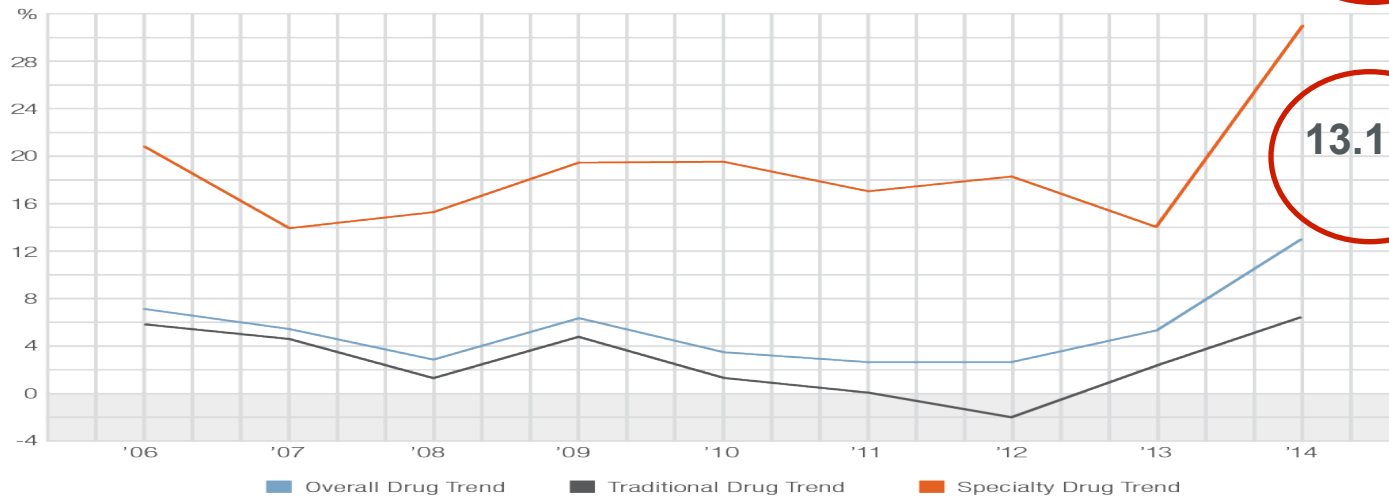
## MILLIMAN MEDICAL INDEX GROWTH RATE: 2014-2015



Source: 2015 Milliman Medical Index

## COMPONENTS OF OVERALL DRUG TREND

### EXPRESS SCRIPTS 2006-2014



Milliman, Inc. 2015 Milliman Medical Index: Will the typical American family for four be driving a "Cadillac plan" by 2018? Milliman Research Report, May 2015. Milliman, Inc., Denver, 2015.

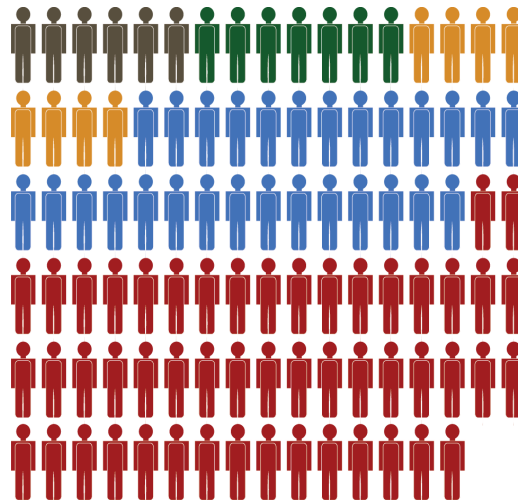
Express Scripts 2015 Drug Trend Report. Available at <http://lab.express-scripts.com/lab/drug-trend-report>. Accessed on April 1, 2016.

# Engaging All Stakeholders

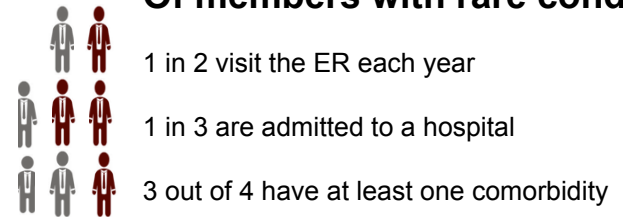
*Beyond Pharmacy – Impact on Total Cost of Care*



94% of UPMC Commercial members who are using a specialty drug for MS, IBD, Hep C, or HIV and are managing at least one comorbidity

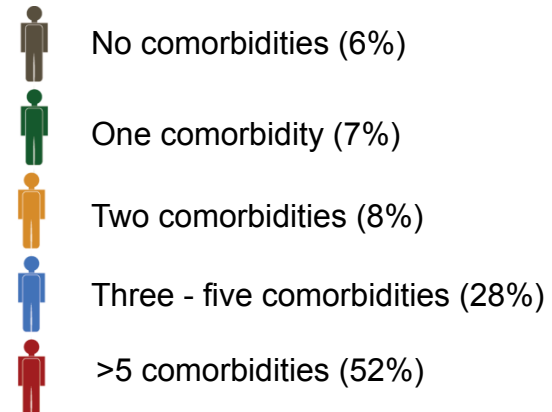


## Of members with rare conditions:



➤ **4.5x** as expensive as an average member

➤ **3x** as expensive as a common chronic member



1. Accordant Data Warehouse, all medical and pharmacy claims incurred through 12/31/12
2. UPMC Insurance Data Warehouse, all medical and pharmacy claims incurred in CY 2013

# Integrated Clinical Collaboration Model

‘The Secret Sauce’



## Enterprise-wide Clinical Collaboration

Pathway Development  
Efficient and Smarter  
Clinical Pharmacy  
Algorithms

New Models of Care  
Shared Savings Model  
Specialty Medical  
Homes

## Differentiating Clinical Framework

Unified System/Plan  
P&T Methodology

Enterprise-wide  
Clinical Consensus  
Efficient Care  
Transitions

## Facilitates Comprehensive Management of Complex Issues

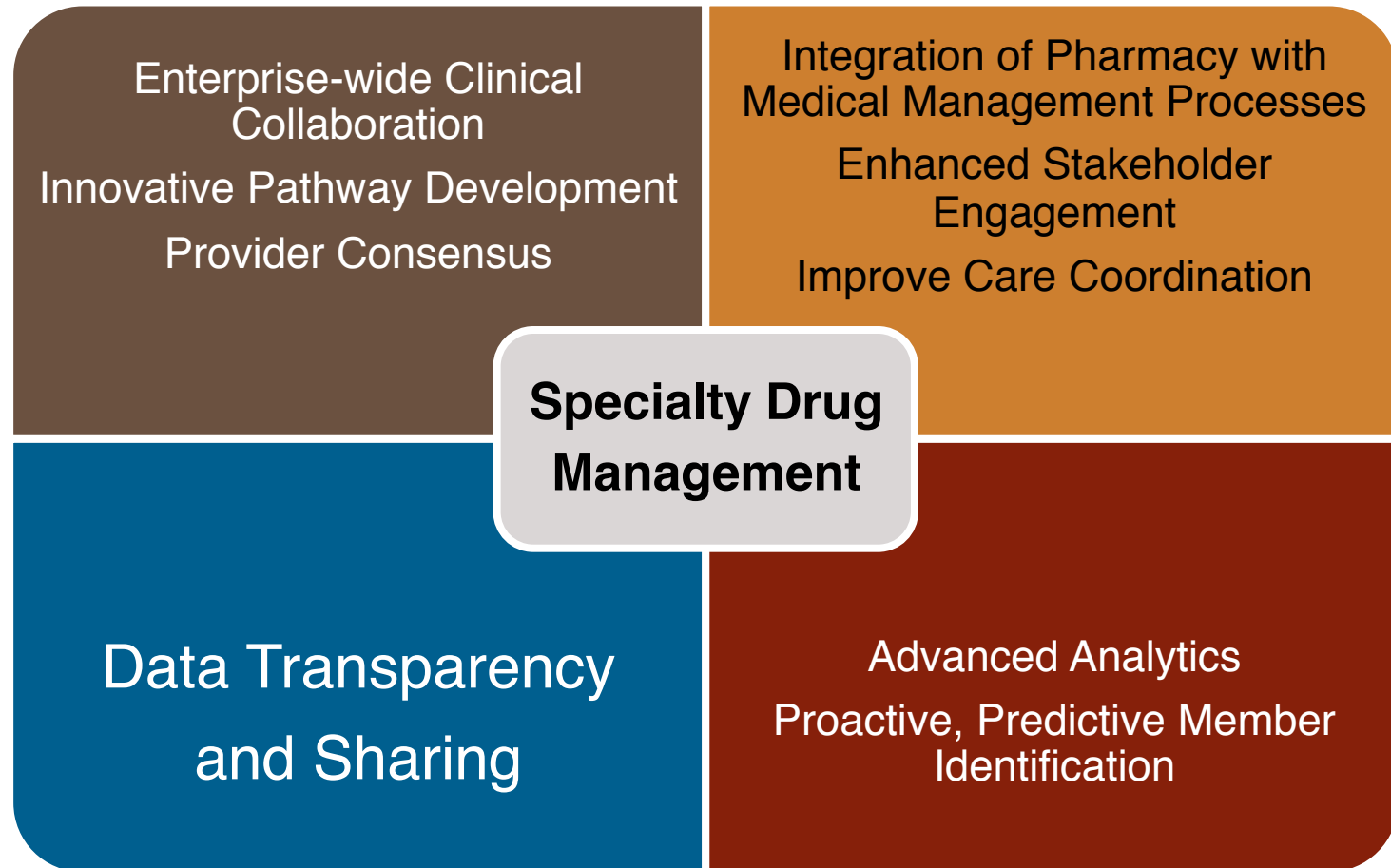
Drugs of Abuse  
Opioids  
Behavioral Health

Polypharmacy  
High Risk Drugs  
Specialty Drugs

Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.

# UPMC HP Specialty Pharmacy Management

*Multi-pronged and Comprehensive Support Infrastructure*

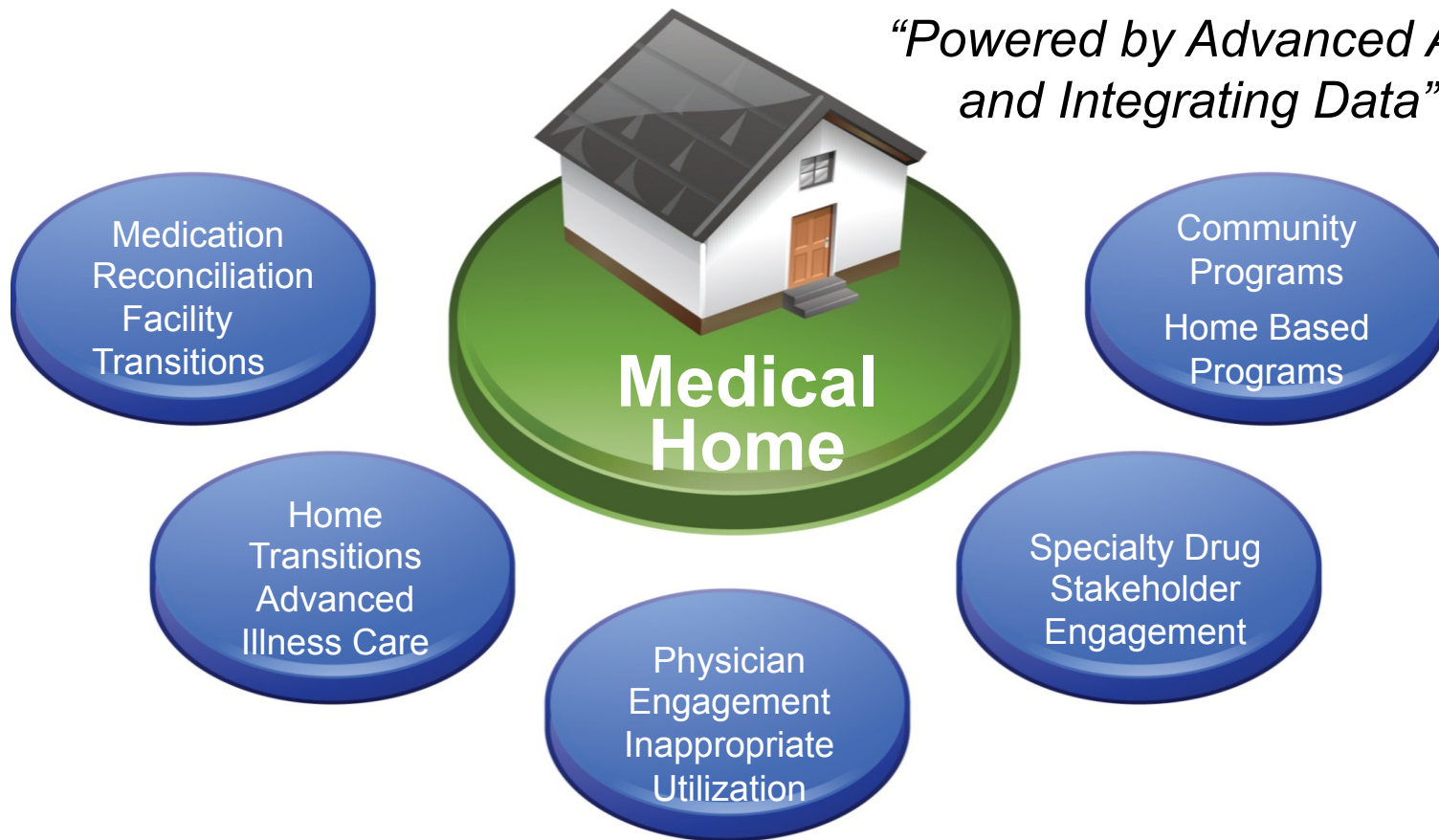


Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.

# Pharmacist Supported Medical Home

## *Integrating Pharmacists onto the Care Team*

*“Powered by Advanced Analytics  
and Integrating Data”*



Regueiro M., et al. *The IBD Journal*. The Inflammatory Bowel Disease Specialty Medical Home: A New Model of Patient-Centered Care. In press.



# Summary



# Clinical Connections



- Treatment strategies for disease progression should be not be based upon location, rather based on phenotypes and risk assessment
- The debate between top down versus bottom up treatment strategies must be combined with risk assessments
- The AGA's Crohn's Disease and Ulcerative Colitis Care Pathways provides:
  - Appropriate risk assessment strategy
  - Treatment pathways
  - Clinical Decision Tools
- Further study is needed to determine the relative values of the risk metrics in the pathways
- A coordinated, cross-functional strategy, such as an IBD Medical Home, may improve care and cut costs



**Sponsored by**

**CME**  
**Outfitters**   
CONTINUING MEDICAL EDUCATION