IMPROVECARENOW™

Revised Definitions of Remission and Continuous Remission

Community Wide Webinar

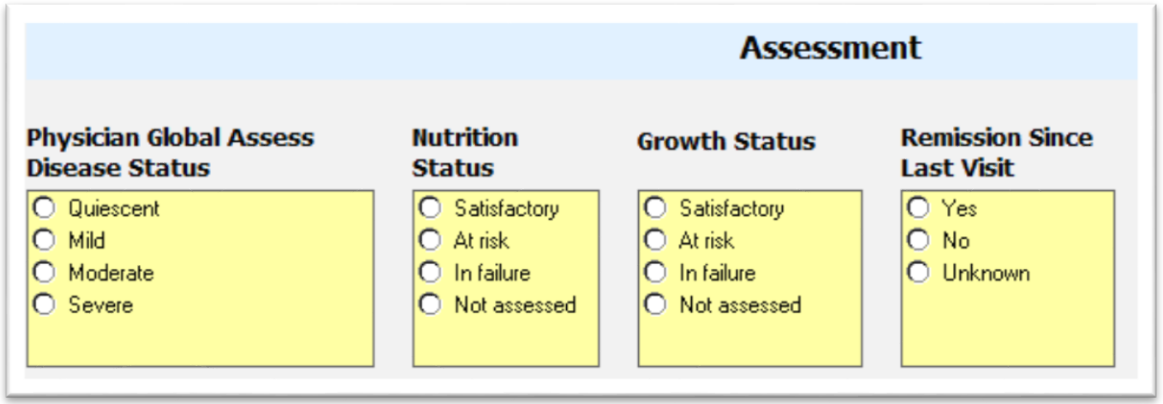
January 2020

Background

- March 2019, Spring Community Conference Sustained Remission Pathway discussion
- Steve Steiner asked to lead a sub-committee to develop a new definition/guidance
  - Brendan Boyle (Nationwide), Dick Colletti (ICN), Andrew Grossman (CHOP), Phil Minar (CCHMC)
- September 2019, Fall Community Conference
  - Update provided to SREM Learning Labs- Adherence and Clinical Standardization/Personalized care
  - Case study presentation during Physician role specific breakout
- Implement new definition/guidance – January 2020

New Guidance- Continuous Remission

Cerner Instructions



EPIC Smartform Instructions

Remission- ICN Definitions

- Provider response
  - Clinical Remission – a “visit” assessment
  - Continuous Remission – a “between visit” assessment

- Registry function
  - Sustained Remission – calculated from Clinical Remission and Continuous Remission responses

Clinical Remission

- Assessed at the time of every outpatient clinic visit
- A “snapshot” of clinical status
- Assessed via Physician Global Assessment (PGA)

Clinical Remission- Prior Version

ImproveCareNow Physician Global Assessment

Based on the information available, choose one category that best describes the overall disease activity

INACTIVE DISEASE	In the past week the patient has had minimal or no symptoms thought to be secondary to IBD
Abdominal pain Diarrhea, bloody stools Fatigue Activity	– Asymptomatic – Mild symptoms on one or two occasions that resolved spontaneously – Significant symptoms felt to be secondary to another disorder such as IBS or depression
Fistula	None, or a non-inflamed, indolent fistula with no or minimal drainage.
Weight loss	No unexplained wt loss
Abd mass, tenderness	None
Toxic appearance	No
Lab tests (if available)	Normal or minimal transient abnormalities

Clinical Remission- Revised

Quiescent IBD	In the past week the patient has had minimal or no symptoms thought to be secondary to IBD and no recent biochemical markers of active IBD
Abdominal pain Diarrhea Bloody stools Fatigue	Asymptomatic **–or-** Mild symptoms that resolved spontaneously **–or-** Significant symptoms felt to be secondary to another disorder (such as IBS, constipation, depression, or anxiety)
Fistula	None, or a non-inflamed, indolent fistula with no or minimal drainage
Weight loss	No unexplained weight loss (exclude weight loss after prednisone use)
Abdominal mass, tenderness	None (no new finding since last PE)
Toxic appearance	No
Blood tests*	No blood markers suggesting active disease
Stool inflammatory markers*	No stool markers suggesting active disease

*if performed in last 7 days

Continuous Remission

Since the previous visit, has the patient been in continuous remission? (select one):

☐ Yes ☐ No ☐ Don't know

Continuous Remission- Revised

Continuous Remission	Since the last visit…
PGA	Quiescent
Corticosteroids	No use of oral, rectal, or IV steroid
IBD medications/ treatments*	No significant medication intensification (exclude biologic or IMM dose adjustment based on weight gain or asymptomatic, subtherapeutic trough) –or- No medication addition secondary to active IBD *(does not include addition of MTX or 6MP 2nd to asymptomatic immunogenicity) No initiation of enteral therapy or exclusion diet as specific treatment for active IBD
IBD-related hospitalization/ED visit	None
IBD-related surgery	None
Laboratory markers	No blood or stool markers suggesting active disease
Growth	Absence of linear growth failure deemed secondary to active IBD
If the following were performed/obtained since the last clinic visit:	
Endoscopy	No significant endoscopic abnormalities consistent with active IBD
Abdominal imaging	No significant active inflammation, luminal narrowing, fistula, or abscess

*If biologic or IMM dose was intensified secondary to active IBD (endoscopic, abdominal imaging or biomarker change) then patient DOES NOT meet definition of continuous remission

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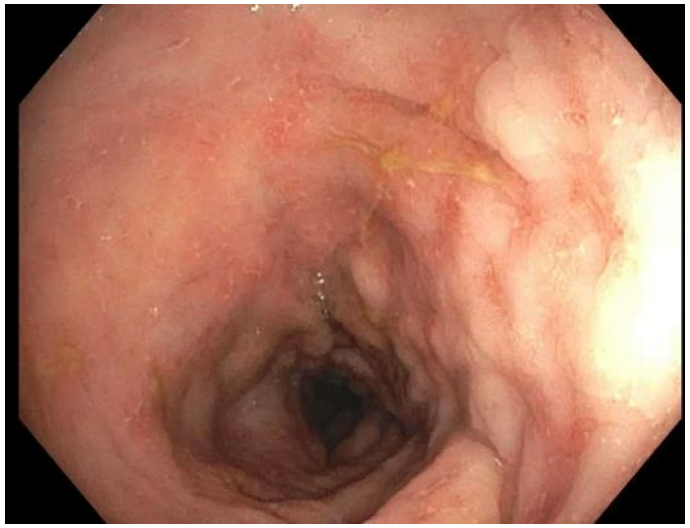
Case Review for PGA and Continuous Remission

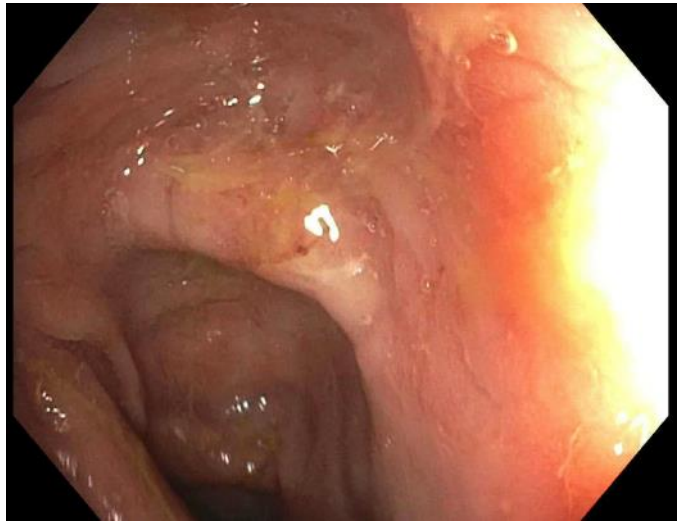
Case 1

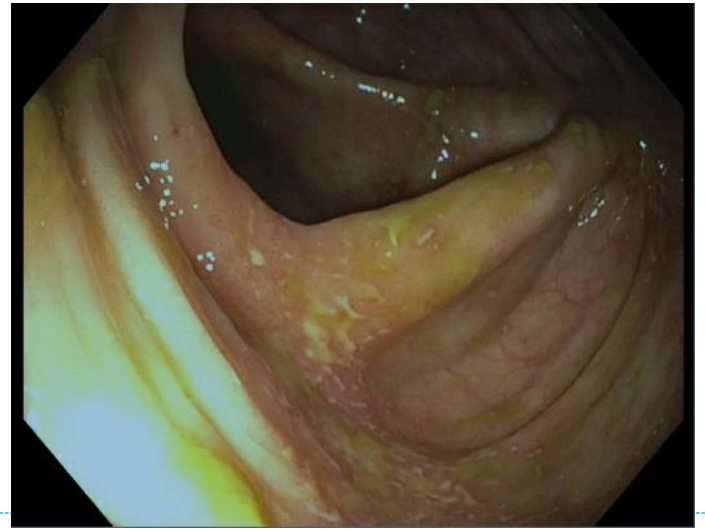
- 16 year old girl with ulcerative pancolitis
  - Mild to moderate pancolitis dx 2017 (PUCAI 30 at time)
  - Steroid and 5-ASA non-responsive
  - 01/2018: PUCAI 50 on prednisone, started infliximab
- Immediate response to IFX, but frequent break-through sx and CRP elevation until dose ↑ to 10 mg/kg q5
- Asymptomatic x 1 year, PUCAI=0, Hb 14.3, CRP <0.5, albumin 4.6, PLT 318

Case 1

- Surveillance scope:
  - Moderately ulcerated mucosa transverse and ascending colon, mildly inflamed cecum
  - Biopsies: Moderately active colitis







Case 1 clinic visit one week after procedure:

- Feels great, labs normal, scope with ongoing mild to moderate inflammation (not much different than initial scope)

- What is her Physician Global Assessment?
- Has she been in continuous remission since last visit?

Case 1 Recommendations

- What is Physician Global Assessment? = Quiescent
- Has the patient been in continuous remission? = No

- Patient is NOT in continuous remission because endoscopy since last clinic visit demonstrated evidence of active IBD

Case 2

- 16 yo girl with long-standing IBS diagnosed with UC
  - Initial scope: Confluent moderate chronic colitis to hepatic flexure
  - Failed 5-ASA/budesonide → Started infliximab
- Reports multiple ongoing GI sx, no bleeding, PUCAI = 30
- 1 recent ED visit, frequently late or misses school
- Labs and calprotectin WNL
- Repeat EGD/colonoscopy: Unremarkable except pseudopolyps at the hepatic flexure. Biopsies: no inflammation

Case 2 clinic visit one week after procedure:

- Feels terrible, recent ED eval, QOL very poor
- Labs and stool testing normal
- Colonoscopy with no active inflammation

- What is her Physician Global Assessment?
- Has she been in continuous remission since last visit?

Case 2 Recommendations

- What is Physician Global Assessment? = Quiescent
- Has the patient been in continuous remission? = Yes

- Patient's symptoms are consistent with IBS and there is no evidence of active IBD. Therefore PGA is quiescent and the patient has been in continuous remission

Case 3

- 12 yo girl with inflammatory ileocolonic Crohn's disease
  - Dx 3 year ago; weight loss, linear growth failure, IDA, albumin 3.3, CRP/ESR elevated, calprotectin 1250
- Treated with EEN x 8-12 weeks → clinical remission
  - Maintained on ~50% EN, 50% modified SCD
- Asymptomatic; normal Hb, albumin, ESR, CRP
- Good weight gain and linear growth
- Calprotectin consistently 250-450; 450 week before clinic visit

Case 3 clinic visit

- Feels great
- Labs normal
- Stool testing with consistently and recently elevated calprotectin
- Repeat colonoscopy refused

- What is her Physician Global Assessment?
- Has she been in continuous remission since last visit?

Case 3 Recommendations

- What is Physician Global Assessment? = Mild
- Has the patient been in continuous remission? = No

- Recent calprotectin is elevated, therefore PGA is mild and patient cannot be in continuous remission

Case 4

- 13 yo male dx with moderate ulcerative colitis 3 months ago after seen in outpatient GI clinic
  - Treated with oral prednisone and mesalamine after dx.
- Today in clinic he is feeling great
  - Labs have normalized since visit 2 months ago
  - Tapered prednisone, discontinued 10 days ago
  - PUCAI=5
- What is his Physician Global Assessment?
- Has he been in continuous remission since last visit?

Case 4 Recommendations

- What is Physician Global Assessment? = Quiescent
- Has the patient been in continuous remission? = No

- Patient currently quiescent, but due to recent steroid exposure since last visit, the patient is NOT in continuous remission

Next Steps

- Review with your clinic team
  - Recording will be available
  - Education packet will be sent after this call
- Respond to new narrative report questions in February regarding adoption of new guidance for patients
- Questions?
  - Email info@improvecarenow.org
  - Q&A during Remission and Sustained Remission Learning Lab calls