MM-097LS-050620-20

SYLLABUS AND COURSE GUIDE

Ulcerative Colitis in the 21st Century: *Incorporating Guidelines and Real-World Evidence in Practice to Enhance Patient-Centered Care*

Live Virtual Symposium: Wednesday, May 6, 2020
6:30 PM - 8:00 PM ET (live)
Credit Expiration Date: Thursday, May 6, 2021

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LIVE FACULTY:
Sushila Dalal, MD and Miguel Regueiro, MD, AGAF, FACG, FACP

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

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INFORMATION FOR PARTICIPANTS

Statement of Need

Ulcerative colitis (UC) is a heterogeneous disorder that requires an individualized approach in order to achieve goals of treatment such as mucosal healing and deep, long-term remission. The American College of Gastroenterology (ACG) released updated treatment guidelines in 2019 that include recommendations for disease stratification, prognosis, treatment options, and disease monitoring. These guidelines, along with new efficacy, safety, and comparative effectiveness data and the approval of additional therapies, facilitate the identification of the right treatment for the right patient at the right time. Clinicians who care for patients with UC must ensure that they are aware of these updates and incorporate them into practice in order to optimize patient outcomes.

This CME Outfitters virtual symposium will feature the UC guideline authors discussing the newest recommendations and their translation to practice. Additionally, a shared decision-making (SDM) demonstration video will be integrated into the symposium to illustrate effective and ineffective patient-provider communication on treatment decisions.

Learning Objectives

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

- Follow the updated UC guidelines to incorporate elements of prognosis into diagnosis and treatment decision-making.
- Incorporate data on efficacy, safety, comparative effectiveness, and different routes of administration from clinical trials and real-world experience into treatment decision-making in moderate-to-severe UC.
- Implement strategies for improving patient-centered care and SDM in moderate-to-severe UC.

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

- Identify the updated UC guidelines for diagnosis and treatment decision-making for patients with UC.
- Summarize data on efficacy, safety, comparative effectiveness, and different routes of administration from clinical trials and real-world experience for treatment decision-making in moderate-to-severe UC.
- Describe strategies for improving patient-centered care and SDM in moderate-to-severe UC.

Target Audience

Gastroenterologists, physician assistants (PAs), nurse practitioners, nurses, and pharmacists

Financial Support

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

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CNE Credit (Nurses)

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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.

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Universal Activity Number: Live: 0376-0000-20-008-L01-P; Enduring: 0376-0000-20-008-H01-P
Type: knowledge-based

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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 (Chair)

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.

Sushila Dalal, MD

Dr. Dalal is an assistant professor at the University of Chicago Medicine Inflammatory Bowel Disease Center. She specializes in the care of patients with complex inflammatory bowel disease and has a special interest in pregnancy in IBD, pouchitis, and transition care for teenagers and young adults.

Miguel Regueiro, MD, AGAF, FACG, FACP

Dr. Regueiro earned his bachelor's degree at the University of Pennsylvania and his medical degree at Drexel (Hahnemann) University, and completed his internal medicine internship, residency, and clinical and research fellowship training in gastroenterology at Harvard Medical School's Beth Israel Hospital.

Dr. Regueiro was Professor of Medicine and Clinical and Translational Science at the University of Pittsburgh School of Medicine from 2000 to 2018. There he served as the IBD Clinical Medical Director, Senior Medical Lead of Specialty Medical Homes, was Professor with Tenure, and honored as the UPMC Endowed Chair for Patient Centered Care in Inflammatory Bowel Diseases.

Dr. Regueiro is currently the Chair of the Department of Gastroenterology and Hepatology and Vice Chair of the Digestive Disease and Surgery Institute at Cleveland Clinic in Ohio. He serves as Medical Co-Chair of Digestive Disease and Surgical Institute Research Governance committee and is Professor of Medicine at the Lerner College of Medicine, Cleveland Clinic.

Dr. Regueiro's main clinical and research interest is inflammatory bowel diseases with a focus on the natural course of these diseases and postoperative prevention of Crohn's disease. Recently, he has been involved in transformative medicine initiatives and developing new models of health care, including the first-of-its kind specialty medical home for IBD. Dr. Regueiro is investigating alternative models of care in population-based health that integrates patients, payers, providers, pharmaceutical industry, and other facets of health care delivery around these novel programs.

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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 receives other financial or material support as a member of the Board of Trustees for the American College of Gastroenterology and Crohn's & Colitis Foundation; and as Co-Founder and CFO of Cornerstones Health, Inc. (non-profit).

Dr. Dalal reports that she serves on the advisory committee for Pfizer Inc. She is on the speakers bureau for AbbVie Inc.

Dr. Regueiro reports that he receives research support from AbbVie Inc.; Janssen Pharmaceuticals, Inc.; Pfizer Inc.; and Takeda Pharmaceuticals U.S.A., Inc. He receives unrestricted educational grants from AbbVie Inc.; Janssen Pharmaceuticals, Inc.; Pfizer Inc.; Salix Pharmaceuticals; Shire; Takeda Pharmaceuticals U.S.A., Inc.; and UCB, Inc. He is on advisory boards and a consultant for AbbVie Inc.; Allergan; Amgen Inc.; Celgene Corporation; Genentech, Inc.; Janssen Pharmaceuticals, Inc.; Miraca Laboratories; Pfizer Inc.; Salix Pharmaceuticals; Seres Therapeutics; Takeda Pharmaceuticals U.S.A., Inc.; and UCB, Inc.

Jeffrey Helfand, DO (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.

Susan Perry (planning committee) has no disclosures to report.

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

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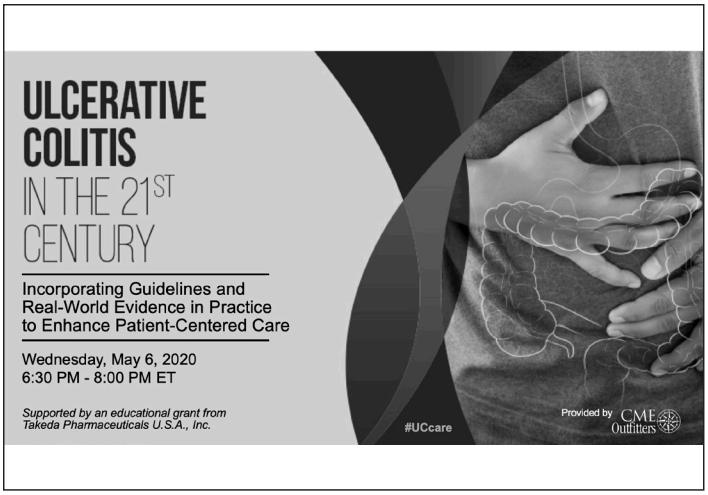

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- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation
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CME for MIPS IMPROVEMENT ACTIVITY

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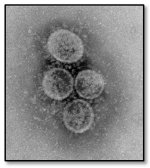
Coronavirus Disease 2019 (COVID-19) and Inflammatory Bowel Disease (IBD)

COVID-19: Key Facts

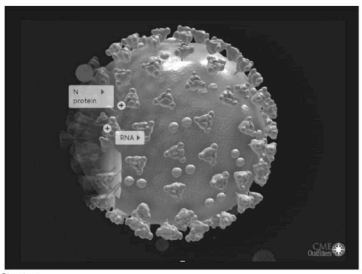
- There are hundreds of coronaviruses
  - Most circulate among animals (pigs, camels, bats, cats)
  - Sometimes jump to humans (SARS 2002-2004) (MERS 2012)
  - COVID-19 caused by SARS-CoV-2
- Incubation median 5 days, range 2-11.5 days
- Clinical presentation
  - Respiratory tract infection (fever, cough)
  - Bilateral pneumonia, lymphopenia
  - Up to 50% report gastrointestinal (GI) symptoms: anorexia, diarrhea, vomiting, abdominal pain



COVID-19 = coronavirus; MERS = Middle East respiratory syndrome; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

1. van Doremalen N, et al. New England Journal of Medicine (NEJM) Website. 2020. https://www.nejm.org/doi/full/10.1056/NEJMc2004973?query=featured_home.
2. Guan W, et al. NEJM Website. 2020. https://www.nejm.org/doi/pdf/10.1056/NEJMoa2002032?articleTools=true. 3. Lauer SA, et al. Annals of Internal Medicine Website. 2020. https://annals.org/aim/fullarticle/2762808/incubation-period-coronavirus-disease-2019-covid-19-from-publicly-reported. 4. Pan L, et al. *Am J Gastroenterol*. 2020 March 18. [Epub ahead of print]. Image from National Institute of Allergy and Infectious Diseases Website. 2020. https://www.niaid.nih.gov/diseases-conditions/coronaviruses.

SARS-CoV-2



BioDigital. COVID-19 Inside Virus Structure. https://human.biodigital.com/viewer/?id=production/maleAdult/coronavirus_RNA_n_protein&ui-chapter-list=true&ui-label-list=true&ui-fullscreen=false&ui-all=true&ui-search=false&load-rotate=1&uaid=5H4F. Accessed 5/4/2020.

AGA Guidance: Management of IBD During COVID-19 Pandemic

- Patients with IBD **should continue IBD therapies and infusions**
- Having IBD **does not appear to increase the risk** of SARS-CoV-2 infection or development of COVID-19
- Instructions for patients who develop COVID-19:
  - a. **Stop immune-modulating therapies**
  - c. Can restart therapies **after complete resolution of COVID-19 symptoms**
- Submit cases of IBD and confirmed COVID-19 to SECURE-IBD registry (**COVIDIBD.org**)

AGA = American Gastroenterological Association; TNF = tumor necrosis factor.

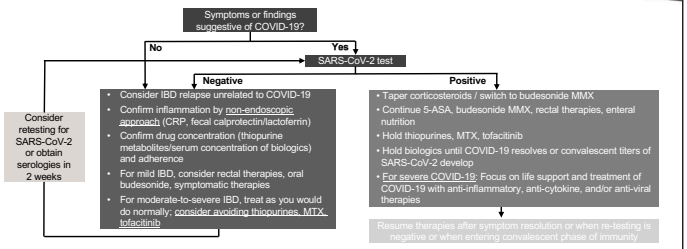
Rubin DT, et al. *Gastroenterology*. 2020. [Epub ahead of print]. https://www.gastrojournal.org/article/S0016-5085(20)30482-0/fulltext.

Clinical Case: Meet Monica

- Monica is a 42-year-old woman with a 3-year history of UC
- Medications: anti-TNF
- Currently 4 BMs/day with blood, fever 39°C, dry cough
- Assessment:
  - CRP 6 mg/dL
  - Negative for *Clostridioides difficile (C. diff)*
  - **Positive for SARS-CoV-2** (rapid test)

BMs = bowel movements; CRP = C-reactive protein; UC = ulcerative colitis.

Management of IBD Relapse During the COVID-19 Pandemic



5-ASA = 5-aminosalicylic acid; MTX = methotrexate.
Rubin DT, et al. *Gastroenterology*. 2020. [Epub ahead of print]. https://www.gastrojournal.org/article/S0016-5085(20)30482-0/fulltext.

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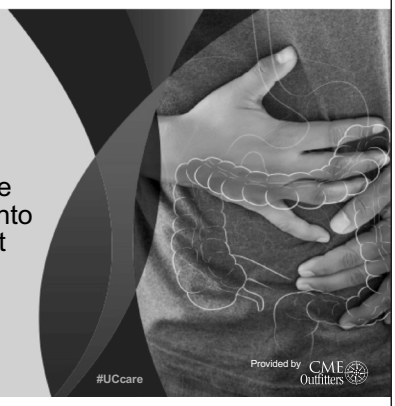
Learning Objective 1

Follow the updated UC guidelines to incorporate elements of prognosis into diagnosis and treatment decision-making.



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Clinical Case: Meet Ross

- Ross is a 70-year-old man who presents to you with newly onset symptoms (past month):
  - Weight loss (6 lb)
  - Diarrhea: up to 5 BMs/day, 50% with bleeding
  - Urgency
- Generally healthy; runs every day; still works as a consultant, which requires occasional travel
- Labs:
  - Hemoglobin 11.2 g/dL
  - CRP 12 mg/L
  - Fecal calprotectin 308 mcg/g
  - *C. diff* negative; SARS-CoV-2 negative
  - Colonoscopy: Mayo score 2

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CLINICAL GUIDELINES

ACG Clinical Guideline: Ulcerative Colitis in Adults

David T. Rubin, MD, FACG[1], Ashwin N. Ananthakrishnan, MD, MPH[2], Corey A. Siegel, MD, MS[3], Bryan G. Sauer, MD, MSc (Clin Res), FACG (GRADE Methodologist)[4] and Millie D. Long, MD, MPH, FACG[5]

Ulcerative colitis (UC) is an idiopathic inflammatory disorder. These guidelines indicate the preferred approach to the management of adults with UC and represent the official practice recommendations of the American College of Gastroenterology. The scientific evidence for these guidelines was evaluated using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process. In instances where the evidence was not appropriate for GRADE, but there was consensus of significant clinical merit, "key concept" statements were developed using expert consensus. These guidelines are meant to be broadly applicable and should be viewed as the preferred, but not only, approach to clinical scenarios.

Am J Gastroenterol 2019;114:384–413. https://doi.org/10.14309/ajg.0000000000000152; published online February 22, 2019

Gastroenterology 2020;158:1450–1461

aga American Gastroenterological Association

CLINICAL PRACTICE GUIDELINES

AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis

Joseph D. Feuerstein,[1] Kim L. Isaacs,[2] Yecheskel Schneider,[3] Shazia Mehmood Siddique,[3] Yngve Falck-Ytter,[4,5] and Siddharth Singh,[5] on behalf of the AGA Institute Clinical Guidelines Committee

ACG = American College of Gastroenterology.
Rubin DT, et al. *Am J Gastroenterol*. 2019;114(3):384-413. Feuerstein JD, et al. *Gastroenterology*. 2020;158(5):1450-1461.

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New to 2019 ACG UC Guidelines

- Differentiated activity from severity
- ACG Disease Activity Index
- Mildly vs. moderately to severely active disease
- Treatment of hospitalized patients
- Updated colorectal cancer prevention guidelines
- 48 GRADE recommendations
- 54 key concept statements

GRADE = Grading of Recommendations Assessment, Development and Evaluation.
Rubin DT, et al. *Am J Gastroenterol.* 2019;114(3):384-413.

2020 AGA Moderate-Severe UC Guidelines
Focus on Therapies

- Management of treatment-naïve and biologic-naïve patients
- Management after TNF failure
- Early use of biologics instead of step-up approach
- Management of hospitalized patients

Feuerstein JD, et al. *Gastroenterology.* 2020;158(5):1450-1461.

New ACG UC Activity Index

	Remission	Mild	Moderate-Severe	Fulminant
Stools (#/day)	Formed stools	< 4	> 6	> 10
Blood in stools	None	Intermittent	Frequent	Continuous
Urgency	None	Mild, occasional	Often	Continuous
Hemoglobin	Normal	Normal	< 75% of normal	Transfusion required
ESR	< 30	< 30	> 30	> 30
CRP (mg/L)	Normal	Elevated	Elevated	Elevated
Fecal calprotectin (µg/g)	< 150-200	> 150-200	> 150-200	> 150-200
Endoscopy (Mayo subscore)	0-1	1	2-3	3
UCEIS	0-1	2-4	5-8	7-8

ESR = erythrocyte sedimentation rate; UCEIS = Ulcerative Colitis Endoscopic Index of Severity.
Rubin DT, et al. *Am J Gastroenterol.* 2019;114(3):384-413.

Case Recap

- Ross is a 70-year-old man with no prior history of GI symptoms
- Since the last month: weight loss, diarrhea (5 BMs/day, 50% with blood)

- Assessment:
  - Hemoglobin 11.2 g/dL
  - CRP 12 mg/L
  - *C. diff* and SARS-CoV-2 negative
  - Fecal calprotectin 308 mcg/g
  - Mayo score 2

Poor Prognostic Factors in UC Disease Severity

Poor Prognostic Factors
Age < 40 at diagnosis
Extensive colitis
Severe endoscopic disease (Mayo endoscopic subscore 3, UCEIS ≥ 7)
Hospitalization for colitis
Elevated CRP
Low serum albumin

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

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Updated Goals of Management of UC

- Diagnosis including extent of disease and biopsy
- Movement to separate activity and severity
- Induction of clinical response/remission and mucosal healing
- Maintenance therapy identified based on induction therapy and prognosis
- Screen and treat for anxiety/depressive disorders
- Prevention of complications (cancer, hospitalization, infections, other drug-related)
- Organ-selective before systemic treatments

ACTIVITY: How sick the patient is NOW
SEVERITY: Includes elements of PROGNOSIS

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

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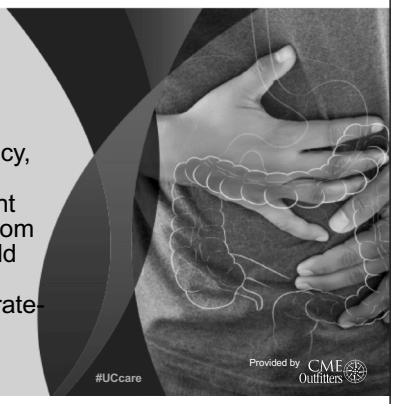
Learning Objective 2

Incorporate data on efficacy, safety, comparative effectiveness, and different routes of administration from clinical trials and real-world experience into treatment decision-making in moderate-to-severe UC.



Clinical Case: Meet Rachel

- Rachel is a 30-year-old woman with a history of UC rectosigmoiditis
- Since the diagnosis 4 year ago, she has been on mesalamine and more recently (since 1 year ago) on adalimumab 40 mg subcutaneously (SC) every 2 weeks + azathioprine 2 mg orally (PO) every day
- Rachel has required 2 tapers of prednisone since her diagnosis to reduce the number of BMs and urgency
- Currently has 7 BMs/day with blood
- Labs:
  - Hemoglobin 12.2 g/dL
  - CRP 22 mg/L
  - *C. diff* negative
  - SARS-CoV-2 negative

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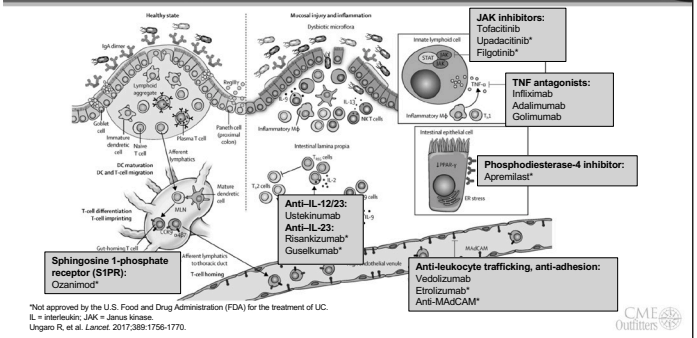
Novel Targets and Therapies in UC



*Not approved by the U.S. Food and Drug Administration (FDA) for the treatment of UC.
IL = interleukin; JAK = Janus kinase.
Ungaro R, et al. *Lancet*. 2017;389:1756-1770.

Targeted Therapies Approved by the FDA for Moderate-Severe UC

	Mechanism	Induction of Clinical Response and Remission	Adverse Events*
Infliximab	Anti-TNF	ACT[1]	Serious infections, opportunistic infections; need to test for tuberculosis (TB) and hepatitis B virus (HBV) prior to initiation of therapy
Adalimumab	Anti-TNF	ULTRA[2]	
Golimumab	Anti-TNF	PURSUIT-SC[3]	
Vedolizumab	Selective α4β7 integrin antagonist	GEMINI[4]	Nasopharyngitis
Tofacitinib	JAK inhibitor	OCTAVE Induction[5]	Serious infections, opportunistic infections; need to test for TB and HBV prior to initiation of therapy (increased risk of herpes zoster)
Ustekinumab	Anti–IL-12/23	UNIFI[6]	Nasopharyngitis

*See prescribing information for full list of warnings, precautions, and adverse events.

1. Rutgeerts P, et al. *N Engl J Med*. 2005;353(23):2462-2476. 2. Sandborn WJ, et al. *Gastroenterology*. 2012;142(2):257-265. 3. Sandborn WJ, et al. *Gastroenterology*. 2014;146(1):96-109. 4. Feagan BG, et al. *N Engl J Med*. 2013;369(8):699-710. 5. Sandborn WJ, et al. *N Engl J Med*. 2017;376:1723-1736. 6. Sands BE, et al. *N Engl J Med*. 2019 381(13):1201-1214.

Induction of Remission: Moderate-Severe UC

- UC failing to respond to 5-ASA therapy → oral systemic corticosteroids[1-4]
- Moderate UC → oral budesonide multi-matrix (MMX)[1]
- Moderate-severe UC of any extent → oral systemic corticosteroids[1,3,4,5]
- Anti-TNF therapy using adalimumab, golimumab, or infliximab[1,3,5]
- Infliximab in combination with a thiopurine[1-5]
- Vedolizumab[1-3,5] *or* ustekinumab[5] *or* tofacitinib[1,5]
- If failed anti-TNF → vedolizumab[1-4] *or* tofacitinib[1] *or* ustekinumab[5]
- **Recommend against** monotherapy with thiopurines *or* methotrexate[1,3,5]

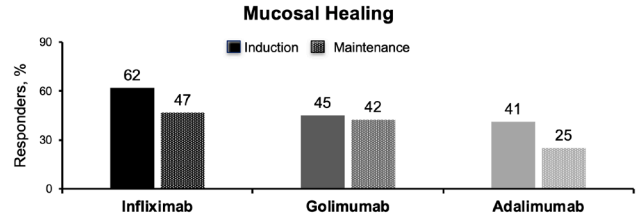
1. Rubin DT, et al. *Am J Gastroenterol*. 2019;114:384-413. 2. Harbord M, et al. *J Crohns Colitis*. 2017;11(7):769-784. 3. Bressler B, et al. *Gastroenterology*. 2015;148(5):1035-1058.e3. 4. Choi CH, et al. *Intest Res*. 2017;15(1):7-37. 5. Feuerstein JD, et al. *Gastroenterology*. 2020;158:1450-1461.

Maintenance of Remission: Moderate-Severe UC

- **Recommend against** systemic steroids[1,3,5]
- Thiopurines[1-6]
- **Recommend against** using methotrexate[1-3,6]
- Anti-TNF therapy using adalimumab, golimumab, or infliximab[1-6]
- Vedolizumab[1,4,6] *or* tofacitinib[1,6] *or* ustekinumab[6]

1. Rubin DT, et al. *Am J Gastroenterol*. 2019;114:384-413. 2. Harbord M, et al. *J Crohns Colitis*. 2017;11(7):769-784. 3. Bressler B, et al. *Gastroenterology*. 2015;148(5):1035-1058.e3. 4. Choi CH, et al. *Intest Res*. 2017;15(1):7-37. 5. Wei CS, et al. *Intest Res*. 2017;15(3):266-284. 6. Feuerstein JD, et al. *Gastroenterology*. 2020;158:1450-1461.

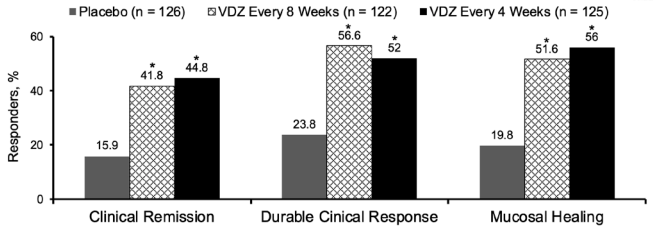
Anti-TNF Therapy: Overall Efficacy



Data presented from different trials and cannot be directly compared

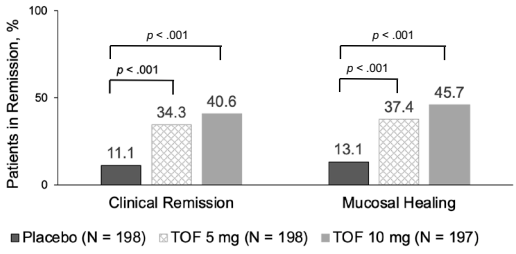
Rutgeerts P, et al. *N Engl J Med.* 2005;353(23):2462-2476. Sandborn WJ, et al. *Gastroenterology.* 2012;142(2):257-265.e251-253. Sandborn WJ, et al. *Gastroenterology.* 2014;146(1):96-109. Sandborn WJ, et al. *Gastroenterology.* 2014;146(1):85-95; quiz e14-85.

Vedolizumab Maintenance in UC: Week 52 (GEMINI)



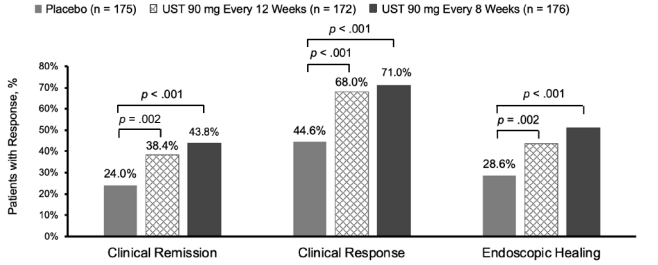
Durable clinical response = clinical response (reduction in Mayo score of at least 3 points + > 30% decrease from baseline + at least 1 point decrease in rectal bleeding) at weeks 6 and 52.
Clinical remission = Mayo score ≤ 2 and no subscore higher than 1. Mucosal healing = Mayo endoscopic subscore of 0 or 1.
*$p < .001$.
Feagan BG, et al. *N Engl J Med.* 2013;369:699-710.

Tofacitinib Maintenance in UC: Week 52 (OCTAVE Sustain)



TOF = tofacitinib.
Sandborn W, et al. *N Engl J Med.* 2017;376(18):1723-1736.

Ustekinumab Maintenance in UC: Week 44 (UNIFI)

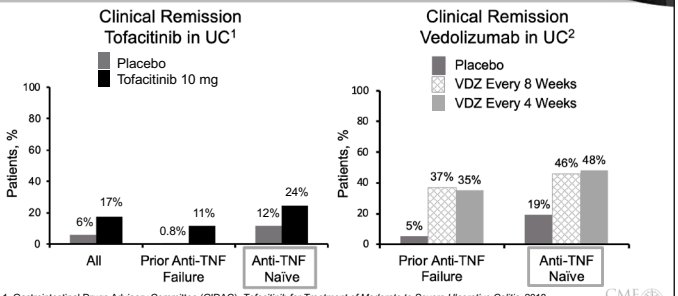


Clinical remission = total score of ≤ 2 on the Mayo scale. Endoscopic healing = Mayo endoscopic subscore of 0 or 1.
Clinical response = decrease in the total Mayo score of at least 30% and of at least 3 points from baseline.
Sands BE, et al. *N Engl J Med* 2019 381(13):1201-1214.

Case Recap

- Rachel is a 30-year-old woman with a history of UC rectosigmoiditis
- Diagnosed 4 years ago; has been on mesalamine and then adalimumab; required 2 tapers of prednisone
- Currently 7 BMs/day with blood
- Labs:
  - Hemoglobin 12.2 g/dL
  - CRP 22 mg/L
  - *C. diff* and SARS-CoV-2 negative

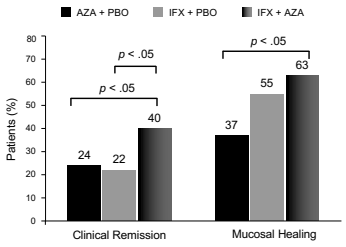
TNF-Naïve Patients Respond Better to Tofacitinib or Vedolizumab vs. Those Who Have Failed a TNF



1. Gastrointestinal Drugs Advisory Committee (GIDAC). *Tofacitinib for Treatment of Moderate to Severe Ulcerative Colitis*. 2018. https://www.fda.gov/media/112149/download. 2. Feagan BG, et al. *N Engl J Med*. 2013;369(8):699-710.

Infliximab + Azathioprine vs. Monotherapy: Week 16 (UC SUCCESS)

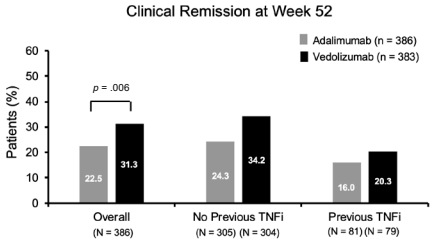
- N = 239
- Randomized, double-blind trial in anti-TNF-naïve patients with moderate-to-severe UC
- Primary endpoint: corticosteroid-free clinical remission at week 16



AZA = azathioprine; IFX = infliximab; PBO = placebo.
Panaccione R, et al. *Gastroenterology*. 2014;146(2):392-400.e3.

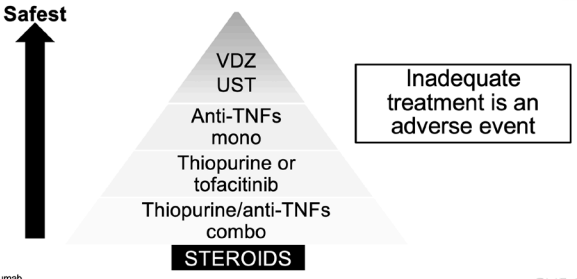
Vedolizumab vs. Adalimumab: Week 52 (VARSITY)

- N = 769
- Phase IIIb, double-blind, double-dummy, multi-center, active-controlled trials for patients with moderately to severely active UC who failed conventional therapies
- Primary endpoint: clinical remission at week 52



TNFi = TNF inhibitor.
Sands BE, et al. *N Engl J Med*. 2019;381:1215-1226.

Safety Pyramid of Current IBD Medications



UST = ustekinumab
Click B, Regueiro M. *Inflamm Bowel Dis.* 2019;25(5):831-842.

Individualized Therapy of Moderate-Severe UC: Sub-Populations

- **Age > 65:** Ustekinumab, vedolizumab
- **Inpatient:** Infliximab (induction and maintenance), cyclosporine (induction followed by azathioprine or vedolizumab maintenance)
- **Significant cancer history, lymphoma:** Ustekinumab, vedolizumab
- **Pregnancy:** Anti-TNF, azathioprine, ustekinumab, vedolizumab
- **Steroid responsive mild-moderate disease:** Thiopurine
- **Extraintestinal joint pain or inflammation:** Anti-TNF, tofacitinib, ustekinumab
- **Previous anti-TNF failure:** Tofacitinib, ustekinumab, vedolizumab

Rubin DT, et al. *Am J Gastroenterol.* 2019;114(3):384-413. Click B, Regueiro M. *Inflamm Bowel Dis.* 2019;25(5):831-842.

Learning Objective 3

Implement strategies for improving patient-centered care and shared decision-making (SDM) in moderate-to-severe UC.

Clinical Case: Meet Joey

- Joey is a 32-year-old man with extensive UC
- Since diagnosis, he has been in remission on mesalamine 4.8 gm daily; recently developed worsening symptoms with 8 loose, urgent BMs/day with blood; currently on prednisone 40 mg daily
- Flexible sigmoidoscopy showed moderately active inflammation
- Labs:
  - Hemoglobin 11.2 g/dL
  - CRP 14 mg/L
  - *C. diff* negative
  - SARS-CoV-2 negative

SDM: 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 tells me what the treatment is. I just do what she tells me. I would like to feel like we make decisions together but she never seems to have time for that.

CME Outfitters

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

CME Outfitters

Incorporating Patient Preferences: Routes and Frequency of Administration

Intravenous Infusion	Subcutaneous Infusion	Oral
Infliximab *every 8 weeks*	**Adalimumab** *every 2 weeks*	**Tofacitinib** *once or twice per day depending on formulation*
Vedolizumab *every 8 weeks*	**Golimumab** *every 4 weeks*	
	Ustekinumab* *every 8 weeks*	

*Maintenance dose.
FDA. FDA Website. https://www.accessdata.fda.gov/scripts/cder/daf/.

CME Outfitters

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 patients up to additional considerations
- Provide information when and where it is needed
- Create a shared set of goals and check them off at each appointment

CME Outfitters

Digital Tools to Empower Patients

- **Decision aid:** IBD&me generates a personalized therapy preferences report for patients to discuss with their physician
- **GI symptom trackers:** MyTherapy, My IBD Manager, myColitis help patients track their symptoms and share this information with their physician

Visit CME Outfitters' GI Patient Hub to find more digital apps and other resources to share with your patients

Effective and Ineffective Communication

- Effective communication:
  - "Let's discuss the risks and benefits of the options to find out what is best for you"
  - "What questions do you have?" "Good question; many people wonder about that…"
  - "Feel free to call me back or send me a message later if you have more questions as you think this over"
- Ineffective communication:
  - Feels rushed, as if the provider is not paying attention
  - Patient doesn't feel as if his/her concerns were answered
  - Patient doesn't report his/her symptoms or mention questions

SMART Goals

Specific, **M**easurable, **A**ttainable, **R**elevant, **T**imely

- Choose appropriate therapies during the COVID-19 pandemic
- Differentiate **activity** from **severity** in UC
- Choose therapy based on:
  - Activity, severity, extent of inflammation, and prognostic factors
  - Include oral, topical (rectal), systemic therapies, and surgery
  - Comparative effectiveness
- Prompt patients with open-ended questions to encourage SDM

Questions & Answers

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Visit the NEW ***COVID-19 Hub*** to find an evolving curation of educational videos, links, and tools for both HCPs and patients that address a variety of topics related to COVID-19 – from anxiety and depression to preparing for TeleHealth visits.

Access the Hub:
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MM-097LS-050620-20

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Please complete and FAX to **614.929.3600**

Activity Title and Faculty:

Ulcerative Colitis in the 21st Century: Incorporating Guidelines and Real-World Evidence in Practice to Enhance Patient-Centered Care

with David T. Rubin, MD, FACG, AGAF, FACP, FASGE (Chair); Sushila Dalal, MD; Miguel Regueiro, MD, AGAF, FACG, FACP

Site/Institution Name: ____

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

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Completion Date: ____________ We participated in: ______________________

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