SYLLABUS AND COURSE GUIDE

Who's in Charge: You or Your Crohn's Disease?

A Free, 60-Minute Live and On-Demand Activity for Patients with Crohn's Disease

Premiere Date: Thursday, December 12, 2019

7:00 PM - 8:00 PM ET (live)

On the Web: http://bit.ly/TV-107

FACULTY:

David T. Rubin, MD, FACG, AGAF, FACP, FASGE and Bruce E. Sands, MD, MS

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

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

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INFORMATION FOR PARTICIPANTS

Statement of Need

To provide the best care for your Crohn's disease (CD), guidelines for treatment and monitoring have been designed for gastroenterology care teams. As a patient and advocate of your care, it is important to have knowledge regarding how the guidelines are developed, be aware of the research behind them, and understand how they apply to you as a patient.

Join this webcast, ask the renowned CD specialists your questions during LIVE Q&A, and learn how to:

- Recognize the importance of practice guidelines and how they apply to CD.
- Establish long-term treatment goals to heal the inflamed bowels instead of masking the symptoms.
- Identify key markers of inflammation in CD and how they are used in practice.
- Evaluate the risk of colorectal cancer and colostomy in CD.
- Engage with your CD doctor to discuss your disease and strategies to establish and maintain clinical remission.

Target Audience

Individuals with Crohn's disease

Financial Support

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

FACULTY BIOS & DISCLOSURES

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

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 as 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.

Bruce E. Sands, MD, MS

Dr. Sands is the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York, NY.

Dr. Sands is an expert in the management of inflammatory bowel diseases (IBD) and has earned an international reputation for his care of patients with complex and refractory disease. He was awarded his BA and MD from Boston University, and trained in internal medicine at the Hospital of the University of Pennsylvania. After completing GI fellowship at the Massachusetts General Hospital (MGH), he joined the faculty of Harvard Medical School and served as the Acting Chief of the Gastrointestinal Unit at MGH before moving to Mount Sinai in 2010 as Chief of the Dr. Henry D. Janowitz Division of Gastroenterology.

Dr. Sands is widely recognized for his innovative treatment of Crohn's disease and ulcerative colitis and for his clinical investigations of new therapeutics. His research also explores IBD epidemiology and includes the creation of a population-based cohort of IBD in Rhode Island, a project funded by both the National Institutes of Health and the Centers for Disease Control and Prevention.

Dr. Sands is a past chair of the Clinical Research Alliance of the Crohn's & Colitis Foundation of America and served as Chair of the Immunology, Microbiology & Inflammatory Bowel Disease Section of the American Gastroenterological Association. Additionally, he was the Chair of the International Organization for the Study of IBD (IOIBD). In 2016, Dr. Sands was awarded the Dr. Henry D. Janowitz Lifetime Achievement Award from the Crohn's & Colitis Foundation of America, that organization's highest honor.

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Dr. Sands reports he is a consultant for AbbVie Inc.; Allergan; AstraZeneca; Boehringer Ingelheim; Boston Pharmaceuticals; Capella Bioscience; Celltrion Healthcare Co., Ltd; Eli Lilly and Company; Genentech, Inc.; Hoffmann-La Roche AG; Janssen Pharmaceuticals, Inc.; Morphic Therapeutic; Oppilan Pharma Inc.; Otsuka America Pharmaceutical, Inc.; Pfizer Inc.; Progenity, Inc.; Prometheus Laboratories Inc.; Salix Pharmaceuticals; Shire; Takeda Pharmaceuticals U.S.A., Inc.; TARGET PharmaSolutions, Inc.; Theravance Biopharma; and Vivelix Pharmaceuticals. He receives research support from Theravance Biopharma (payment is made to his institution). He is on the advisory committee for Arena Pharmaceuticals, Inc. and Ironwood Pharmaceuticals, Inc.

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

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Thursday, December 12, 2019

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

Joseph B. Kirsner Professor of Medicine
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David T. Rubin, MD
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- ***Research Support:*** AbbVie Inc.; Genentech, Inc./Roche; Janssen Pharmaceuticals, Inc.; Prometheus Laboratories Inc.; Shire; Takeda Pharmaceuticals U.S.A., Inc.
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Bruce E. Sands, MD, MS

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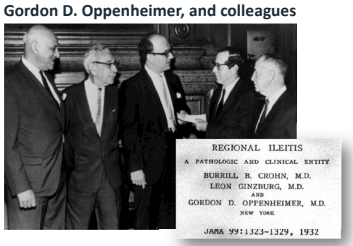
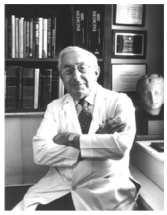
History of Crohn's Disease and Ulcerative Colitis

Burrill Crohn, Leon Ginzberg, Gordon D. Oppenheimer, and colleagues



Joseph Kirsner, "GI Joe"



American College of Gastroenterology Website. 2015. https://gi.org/2015/04121/team-medicine/. Crohn's & Colitis Foundation Website. https://www.crohnscolitisfoundation.org/about/our-beginning. Crohn BB, et al. *Mt Sinai J Med.* 1932;67(3):263-268.

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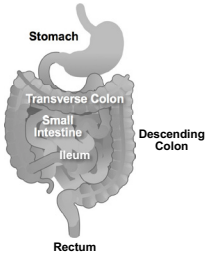
New Guidelines in Crohn's Disease

What Should I Know?

What Is Crohn's Disease?

- Chronic inflammation commonly found at the end of the small intestine (ileum)
- Can also affect eyes, skin, and joints
- Cause unknown
- Relapsing + remitting
- Progressive (for most patients)
- Treatable! New treatments and treatment goals

Crohn's Disease



Adapted from Crohn's & Colitis Australia Website. 2019. https://www.crohnsandcolitis.com.au/about-crohns-colitis/.

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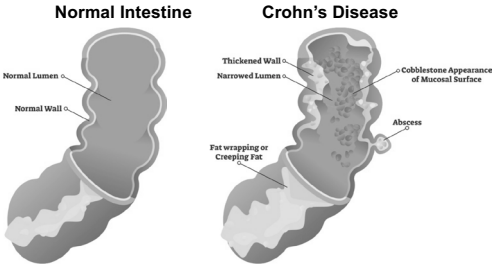
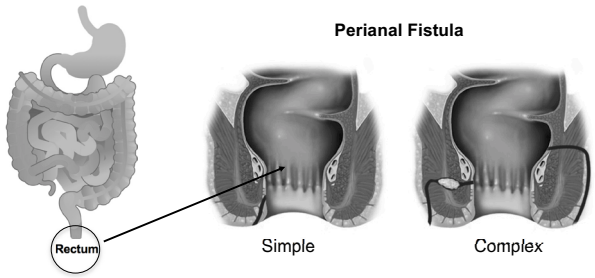
What Is Crohn's Disease?



Adapted from Harvard Health Publishing Website. 2018. https://www.health.harvard.edu/a_to_z/crohns-disease-a-to-z.

Perianal Crohn's Disease



Adapted from Honor A, Schwartz DA. Chapter 17 - Endoscopic Evaluation and Management of Perianal Crohn's Disease. In: Shen B, ed. *Interventional Inflammatory Bowel Disease: Endoscopic Management and Treatment of Complications.* Academic Press; 2018:203-209.

Why Are Clinical Practice Guidelines Important?

- Guidelines are written by experts in the field
- They contain recommendations for clinicians about patient care
- These recommendations are based on the most recent clinical research and are usually updated every few years
- Clinicians should refer to the guidelines to ensure that their treatment decisions are in line with the current standards

Remember!
Guideline recommendations are an important topic to discuss with your doctor

Levels of Evidence

Increasing quality + strength of evidence

- Opinion of experts without research
- Cases reported
- Randomized, blind trials
- Multiple randomized trials

Who's in Charge: You or Your Crohn's Disease?

What Do Patients with Inflammatory Bowel Disease (IBD) Say?

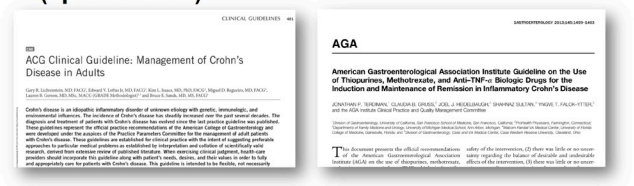
Are you aware of clinical guidelines for the care of patients with IBD?

Limitations of Guidelines

- Not all doctors know about them; most patients do not know about them
- Can become out of date quickly
- Don't apply to ALL patients
- Sometimes ignored by payers

U.S. Crohn's Disease Guidelines

- American College of Gastroenterology (ACG) Guideline **(updated 2018)**
- American Gastroenterological Association (AGA) Guideline **(updated 2013)**


ACG Clinical Guideline: Management of Crohn's Disease in Adults

AGA

American Gastroenterological Association Institute Guideline on the Use of Thiopurines, Methotrexate, and Anti-TNF-α Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease

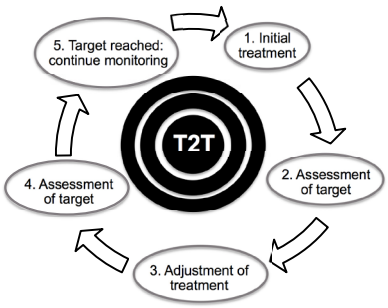
Lichtenstein GR, et al. *Am J Gastroenterol.* 2018;113(4):481-517; Terdiman JP, et al. *Gastroenterology.* 2013;145(6):1459-1463.

What's New in the 2018 Crohn's Disease Guidelines?

1. Move from "step-up" approach to choosing therapy based on a patient's prognosis
2. Incorporation of "treat-to-target" approach
3. New treatments (anti–tumor necrosis factor [TNF], vedolizumab, ustekinumab)
4. Therapeutic drug monitoring: adjusting drug dose based on its concentration in blood

Lichtenstein GR, et al. *Am J Gastroenterol.* 2018;113(4):481-517; Terdiman JP, et al. *Gastroenterology.* 2013;145(6):1459-1463.

What Is Treat-to-Target (T2T)?



Goals of Management of Crohn's Disease

- Clarify disease activity and severity
  - How much bowel is involved?
  - What is the risk for surgery?
- Induction of remission (fast!)
  - Remission of symptoms
  - Healing the bowel
- Prevention of relapse (maintenance)
- Prevention of disease + drug-related complications (infections, hospitalization, surgery, disability)

What Do Patients with IBD Say?

What would remission look like to you?

Charity

Remission looks like being able to live my life fully without suffering from IBD, without putting things aside. I have activities that I can't participate in just from the symptoms and the pain from IBD. I have had to sit out from things. I've had to leave work early because of my symptoms. So remission to me is not having to do things like that where my life is impacted in a negative way.

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Controlling Symptoms and Inflammation

Why Do Both Matter?

Symptomatic Remission Is Not Enough

1. Up to 75% of patients in clinical remission have persistent inflammation
2. Inflammation that persists increases risk of relapse
3. Mucosal healing means healing of the inflammation of the bowel lining
4. Studies show that mucosal healing lowers the risk for relapse and surgery

Bhattacharya A, et al. *Inflamm Bowel Dis.* 2016;22(11):2665-2671; Klenske E, et al. *Ther Adv Gastroenterol.* 2019;12:1756284819856865.

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Treatments for Crohn's Disease

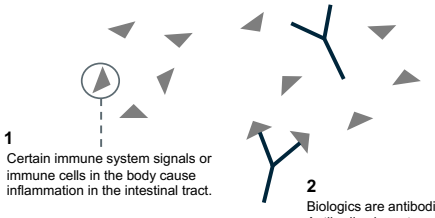
Why Are Treatments for Crohn's Disease Directed at the Immune System?

- Crohn's disease is a state of increased and uncontrolled immune activity of the bowel
- The goal of immune-directed therapy:
  - IS NOT to suppress the patient's immunity
  - IS to modify or turn down the active immune system just enough for the body to "reset" itself and to heal

Treatments for Crohn's Disease

- **Sulfasalazine**
- Steroids (**prednisone, budesonide**)
- Antibiotics
- Elemental diet (children)
- Thiopurines (**azathioprine, 6-mercaptopurine**)
- **Methotrexate**
- Biologics
  - Anti-TNF therapies: Remicade®/Inflectra®/Renflexis® (**infliximab**), Humira® (**adalimumab**), Cimzia® (**certolizumab pegol**)
  - Anti-integrin therapy: Entyvio® (**vedolizumab**), Tysabri® (**natalizumab**)
  - Anti–interleukin-12/23 therapy: Stelara® (**ustekinumab**)
- Surgery

What Is Biologic Therapy?



General Principles of Treatments for Crohn's Disease

1. **Start with symptom resolution**
2. **Get to a healed bowel and normal labs**
   - Objective evidence of disease control
3. **Develop customized treatment plans**
   - Do you know where your disease is located?
   - What is your individual prognosis?
   - What is your plan at the earliest sign of relapse?

General Principles of Treatments for Crohn's Disease

4. **Choose induction therapy based on activity (how sick now) and severity (prognosis)**
   - Optimize first therapy
   - Don't use steroids for too long!
5. **Choose maintenance therapy based on disease severity and induction therapy**
6. **Monitor for stable disease control over time!**

General Principles of Treatments for Crohn's Disease

7. **Prevention is the key to good health!**
   - Vaccination for preventable illnesses
   - Cancer prevention
     - Colon cancer (for patients with extensive with large bowel Crohn's disease): prevention with regular colonoscopies
     - Skin cancer monitoring with annual dermatology visits
     - Annual Pap smears
     - Bone health monitoring with bone density scans
   - Regular visits to your IBD doctor

Mild-Moderate or Low-Risk Crohn's Disease: ACG Recommendations 2018

- Antidiarrheals and over-the-counter medications
- Dietary modification
- Close observation for disease progression
- **Sulfasalazine**, **budesonide**

Lichtenstein GR, et al. *Am J Gastroenterol.* 2018;113(4):481-517.

Moderate-Severe Crohn's Disease: ACG Recommendations 2018

- Oral **steroids** for short-term use only
- **Thiopurines** for steroid sparing
- **Methotrexate** for steroid-dependent disease and maintenance of remission
- **Thiopurines** for maintenance of remission
- **Anti-TNF agents** for disease refractory to steroids, thiopurines, or methotrexate
- **Vedolizumab** and **ustekinumab** for induction and maintenance of remission
- **Infliximab** + **thiopurines** is more effective than either infliximab or thiopurines alone

Lichtenstein GR, et al. *Am J Gastroenterol.* 2018;113(4):481-517.

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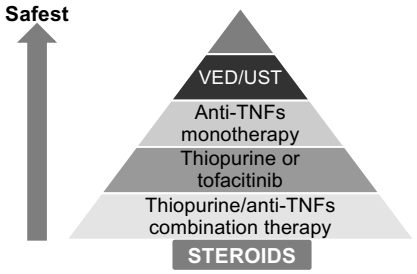
Safety of IBD Medications



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

Phew. I'm in Remission, Now What?

- Monitoring
- Long-term, sustained healing is maintained through regular monitoring and testing
- Stool tests for calprotectin and C-reactive protein (CRP) blood levels are efficient ways to monitor remission

Remember!
If you stop your medications, you risk returning to inflammation and Crohn's disease symptoms

Lichtenstein GR, et al. *Am J Gastroenterol.* 2018;113(4):481-517.

What Do Patients with IBD Say?

Has your clinician discussed with you markers of disease activity, why they are important, and how often they need to be evaluated?

When I am having any type of symptoms, my doctor will order labs and I know that she is looking for specific markers. I never have discussions with her about what the markers are specifically that she is looking for. I wish that I did have a better idea of what it is in the labs that she is trying to get.

Wendy

Why Do Treatments Stop Working?

Reasons for loss of response

- Body finds a new pathway of inflammation
- Infection on top of the Crohn's disease
- For biological therapies, your body can develop immunity to the therapy (like a reaction to a vaccination)
- You stop taking the medicine

What to Do if Your Medicine Stops Working

- Confirm inflammation
- Rule out infection
- Check on the drug level
- Consider dose changes
- Consider short-term fix (steroids?...)
- Cycle to another therapy in the same class
- Switch to a new mechanism

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Complications of Crohn's Disease

Am I at Risk?

When Is Surgery the Right Option in Crohn's Disease?

- When existing medications are not enough to relieve severe symptoms
- When Crohn's disease creates complications that become a medical emergency:
  - Bowel abscess
  - Bowel perforation
  - Fistula (abnormal connection between two cavities)
  - Intestinal blockage or obstruction
  - Toxic megacolon (severe abnormal expansion of the colon)
  - Uncontrolled bleeding
  - Cancer

What Types of Surgery Do Patients with Crohn's Disease Have?

Bowel resection
Removal of a damaged portion of intestine

Strictureplasty
Repairing a "stricture" (narrowing of intestine) to prevent intestinal blockage

Colectomy/proctocolectomy
Removal of the entire colon ± rectum

Abscess drainage
Surgical drainage of pus cavity

Exam under anesthesia
For perianal Crohn's disease

Preventing Crohn's Disease from Coming Back

- Continue/start taking your medicine
- Quit smoking
- Follow your personal dietary recommendations
- Schedule regular check-ups with your IBD specialist
  - Patients with certain risk factors for recurrence should have more frequent check-ups

Remember!
Monitoring and preventive measures will help you avoid future surgery

Regueiro MD. *Gastroenterology & Hepatology.* 2011;7(3):170-172.

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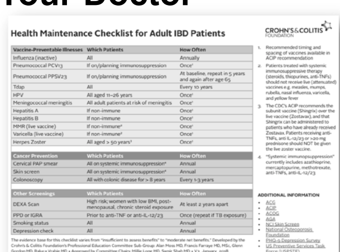
Checklists Are Important for You and Your Doctor



Health Maintenance Checklist for Adult IBD Patients

CROHN'S & COLITIS FOUNDATION

Vaccine-Preventable Illnesses	Which Patients	How Often
Influenza (inactive)	All	Annually
Pneumococcal PCV13	If on/planning immunosuppression	Once[1]
Pneumococcal PPSV23	If on/planning immunosuppression	At baseline, repeat in 5 years and again after age 65
Tdap	All	Every 10 years
HPV	All aged 11–26 years	Once[1]
Meningococcal meningitis	All adult patients at risk of meningitis	Once[1]
Hepatitis A	If non-immune	Once[1]
Hepatitis B	If non-immune	Once[1]
MMR (live vaccine)	If non-immune[2]	Once[1]
Varicella (live vaccine)	If non-immune[2]	Once[1]
Herpes Zoster	All aged > 50 years[3]	Once[1]

Cancer Prevention	Which Patients	How Often
Cervical PAP smear	All on systemic immunosuppression[4]	Annual
Skin screen	All on systemic immunosuppression[4]	Annual
Colonoscopy	All with colonic disease for > 8 years	Every 1-3 years

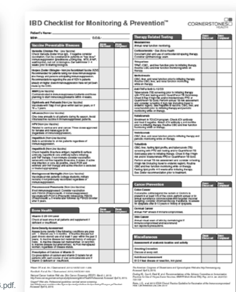
Other Screenings	Which Patients	How Often
DEXA Scan	High risk; women with low BMI, post-menopausal, chronic steroid exposure	At least 2 years apart
PPD or IGRA	Prior to anti-TNF or anti-IL-12/23	Once (repeat if TB exposure)
Smoking status	All	Annual
Depression check	All	Annual

The evidence base for this checklist varies from "insufficient to assess benefits" to "moderate net benefits." Developed by the Crohn's & Colitis Foundation's Professional Education Committee Sub-Group: Alan Moss MD, Francis Farraye MD, MSc, Glenn Gordon MD, Raluca Vrabie MD • Approved by Committee Chairs: Millie Long MD, Samir Shah MD • V3_January_2018

1. Recommended timing and spacing of vaccines available in ACIP recommendation
2. Patients treated with systemic immunosuppressive therapy (steroids, thiopurines, anti-TNFs) should not receive live (attenuated) vaccines e.g. measles, mumps, rubella, nasal influenza, varicella, and yellow fever
3. The CDC's ACIP recommends the subunit vaccine (Shingrix) over the live vaccine (Zostavax), and that Shingrix can be administered to patients who have already received Zostavax. Patients receiving anti-TNFs, anti IL-12/23 or >20 mg prednisone should NOT be given the live zoster vaccine.
4. "Systemic immunopsuppression" currently includes azathioprine, mercaptopurine, methotrexate, anti-TNFs, anti-IL-12/23

ADDITIONAL INFORMATION

- ACG
- ACIP
- ACOG
- AGA
- NCI Skin Screen
- National Osteoporosis Foundation
- PHQ-9 Depression Survey
- US Preventive Services Task Force (USPSTF)



IBD Checklist for Monitoring & Prevention

Crohn's and Colitis Foundation Website. 2019. www.crohnscolitisfoundation.org/sites/default/files/2019-09/Health%20Maintenance%20Checklist%202019-3.pdf.
Cornerstones Health Website. https://www.cornerstoneshealth.org/ibd-checklists/.
Farraye FA, et al. *Am J Gastroenterol.* 2017;112:241-258.

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