TV-105-110419-02

SYLLABUS AND COURSE GUIDE

Caring for Patients with IBD in an Evolving Treatment Landscape: Optimizing Outcomes and Minimizing Complications

A Free, 90-Minute CME/CNE/CPE/MIPS/ABIM MOC Live and On-Demand Activity

Premiere Date: Monday, November 4, 2019

6:00 PM - 7:30 PM ET (live)

Credit Expiration Date: Wednesday, November 4, 2020

On the Web: http://bit.ly/TV105

LIVE FACULTY: Jami Kinnucan, MD; Gil Y. Melmed, MD, MS

MODERATOR: David T. Rubin, MD, FACG, AGAF, FACP, FASGE

Take advantage of our LIVE Q&A segment during this webcast!

During the webcast **type a question in the box under the presentation**

Email your question or comment: **questions@cmeoutfitters.com**

All other questions: Call CME Outfitters at 877.CME.PROS

This continuing education activity is provided by

CME Outfitters

INFORMATION FOR PARTICIPANTS

Statement of Need

With the introduction of new treatments, treatment targets, and updated guidelines, the management of inflammatory bowel disease (IBD) is constantly evolving yet remains suboptimal. Despite being treated, many patients with IBD are not in remission or lose response to their current therapy over time. Personalized approaches are necessary, as they optimize response and integration of new drug classes, which are both important to the treatment paradigm.

Janus kinase (JAK) inhibitors are one of the new treatment options for patients with IBD, and many patients prefer them over infusions and/or injections, as they are administered orally. Being rapid-acting and effective, they, along with appropriate monitoring, can reduce the risk of common complications like anemia, which is frequently overlooked in patients with IBD.

This CME Outfitters webcast features a panel of expert faculty utilizing an interactive, animated 3-D model to enhance the discussion on the mechanism of action (MOA) of JAK inhibitors, the pathophysiology of IBD, and the development of anemia, to assist health care professionals (HCPs) in selecting the appropriate therapy for patients with IBD.

Learning Objectives

At the end of this CE activity, participants should be able to:

- Evaluate JAK inhibitors for IBD in terms of MOA, efficacy, and safety.
- Monitor patients with IBD for iron deficiency and anemia.
- Select treatment for patients with IBD, taking into account disease history, disease severity, and patient preference.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Evaluate JAK inhibitors for IBD in terms of MOA, efficacy, and safety.
- Explain how to monitor patients with IBD for iron deficiency and anemia.
- Identify treatments for patients with IBD, taking into account disease history, disease severity, and patient preference.

Target Audience

Gastroenterologists, gastroenterology fellows, nurse practitioners, physician assistants, nurses, and pharmacists

Financial Support

Supported by an educational grant from Pfizer Inc.

CREDIT INFORMATION

CME Credit (Physicians)

CME Outfitters, LLC, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. CME Outfitters, LLC, designates this live activity for a maximum of 1.5 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Note to Physician Assistants: AAPA accepts certificates of participation for educational activities certified for *AMA PRA Category 1 Credit™* from organizations accredited by the Accreditation Council for Continuing Medical Education.

CBRN Credit (Nurses)

Provider approved by the California Board of Registered Nursing, Provider Number CEP 15510, for 1.5 contact hours.

Note to Nurse Practitioners: Nurse practitioners can apply for *AMA PRA Category 1 Credit™* through the American Academy of Nurse Practitioners (AANP). AANP will accept *AMA PRA Category 1 Credit™* from organizations accredited by the Accreditation Council for Continuing Medical Education. Nurse practitioners can also apply for credit through their state boards.

CPE Credit (Pharmacists)

CME Outfitters, LLC, is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. 1.5 contact hours (0.15 CEUs)

Universal Activity Number:
Live: 0376-0000-19-059-L01-P; Enduring: 0376-0000-19-059-H01-P
Type: knowledge-based

ABIM/MOC Credit:

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Formats:

Live activity

Enduring Material

MIPS Improvement Activity:

This activity counts towards MIPS Improvement Activity requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

CREDIT REQUIREMENTS

Post-tests, credit request forms, and activity evaluations must be completed online (requires free account activation), and participants can print their certificate or statement of credit immediately (75% pass rate required). This website supports all browsers except Internet Explorer for Mac. For complete technical requirements and privacy policy, visit https://www.cmeoutfitters.com/privacy-and-confidentiality-policy.

There is no fee for participation in this activity. The estimated time for completion is 90 minutes. Questions? Please call **877.CME.PROS**.

FACULTY BIOS & DISCLOSURES

David T. Rubin, MD, FACG, AGAF, FACP, FASGE (Moderator)

Dr. Rubin is Chief of the Section of Gastroenterology, Hepatology & Nutrition and the Co-Director of the Digestive Diseases Center at The University of Chicago Medicine. Dr. Rubin earned a medical degree with honors at The University of Chicago Pritzker School of Medicine. He completed his residency in internal medicine and fellowships in gastroenterology and clinical medical ethics at the University of Chicago, where he served as Chief Resident and Chief Fellow. Prior to his current appointments, Dr. Rubin served for 11 years as Director of the Gastroenterology, Hepatology and Nutrition fellowship program. He also currently serves as an associate faculty member at the MacLean Center for Clinical Medical Ethics and an associate investigator at the University of Chicago Comprehensive Cancer Center.

Dr. Rubin is a Fellow of the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), the American Society for Gastrointestinal Endoscopy (ASGE), and the American College of Physicians (ACP) as well as an active national member of the Crohn's & Colitis Foundation (CCF) and is on the Board of Trustees for the ACG. Among numerous awards and honors, Dr. Rubin was chosen by his peers as a member of Best Doctors (recognized for superior clinical ability) and America's Top Physicians (gastroenterology). Additionally, he twice received the ACG's Governor's Award of Excellence in Clinical Research (2003 and 2013), the Cancer Research Foundation Young Investigator's Award (2004), and the UC Postgraduate Teaching Award in recognition of significant contributions for fellowship education (2006). In 2012, he received the CCF Rosenthal Award, a national leadership award bestowed upon a volunteer who has contributed in an indisputable way to the quality of life of patients and families. He is currently the Chair-Elect of the National Scientific Advisory Committee of the CCF. He is an Associate Editor of the journal *Gastroenterology* and Co-Editor of the ACG On-Line Educational Universe.

Dr. Rubin is the editor of a best-selling book on inflammatory bowel disease (IBD), now in its 3rd edition, and an author or coauthor of many peer-reviewed articles on treatment and management of IBD as well as cancer in IBD and novel paradigms. He is also first author of the in-progress ACG Guidelines for ulcerative colitis. His current research is in the area of progressive complications from uncontrolled inflammation, the doctor-patient relationship in IBD, and a variety of collaborative studies related to the microbiome and intestinal disease. He is also a featured media contact for issues related to IBD (satellite radio, television, and print media) and maintains a popular twitter feed @IBDMD (> 6,000 followers). His principal research interests include novel IBD therapies and outcomes, colon cancer prevention, and clinical medical ethics.

Jami Kinnucan, MD

Dr. Kinnucan is an Assistant Professor of Medicine at Michigan Medicine, University of Michigan. She is an inflammatory bowel disease specialist with a focus on professional and patient education. She is the Assistant Program Director for the Gastroenterology and Hepatology Fellowship Program and Program Director for the Advanced Inflammatory Bowel Disease Fellowship Program. She currently serves as the Patient Education Chair for the Crohn's and Colitis Foundation's National Scientific Advisory Committee.

Gil Y. Melmed, MD, MS

Dr. Melmed is the Co-Director of the Inflammatory Bowel Disease Center at Cedars-Sinai Medical Center in Los Angeles, California. He earned his medical degree from Albert Einstein College of Medicine in the Bronx, New York, and master of science in clinical research from UCLA School of Medicine, Los Angeles. Dr. Melmed completed his gastroenterology fellowship at the University of California, Los Angeles.

He has authored or coauthored more than 130 articles in peer-reviewed journals and several book chapters. Dr. Melmed is an Associate Editor of the *American Journal of Gastroenterology*, an ad hoc reviewer for several journals, and previously a clinical research editor for *Inflammatory Bowel Disease*. His research interests include clinical outcomes and quality of care in IBD. He has given more than 100 invited lectures and presentations nationally and internationally. He is a committee member of several professional organizations, including the American College of Gastroenterology and the Crohn's and Colitis Foundation, where he serves as co-chair of the IBD Quality of Care committee. Dr. Melmed has led or participated in the development of quality measures for IBD with the American Gastroenterology Association, the Crohn's and Colitis Foundation, and the Canadian Crohn's and Colitis organizations.

Disclosure of Relevant Financial Relationships with Commercial Interests

It is the policy of CME Outfitters, LLC, to ensure independence, balance, objectivity, and scientific rigor and integrity in all of their CE activities. Faculty must disclose to the participants any relationships with commercial companies whose products or devices may be mentioned in faculty presentations, or with the commercial supporter of this CE activity. CME Outfitters, LLC, has evaluated, identified, and attempted to resolve any potential conflicts of interest through a rigorous content validation procedure, use of evidence-based data/research, and a multidisciplinary peer review process. The following information is for participant information only. It is not assumed that these relationships will have a negative impact on the presentations.

Dr. Rubin reports that he receives grants from AbbVie Inc.; Genentech, Inc./Roche; Janssen Pharmaceuticals, Inc.; Prometheus Laboratories Inc.; Shire; and Takeda Pharmaceuticals U.S.A., Inc. He is a consultant for AbbVie Inc.; AbGenomics; Allergan; Arena Pharmaceuticals, Inc.; Biomica; Bristol-Myers Squibb Company; Dizal Pharmaceutical; Eli Lilly and Company; Ferring Pharmaceuticals Inc.; Genentech, Inc./Roche; Janssen Pharmaceuticals, Inc.; Medtronic; Merck & Co., Inc.; Napo Pharmaceuticals, Inc.; Pfizer Inc.; Shire; Takeda Pharmaceuticals U.S.A., Inc.; and TARGET PharmaSolutions, Inc. He is a member of the Board of Trustees for the American College of Gastroenterology; is Co-Founder, CFO of Cornerstones Health, Inc. (non-profit); and is Co-Founder of GoDuRn, LLC.

Dr. Kinnucan reports that she serves on the advisory committee for AbbVie Inc.; Genentech, Inc.; Janssen Pharmaceuticals, Inc.; and Pfizer Inc.

Dr. Melmed reports that he receives grants and research support from Pfizer Inc. He is a consultant for AbbVie Inc.; Celgene Corporation; Janssen Pharmaceuticals, Inc.; Medtronic; Pfizer Inc.; Samsung Bioepis; and Takeda Pharmaceuticals U.S.A., Inc.

Tony Graham, MD (peer reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Olga Askinazi, PhD (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

Disclosures were obtained from the CME Outfitters, LLC staff: No disclosures to report.

Unlabeled Use Disclosure

Faculty of this CE activity may include discussions of products or devices that are not currently labeled for use by the FDA. The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational uses (any uses not approved by the FDA) of products or devices.

Activity Slides

The slides that are presented in this activity will be available to download and print out at the CME Outfitters website: **www.cmeoutfitters.com**. Activity slides may also be obtained via fax or email by calling **877.CME.PROS**.

CME Outfitters
CONTINUING MEDICAL EDUCATION

Caring for Patients with IBD in an Evolving Treatment Landscape: Optimizing Outcomes and Minimizing Complications

Monday, November 4, 2019

CME Outfitters, LLC, is the accredited provider for this continuing education activity.

CME Outfitters, LLC, gratefully acknowledges educational grants from Pfizer Inc. in support of this CME/CE activity.

The course guide for this activity includes slides, disclosures of faculty financial relationships, and biographical profiles.

View and/or print the course guide from the *Resources* tab on the top right of your window.

To receive CME/CE credits for this activity, participants must complete the post-test and evaluation online.

Go to the *Credit Tab* at the top of the video box and click on the link to complete the process and print your certificate.

Please be sure to indicate the media format utilized and the date of participation when completing the online evaluation.

The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational uses (any use not approved by the FDA) of products or devices.

CME Outfitters
CONTINUING MEDICAL EDUCATION

David T. Rubin, MD, FACG, AGAF, FACP, FASGE

Joseph B. Kirsner Professor of Medicine
Section Chief,
Gastroenterology, Hepatology and Nutrition
Co-Director, Digestive Diseases Center
University of Chicago Medicine
Chicago, IL

David T. Rubin, MD, FACG, AGAF, FACP, FASGE
Disclosures

- ***Research Support:*** AbbVie Inc.; Genentech, Inc./Roche; Janssen Pharmaceuticals, Inc.; Prometheus Laboratories Inc.; Shire; Takeda Pharmaceuticals U.S.A., Inc.
- ***Consultant:*** AbbVie Inc.; AbGenomics; Allergan; Arena Pharmaceuticals, Inc.; Biomica; Bristol-Myers Squibb Company; Dizal Pharmaceutical; Eli Lilly and Company; Ferring Pharmaceuticals Inc.; Genentech, Inc./Roche; Janssen Pharmaceuticals, Inc.; Medtronic; Merck & Co., Inc.; Napo Pharmaceuticals, Inc.; Pfizer Inc.; Shire; Takeda Pharmaceuticals U.S.A., Inc.; TARGET PharmaSolutions, Inc.
- ***Other Financial or Material Support:*** Board of Trustees for the American College of Gastroenterology; Co-Founder, CFO of Cornerstones Health, Inc. (non-profit); Co-Founder of GoDuRn, LLC

CME Outfitters
CONTINUING MEDICAL EDUCATION

Assistant Professor of Medicine
Assistant Program Director, Gastroenterology Fellowship
Program Director, IBD Fellowship Education
Division of Gastroenterology and Hepatology
Department of Internal Medicine
Michigan Medicine, University of Michigan
Ann Arbor, MI

Jami Kinnucan, MD
Disclosures

- ***Advisory Committee:***
  AbbVie Inc.; Genentech, Inc; Janssen Pharmaceuticals, Inc.; Pfizer Inc.

CME Outfitters
CONTINUING MEDICAL EDUCATION

Gil Y. Melmed, MD, MS

Co-Director, Clinical Inflammatory Bowel Disease
Division of Gastroenterology/Department of Medicine
Cedars-Sinai Medical Center
Los Angeles, CA

Professor of Medicine
David Geffen School of Medicine at UCLA
Los Angeles, CA

Gil Y. Melmed, MD, MS

Disclosures

- ***Research Support:*** Pfizer Inc.
- ***Consultant:*** AbbVie Inc.; Celgene Corporation; Janssen Pharmaceuticals, Inc.; Medtronic; Pfizer Inc.; Samsung Bioepis; Takeda Pharmaceuticals U.S.A., Inc.

CME for MIPS Improvement Activity

How to Claim this Activity as a CME for MIPS Improvement Activity

- Actively participate by responding to ARS and/or asking the faculty questions
- Complete activity posttest and evaluation at the link provided
- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation.
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity.

Claim ABIM MOC Credit

3 Things to Do

1. Actively participate in the meeting by **responding to ARS** and/or **asking the faculty questions**
   (It's ok if you miss answering a question or get them wrong, you can still claim MOC)
2. Complete your post-test and evaluation at the conclusion of the webcast
3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so we can submit your credit to ABIM.

ABIM CME MOC ACCREDITED

CME Outfitters
CONTINUING MEDICAL EDUCATION

Caring for Patients with IBD in an Evolving Treatment Landscape: Optimizing Outcomes and Minimizing Complications

Monday, November 4, 2019

CME Outfitters
CONTINUING MEDICAL EDUCATION

Learning Objective 1

Evaluate Janus kinase (JAK) inhibitors for inflammatory bowel disease (IBD) in terms of mechanism of action, efficacy, and safety.

Treatment Options for Moderate-to-Severe IBD

Treatment	Induction	Maintenance	Dosing Comments	Treatment Considerations
Steroids	CD, UC	X	Prednisone 40 mg PO QD	Advise against prolonged tapering
Thiopurines	X	CD, UC	Thiopurine methyltransferase (TPMT) first (possibly NUDT15 too)	Also as concomitant therapy to prevent immunogenicity
Methotrexate	CD	CD	25 mg subcutaneously (SC) for primary therapy with folic acid 1 mg QD	Also as concomitant therapy to prevent immunogenicity
Anti-integrin (natalizumab [NAT], vedolizumab [VED])	NAT: CD VED: CD, UC	NAT: CD VED: CD, UC	NAT: no loading dose VED: 0, 2, 6 weeks then every 8 weeks IV	NAT requires John Cunningham virus (JCV) antibody monitoring
Anti-p40 (ustekinumab)	CD, UC	CD, UC	Weight-based IV load, then 90 mg SC every 8 weeks	
Anti-TNF (adalimumab, certolizumab pegol, golimumab, infliximab)	CD, UC	CD, UC	Variable based on drug, best evidence for therapeutic drug monitoring	
JAK inhibitor (tofacitinib)	UC	UC	Induction: 10 mg BID Maintenance: 10 mg BID, 5 mg BID	Fail TNF inhibitor first (required)

BID = twice a day; CD = Crohn's disease; IV = intravenous; NUDT15 = Nudix hydrolase 5; PO = orally; QD = once a day; TNF = tumor necrosis factor; UC = ulcerative colitis.
Rubin DT, et al. *Am J Gastroenterol.* 2019;114(3):384-413. Dassopoulos T, et al. *Gastroenterology.* 2015;149(1):238-245. Feuerstein JD, et al. *Gastroenterology.* 2017;153(3):827-834.

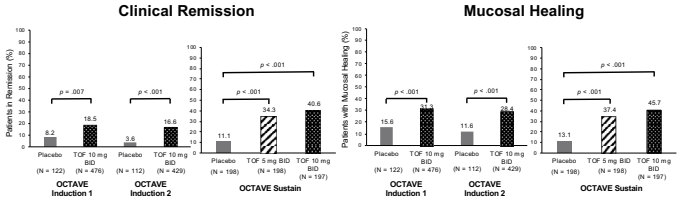
JAK Inhibitors vs. Biologics

- Work intracellularly
- Synthetic drugs, not proteins
- Taken orally
- Not immunogenic
- Stable and predictable pharmacokinetics

Available and Emerging JAK Inhibitors

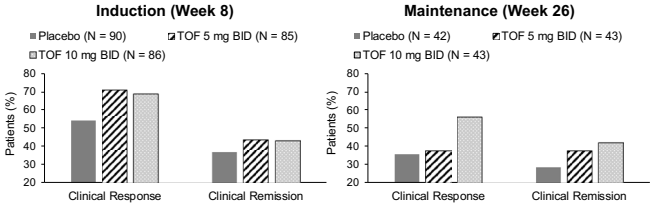
Therapy	Target	Status
Tofacitinib	JAK1-3	UC: **Approved**
		CD: Phase III
Upadacitinib	JAK1	Phase III (both UC and CD)
Filgotinib	JAK1	Phase III (both UC and CD)
TD-1473	JAK1-3	UC: Phase IIb/III
		CD: Phase II
BMS-986165	TYK-2	Phase II (both UC and CD)

Tofacitinib for UC Induction and Maintenance (OCTAVE and OCTAVE Sustain)



Clinical remission: total Mayo score of ≤ 2, with no subscore > 1 and a rectal bleeding subscore of 0.
Mucosal healing: Mayo endoscopic subscore of ≤ 1.
TOF = tofacitinib.
Sandborn W, et al. *N Engl J Med*. 2017;376(18):1723-1736.

Tofacitinib* for CD Induction and Maintenance (Phase IIb)



*Not approved by the FDA for the treatment of Crohn's disease.
Clinical Response: Crohn's disease activity index (CDAI) decrease from baseline ≥ 100 points.
Clinical Remission: CDAI < 150 points.
Panés J, et al. *Gut*. 2017;66(6):1049-1059.

Tofacitinib: Pulmonary Embolism and Mortality Interim Report

- **Phase IV rheumatoid arthritis (RA) study[1]**
  - Patients age ≥ 50 with ≥ 1 cardiovascular risk factors
  - Only at 10 mg BID
  - Not seen in any phase II or phase III RA trials[2]
- **UC post-hoc study[3]** (phase II, III, open-label extension)
  - Out of 1,157 patients, 1 had deep vein thrombosis, 4 had pulmonary embolism
  - Only at 10 mg BID in open-label extension study
  - All had venous thromboembolism (VTE) risk factors
- **Label change; tofacitinib after anti-TNF[4]**

FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR)
FDA Drug Safety Communication

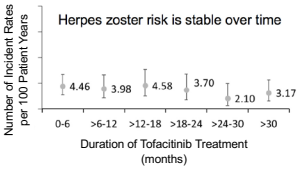
1. U.S. Food and Drug Administration (FDA). 2019. https://www.fda.gov/news-events/fda-brief/fda-brief-fda-responds-safety-signal-reported-required-postmarketing-trial-xeljanz. 2. Mease PJ, et al. *Arthritis Rheumatol*. 2017;69(Suppl 10). 3. Sandborn WJ, et al. *Aliment Pharmacol Ther*. 2019;50(10):1068-1076. 4. FDA. https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and.

Management of Patients on Tofacitinib

- ✓ Screen for VTE risk
- ✓ Pre-initiation and routine lab monitoring

Lab	At Initiation	4-8 Weeks	Every 3 Months
Lymphocytes			
Neutrophils			
Hemoglobin			
Lipids			
Liver enzymes			

- ✓ Vaccinate for Herpes Zoster (use attenuated vaccine)



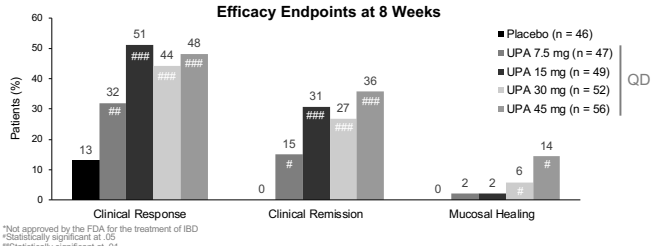
Sandborn W, et al. *N Engl J Med*. 2017;376(18):1723-1736. Winthrop KL, et al. American College of Rheumatology; 2015. Abstract 2050. Pfizer, Inc. Highlights of prescribing information for XELJANZ® (tofacitinib) tablets. Drugs@FDA Website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/203214s018lbl.pdf. Accessed November 1, 2019.

Tofacitinib Summary

- Induction
  - 10 mg PO BID for 8 weeks
- Maintenance
  - 5-10 mg BID
  - Use lowest effective dose
- Risk: herpes zoster and VTE (seen in RA)
- Positioning: after TNF failure

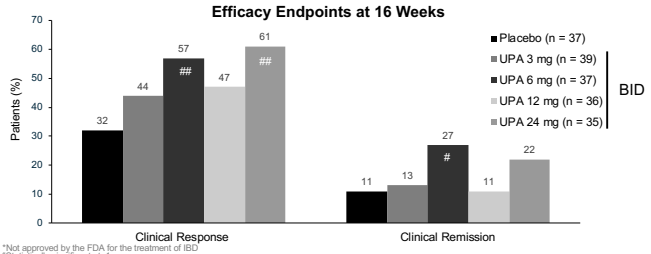
Rubin DT, et al. *Am J Gastroenterol.* 2019;114(3):384-413.

Upadacitinib* for UC Induction (U-ACHIEVE Phase IIb)



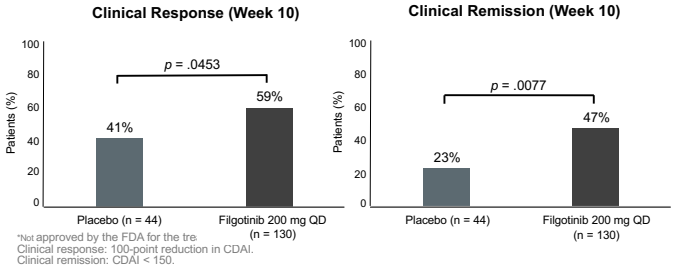
*Not approved by the FDA for the treatment of IBD
*Statistically significant at .05
**Statistically significant at .01
***Statistically significant at .001
QD = once daily; UPA = upadacitinib.
Clinical response: Mayo score decrease from baseline ≥ 2 points and ≥ 30%, plus rectal bleeding subscore (RBS) decrease ≥ 1 or absolute RBS ≤ 1.
Clinical remission: Stool frequency subscore ≤ 1, RBS = 0, endoscopic score ≤ 1. Mucosal healing: endoscopic subscore of 0 and Geboes score < 2.
Panaccione R, et al. *Gastroenterology.* 2019;156(6):S-170. Sandborn WJ, et al. *Gastroenterology.* 2019;156(6):S-170-S-171.

Upadacitinib* for Patients with CD Who Failed ≥ 2 Biologics (CELEST Phase II)



*Not approved by the FDA for the treatment of IBD
*Statistically significant at .1
**Statistically significant at .05
Clinical response: ≥ 30% reduction from baseline in abdominal pain (AP) or stool frequency, with neither worse than baseline.
Clinical remission: SF ≤1.5 and AP ≤1, and both not worse than baseline.
Sandborn WJ, et al. *Gastroenterology.* 2017;152(5)Suppl 1:S1308-S1309.

Filgotinib* for CD (FITZROY Phase II)



*Not approved by the FDA for the tre
Clinical response: 100-point reduction in CDAI.
Clinical remission: CDAI < 150.
Vermeire S, et al. *Lancet.* 2017;389:266-275.

JAK Inhibitors: Key Takeaways

- Tofacitinib is approved for the treatment of UC and is being investigated for the treatment of CD
- Treatments with selectivity for JAK1 are being investigated in phase III studies for CD and UC (e.g., filgotinib, upadacitinib)
- As with all therapies, balance safety and efficacy when prescribing tofacitinib and monitor disease and drug effects regularly

CME Outfitters
CONTINUING MEDICAL EDUCATION

Learning Objective 2

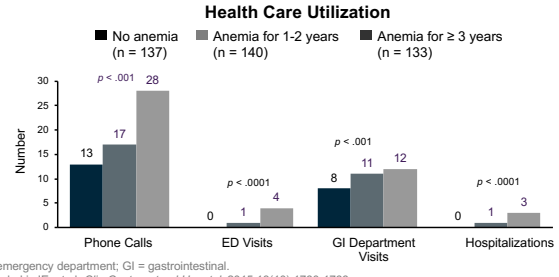
Monitor patients with IBD for iron deficiency and anemia.

What Do Patients Say?

Are you aware of symptoms and the risk for anemia?

"My primary care doctor and I have talked a little bit about anemia. And he does do a check of my iron levels every 3 months. And they have diagnosed me with anemia at a few points. And so I was under the impression that the anemia could come and go, because I don't always have a problem with my iron levels. And I'm not aware of all of the risks of anemia. So maybe that's something that I should look into that I haven't."

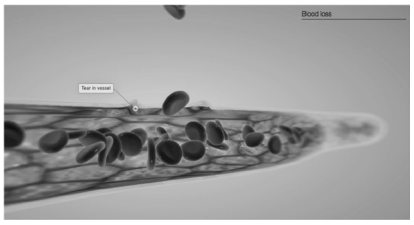
Anemia and Health Care Utilization



ED = emergency department; GI = gastrointestinal.
Koutroubakis IE, et al. *Clin Gastroenterol Hepatol.* 2015;13(10):1760-1766.

Burden of Anemia in IBD

- 16% of outpatients and 68% of hospitalized patients are diagnosed with anemia
- Occurs more frequently in CD than in UC
- Frequently overlooked in patients with IBD



Guagnozzi D, Lucendo AJ. *World J Gastroenterol.* 2014;20(13):3542-3551.

Iron Deficiency in IBD

IRON DEFICIENCY

Absolute

- Low dietary intake
- Blood loss from intestinal mucosa (most common in UC)
- Reduced iron absorption (most common in CD)

Functional

- Despite abundance in the body, iron is not available for erythropoiesis
- Caused by inflammation in IBD

Guagnozzi D, Lucendo AJ. *World J Gastroenterol.* 2014;20(13):3542-3551.

Laboratory Markers of Anemia in IBD

Biomarkers	IDA	ACD	Mixed Anemia
Ferritin (ng/mL)	< 30	> 100	30-100
Transferrin saturation (%)	< 20	< 20	< 20
Ferritin index	> 3.2	< 11	> 2
Mean corpuscular volume (fL)	< 80	Normal or reduced	Normal or reduced

ACD = anemia of chronic disease; IDA = iron deficiency anemia.
Guagnozzi D, Lucendo AJ. *World J Gastroenterol.* 2014;20(13):3542-3551.

Anemia Care Pathway for IBD: Screening

Patient presents with symptoms:
- Fatigue
- Bleeding

AND/OR

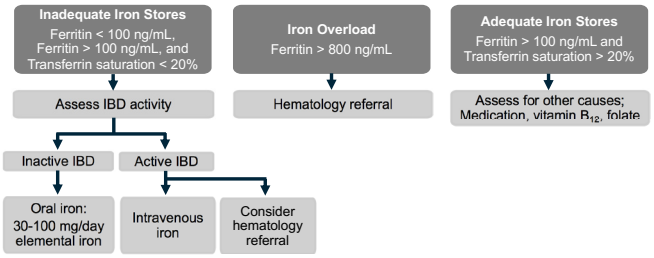
Provider orders lab tests that include ferritin as a universal test

Recognition of anemia or iron deficiency → **Low hemoglobin**
Women: < 12 g/dL
Men: < 13 g/dL

Recognition of non-anemic iron deficiency → **Ferritin levels**
< 30 ng/mL[2]

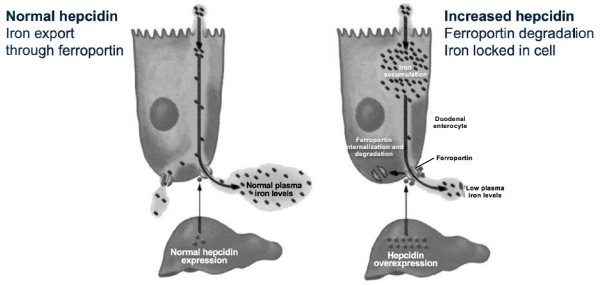
Crohn's & Colitis Foundation (CCF). IBD Qorus. CCF IBD Anemia Care Pathway. 2019. CCF Website. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf.

Anemia Care Pathway for IBD: Evaluation and Intervention



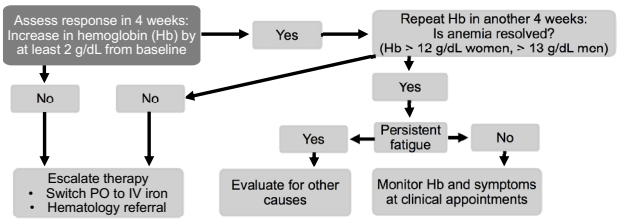
CCF. IBD Qorus. CCF IBD Anemia Care Pathway. 2019. CCF Website. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf.

Hepcidin Regulates Oral Iron Absorption



De Domenico I, et al. *J Clin Invest*. 2007;117(7):1755-1758.

Anemia Care Pathway for IBD: Follow-Up



CCF. IBD Qorus. CCF IBD Anemia Care Pathway. 2019. CCF Website. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf.

Available Iron Formulations

Oral Iron Formulations	Parenteral Iron Formulations
• Ferrous fumarate • Ferrous gluconate • Ferrous sulfate • Polysaccharide-iron complex • Ferric maltol*	• LMW iron dextran* • Ferric gluconate* • Iron sucrose* • Ferumoxytol* • Ferric carboxymaltose* • Iron isomaltoside*

*Requires prescription.
LMW = low-molecular-weight.

CCF. IBD Qorus. CCF IBD Anemia Care Pathway. 2019. CCF Website. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf.

Anemia in IBD: Key Takeaways

- Screen for iron deficiency
  - Quiescent/mild every 6-12 months
  - Active disease every 3-6 months
- Refer to Crohn's and Colitis Foundation Anemia Care Pathway
  - Iron deficiency anemia
  - Non-anemic iron deficiency
- Active inflammation + iron deficiency anemia → IV iron
- Treat underlying blood loss and improve iron absorption

CCF. IBD Qorus. CCF IBD Anemia Care Pathway. 2019. CCF Website. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf.

CME Outfitters
CONTINUING MEDICAL EDUCATION

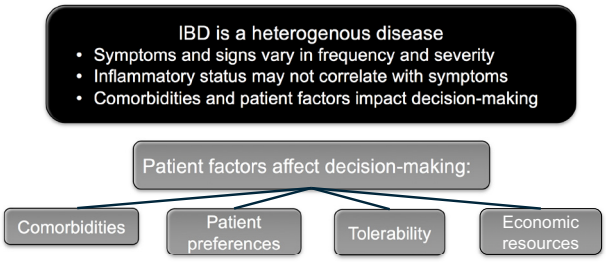
Learning Objective 3

Select treatment for patients with IBD, taking into account disease history, disease severity, and patient preference.

Treatment Selection Should Incorporate Elements of Activity and Severity

- Activity: how sick a patient is now; includes elements of symptoms and objective measures of inflammation and chronicity
- Severity: prognosis; what is the risk of progression and adverse outcomes

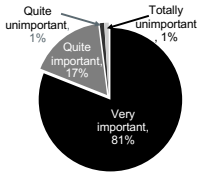
There Is a Need for Individualized Treatment in IBD



Empowering Patients Through Shared Decision-Making

2010 survey of 1,067 Dutch patients with IBD

"How important for you is involvement in treatment decision-making?"



There is a need to:
- Improve patient-physician communication
- Recognize patient preference and desire for "informed" choice
- Present "Best Evidence Available Now" in a patient-friendly way

Baars JE, et al. *Digestion*. 2010;81:113-119.

What Do Patients Say?

Do you feel your clinician engages you in treatment decisions and do you discuss your treatment regimen preference, the history of your disease, and the severity of your disease?

"*The doctor I have now is very engaged with my symptoms, treatment plans, and anything that I want to discuss about IBD. My doctor that I had in the past, I felt wasn't someone that really understood what was going on with my body.*"

The Spectrum of Patient-Provider Communication

Provider-Patient Alignment of:
- Health and wellness goals
- Supportive behaviors
- Expectations and timelines
- Resources needed for change

SHARED DECISION-MAKING

Provider-Dominated PATERNALISM → **SWEET SPOT** ← **Patient-Dominated CONSUMERISM**

Provider strategies to facilitate movement:
1. Be present
2. Listen to learn
3. Ask open-ended questions
4. Identify patient goals

Provider strategies to facilitate movement:
1. Listen to learn
2. Identify patient goals
3. Ask open-ended questions
4. Proactively manage expectations

Treatment Adherence in IBD

- Typical adherence to medications is 50%
  - ~60% for 5-aminosalicylates (ASAs)
  - ~40% for thiopurines
- Effects of non-adherence
  - More flares, hospitalizations
  - Higher medical costs (despite less medication costs)

Kane SV. *Aliment Pharmacol Ther*. 2006;23:577-585.

Strategies to Empower Patients to Communicate About Their Preferences

- Focus on the present moment
- Listen to what patients and caregivers say, not what you think they will say
- Ask situational questions that help open up patients to additional considerations
- Provide information when and where it is needed
- Create a shared set of goals and check them off at each appointment

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

- Recognize the safety and efficacy data for JAK inhibitors in IBD
- Screen, recognize, and treat iron deficiency anemia
- Recognize the multiple factors contributing to management decisions including patient preferences

Additional Resources

Visit **www.cmeoutfitters.com** for clinical information and certified educational activities

Questions for Faculty?

Type a question in the box under the presentation

OR

E-mail:
questions@cmeoutfitters.com

Coming Up...

CME Outfitters

AFTER THE SHOW

CME Outfitters

AFTER THE SHOW

Questions & Answers

CME Outfitters
CONTINUING MEDICAL EDUCATION

After the live webcast, this activity will be available as a web archive at www.cmeoutfitters.com

To receive CME/CE credits for this activity, participants must complete the post-test and evaluation online.

Go to the *Credit Tab* at the top of the video box and click on the link to complete the process and print your certificate.

CME for MIPS Improvement Activity

How to Claim this Activity as a CME for MIPS Improvement Activity

- Actively participate by responding to ARS and/or asking the faculty questions
- Complete activity posttest and evaluation at the link provided
- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation.
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity.

Claim ABIM MOC Credit

3 Things to Do

1. Actively participate in the meeting by **responding to ARS** and/or **asking the faculty questions**
   (It's ok if you miss answering a question or get them wrong, you can still claim MOC)
2. Complete your post-test and evaluation at the conclusion of the webcast
3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so we can submit your credit to ABIM.

ABIM CME MOC ACCREDITED

CME Outfitters
CONTINUING MEDICAL EDUCATION

After the live webcast, this activity will be available as a web archive at www.cmeoutfitters.com

This continuing education activity is provided by CME Outfitters

TV-105-110419-02

Attendance Form for Groups

Please complete and FAX to **614.929.3600**

Activity Title and Faculty:

Caring for Patients with IBD in an Evolving Treatment Landscape: Optimizing Outcomes and Minimizing Complications

with David T. Rubin, MD, FACG, AGAF, FACP, FASGE (Moderator); Jami Kinnucan, MD; Gil Y. Melmed, MD, MS

Site/Institution Name: ______________________________

Practice Setting: ❑ Office-based ❑ Hospital ❑ Clinic ❑ Managed Care ❑ Small Group Practice (less than 5) ❑ Large Group Practice (more than 5) ❑ Other: ______________________________

Address: ______________________________

City: ______________________ State: ________ ZIP: ____________

Site Coordinator: ______________________ Phone: ______________________

Fax: ______________________ Email: ______________________

Completion Date: ____________ We participated in: ______________________

Attendee Name (please print)	Please Circle Discipline						
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________
____________	MD	DO	PA	NP	RN	Pharm	Other: ________

Please FAX completed form to 614.929.3600 and use additional sheets as necessary.
Questions? Call 877.CME.PROS. Thank you for participating in this continuing education activity!