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)
### ImproveCareNow Physician Global Assessment

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

<table>
<thead>
<tr>
<th>Inactive Disease</th>
<th>In the past week the patient has had minimal or no symptoms thought to be secondary to IBD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>- Asymptomatic</td>
</tr>
<tr>
<td>Diarrhea, bloody stools</td>
<td>- Mild symptoms on one or two occasions that resolved spontaneously</td>
</tr>
<tr>
<td>Fatigue</td>
<td>- Significant symptoms felt to be secondary to another disorder such as IBS or depression</td>
</tr>
<tr>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>Fistula</td>
<td>None, or a non-inflamed, indolent fistula with no or minimal drainage</td>
</tr>
<tr>
<td>Weight loss</td>
<td>No unexplained wt loss</td>
</tr>
<tr>
<td>Abd mass, tenderness</td>
<td>None</td>
</tr>
<tr>
<td>Toxic appearance</td>
<td>No</td>
</tr>
<tr>
<td>Lab tests (if available)</td>
<td>Normal or minimal transient abnormalities</td>
</tr>
</tbody>
</table>
**Clinical Remission - Revised**

<table>
<thead>
<tr>
<th>Quiescent IBD</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>Asymptomatic –or-</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Mild symptoms that resolved spontaneously –or-</td>
</tr>
<tr>
<td>Bloody stools</td>
<td>Significant symptoms felt to be secondary to another disorder (such as IBS, constipation, depression, or anxiety)</td>
</tr>
<tr>
<td>Fatigue</td>
<td></td>
</tr>
<tr>
<td>Fistula</td>
<td>None, or a non-inflamed, indolent fistula with no or minimal drainage</td>
</tr>
<tr>
<td>Weight loss</td>
<td>No unexplained weight loss (exclude weight loss after prednisone use)</td>
</tr>
<tr>
<td>Abdominal mass, tenderness</td>
<td>None (no new finding since last PE)</td>
</tr>
<tr>
<td>Toxic appearance</td>
<td>No</td>
</tr>
<tr>
<td>Blood tests*</td>
<td>No blood markers suggesting active disease</td>
</tr>
<tr>
<td>Stool inflammatory markers*</td>
<td>No stool markers suggesting active disease</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Continuous Remission</th>
<th>Since the last visit…</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGA</td>
<td>Quiescent</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>No use of oral, rectal, or IV steroid</td>
</tr>
<tr>
<td>IBD medications/ treatments*</td>
<td>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 <em>(does not include addition of MTX or 6MP 2nd to asymptomatic immunogenicity)</em></td>
</tr>
<tr>
<td></td>
<td>No initiation of enteral therapy or exclusion diet as specific treatment for active IBD</td>
</tr>
<tr>
<td>IBD-related hospitalization/ED visit</td>
<td>None</td>
</tr>
<tr>
<td>IBD-related surgery</td>
<td>None</td>
</tr>
<tr>
<td>Laboratory markers</td>
<td><strong>No blood or stool markers suggesting active disease</strong></td>
</tr>
<tr>
<td>Growth</td>
<td>Absence of linear growth failure deemed secondary to active IBD</td>
</tr>
</tbody>
</table>

**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*
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