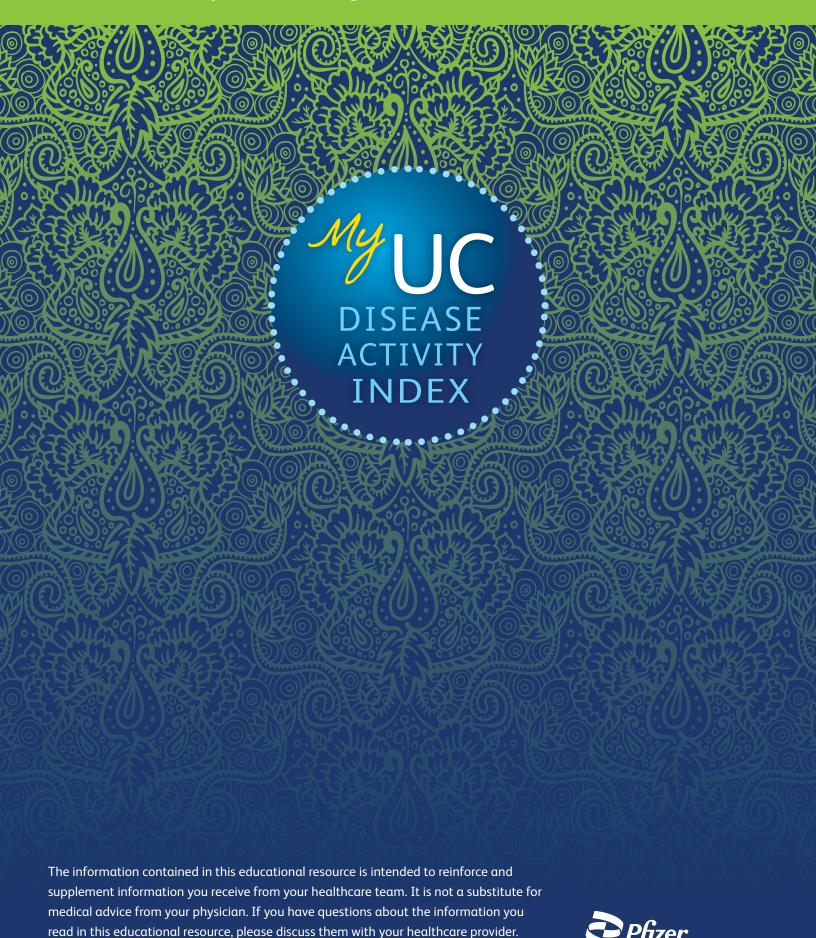
For adult patients being treated for ulcerative colitis (UC)



This has been produced as a patient education resource by Pfizer Inc.

nflammation & Immunology



Playing an Active Role in UC Disease Management

This educational resource is designed to support people with ulcerative colitis (UC). Using it will help you:

- Work with your doctor and healthcare treatment team to measure your level of UC disease activity
- Support a *Treat-to-Target (T2T) Management Strategy*—where you and your healthcare professional team work together to create a treatment plan.¹ While treatment targets for UC continue to be studied, it is important to work with your doctor to come up with a goal that is right for you²
- Improve communication between you and your healthcare team regarding your condition

Communication between patients and healthcare professionals is an important part of managing conditions such as UC.³ It may also help you become a more empowered patient. What does *patient empowerment* mean? It's a process intended to help patients work with their medical team to act on medical and lifestyle issues that they, together, define as important.⁴



The Proposed American College of Gastroenterology (ACG) Ulcerative Colitis Activity Index

The ACG is a leading professional society dedicated to improving the medical care of patients with digestive disorders such as UC.⁵

The ACG has developed a proposed measure—the **Ulcerative Colitis Activity Index**—which can help your healthcare team see how severe your UC is based on symptoms and diagnostic tests.^{6,7}

The proposed ACG index focuses on three symptoms that a patient with UC may experience: stool frequency, blood in stools, and urgency. There are other UC symptoms and physician-ordered tests that are not reflected in the proposed guidelines. All patients are different. People's symptoms and disease severity level may vary. Using the proposed ACG index, you can collect information on some of your symptoms—information that can serve as the basis for discussion with your healthcare team about your UC disease management plan.

Once a diagnosis of UC is made, you and your physician can work together to determine the activity and severity of your disease, which may be helpful in developing a disease management plan that is right for you. A healthcare professional may collect certain information—such as what is proposed by the ACG in the table below—to determine how you are doing.

Proposed ACG Ulcerative Colitis Activity Index^{6,7}

	REMISSION	MILD	MODERATE- SEVERE	FULMINANT
Stools (no./d)	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
FC (mg/g)	<150-200	>150-200	>150-200	>150-200
Endoscopy (Mayo subscore) ^a	0-1	1	2-3	3
UCEIS ^b	0-1	2-4	5-8	7-8

Information to share with your healthcare professional

Additional information that may be collected by your healthcare professional

CRP=C-reactive protein; ESR=erythrocyte sedimentation rate; FC=fecal calprotectin; UCEIS=Ulcerative Colitis Endoscopic Index of Severity. The above factors are general guides for disease activity. With the exception of remission, a patient does not need to have all the factors to be considered in a specific category.

"The Mayo score is a disease activity index typically used in clinical trial research."

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bSimilar to the Mayo score, the UCEIS diagnostic measurement is typically used in clinical trial research.

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Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114(3):384-413.7



Ulcerative Colitis Activity Index: What Patients May Track and Measure

The proposed ACG Ulcerative Colitis Activity Index offers important information for the healthcare team. Some of it is symptom-related information you can share with your physician related to⁷:

- **1. Stool frequency**—A measure of the number of times you have moved your bowels on a given day above normal.
- **2. Blood in stools**—The amount of visible blood appearing in your stool and the frequency with which you see it.
- **3. Urgency**—The uncontrollable feeling of having to go to the bathroom, how severe that feeling is, and how frequently it occurs.

Using the enclosed form, you can regularly track these symptoms and gather information for your healthcare team.

Consider bringing the completed form with you for all telehealth or in-office visits and sharing it with your healthcare provider.

Ulcerative Colitis Activity Index: What Healthcare Professionals May Track and Measure^{6,7}

Your healthcare professional may collect information to check your current condition and make treatment decisions. Generally speaking, the goal of UC treatment is to control the underlying inflammation and get your UC symptoms under control.⁹

Your doctor may order certain tests and procedures.

Refer to the glossary on the next page for more information on the items highlighted in the proposed ACG index that your doctor may use to assess your disease activity. Note that there are other tests your doctor may order that are not reflected in the proposed ACG index.

My Ulcerative Colitis Activity Index:

Patient-Reported Information to Share With Your Healthcare Professional

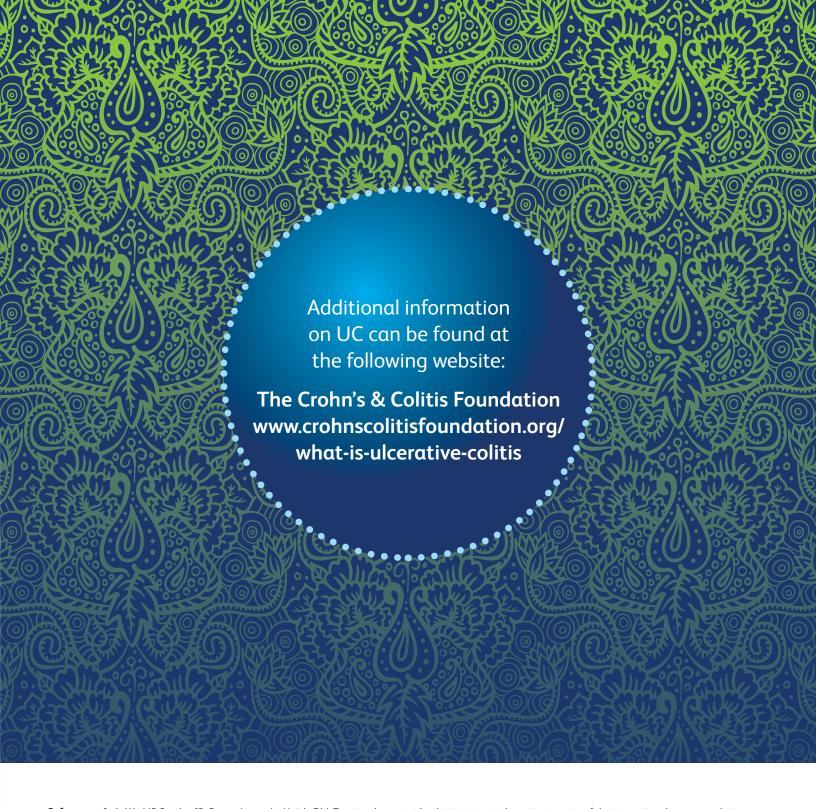


Use the enclosed form to regularly track your symptoms and gather information to share with your healthcare team. The information provides insights they can use to manage your condition and set your personal goals.

Glossary

CRP (C-reactive protein)	A type of blood test, this is a nonspecific marker of inflammation that may be used to complement the clinical assessment of UC disease activity. ⁷	
Endoscopy	The process of examining your colon through use of a lighted tube that is inserted into the anus. 10	
ESR (erythrocyte sedimentation rate)	A protein that may be elevated when inflammation is present. ¹¹	
FC (fecal calprotectin)	A nonspecific marker of inflammation that can be found in stool and which can be elevated in infectious and inflammatory colitis ⁷ ; it may be used in patients with UC as a noninvasive marker of disease activity and to measure treatment response and relapse.	
Hemoglobin	A measurement of this protein in a blood test can help identify the presence of anemia, which may result from UC-related blood loss. ¹⁰	
Mayo Score	A tool used in clinical trial research to evaluate symptoms and disease activity associated with UC.8	
UCEIS (Ulcerative Colitis Endoscopic Index of Severity)	A measurement tool sometimes used in clinical trials to assess UC-related disease activity identified through endoscopy. ⁷	

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References: 1. de Wit MP, Smolen JS, Gossec L, van der Heijde DM. Treating rheumatoid arthritis to target: the patient version of the international recommendations. Ann Rheum Dis. 2011;70(6):891-895. 2. Rubin DT, Krugliak Cleveland N. Using a treat-to-target management strategy to improve the doctor-patient relationship in inflammatory bowel disease. Am J Gastroenterol. 2015;110(9):1252-1256. 3. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. J Gen Intern Med. 2012;27(5):520-526. 4. WHO Guidelines on Hand Hygiene in Health Care First Global Patient Safety Challenge Clean Care is Safer Care. http://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf;jsessionid= 5A9DA78A0E4EDED8E0E4DF474BBA4234?sequence=1. Accessed November 10, 2020. 5. American College of Gastroenterology website. About ACG. https://gi.org/ about/. Accessed August 20, 2020. 6. Truelove SC, Witts LJ. Cortisone in ulcerative colitis; final report on a therapeutic trial. Br Med J. 1955;2(4947):1041-1048. 7. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114(3):384-413. 8. Lewis JD, Chuai S, Nessel L, Lichtenstein GR, Aberra FN, Ellenberg JH. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. Inflamm Bowel Dis. 2008;14(12):1660-1666. 9. Rubin DT, Dubinsky MC, Martino S, Hewett KA, Panes J. Communication between physicians and patients with ulcerative colitis: reflections and insights from a qualitative study of in-office patient-physician visits. Inflamm Bowel Dis. 2017;23(4):494-501. 10. Crohns & Colitis Foundation website. Ulcerative Colitis Diagnosis and Testing. https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/diagnosis-testing. Accessed November 10, 2020. 11. Turner D, Mack DR, Hyams J, et al. C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) or both? A systematic evaluation in pediatric ulcerative colitis. J Crohns Colitis. 2011;5(5):423-429.

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