Adult Inflammatory Bowel Disease
Physician Performance Measures Set

Released for public comment
March 4, 2010
American Gastroenterological Association

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Purpose of Measures

These clinical performance measures were developed by the American Gastroenterological Association (AGA), using the Physician Consortium for Performance Improvement (PCPI) model for performance measure development, and are designed for use in individual quality improvement. The measures may also be used in data registries, continuing medical education (CME) programs, and board certification programs. Unless otherwise indicated, the measures are also appropriate for accountability if the necessary methodological, statistical, and implementation rules are met.

The measure titles listed below may be used for accountability:

<table>
<thead>
<tr>
<th>Measure #1</th>
<th>Measure #7</th>
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<tr>
<td>Assessment of inflammatory bowel disease activity and severity</td>
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<th>Measure #2</th>
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<tr>
<td>Counseling for steroid sparing therapy</td>
<td>Testing for Clostridium difficile-Inpatient measure</td>
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<th>Measure #3</th>
<th>Measure #9</th>
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<tr>
<td>Inflammatory Bowel Disease Preventive Care Composite</td>
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</tbody>
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<th>Measure #4</th>
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<td>Tobacco Use: Screening &amp; Cessation Intervention</td>
<td>Treatment Management</td>
</tr>
</tbody>
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<table>
<thead>
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<th>Measure #5</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Testing for latent TB before initiating anti-TNF therapy</td>
<td>Prophylaxis for Thromboembolism-Inpatient measure</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Measure #6</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Assessment for infection while on anti-TNF therapy</td>
<td>Assessment and Counseling for venous thromboembolism during IBD flare</td>
</tr>
</tbody>
</table>
Intended Audience, Care Setting, and Patient Population

These measures are designed for use by physicians and other eligible health professionals who provide care to individuals diagnosed with inflammatory bowel disease (IBD). The measures may be used in any of the various settings in which care may occur so long as the physician or eligible provider uses the appropriate ICD-9 and CPT® codes as described under each individual measure. The measures are intended to be used to calculate performance and/or to report measurement at the individual physician level.

Measure Specifications

The AGA seeks to specify measures for implementation using multiple data sources, including paper medical records, administrative (claims) data, Electronic Health Record Systems (EHRS) and registries. Specifications to report on the measures for Inflammatory Bowel Disease using administrative (claims) data are included in this document. The AGA has identified codes for these measures, including ICD-9 and CPT (Evaluation and Management and other Category I codes and, where applicable, Category II codes). Specifications for additional data sources, including EHRS and registries, will be fully developed at a later date.

Measure Exclusions

The AGA used the PCPI policy “Specification and categorization of measure exclusions: recommendations to PCPI work groups” as the basis for defining exclusions. (Available at: http://www.ama-assn.org/ama1/pub/upload/mm/370/exclusions053008.pdf Accessed February 2010). This methodology is described below.

For process measures, the PCPI provides three categories of reasons for which a patient may be excluded from the denominator of an individual measure:

Medical Reasons

Includes:
Not indicated (absence of organ/limb, already received/performe, other)
Contraindicated (patient allergy history, potential adverse drug interaction, other)

Patient Reasons

Includes:
Patient declined
Social or religious reasons
Other patient reasons

System Reasons

Includes:
Resources to perform the services not available
Insurance Coverage/Payer-related limitations
Other reasons attributable to health care delivery system
These measure exclusion categories are not available uniformly across all measures; for each measure, there must be a clear rationale to permit an exclusion for a medical, patient, or system reason. The exclusion of a patient may be reported by appending the appropriate modifier to the Category II code designated for the measure:

- **Medical reasons**: modifier 1P
- **Patient reasons**: modifier 2P
- **System reasons**: modifier 3P

Although this methodology does not require the external reporting of more detailed exclusion data, the PCPI recommends that physicians document the *specific* reasons for exclusion in patients’ medical records, for purposes of optimal patient management and audit-readiness. The PCPI also advocates for the systematic review and analysis of each physician’s exclusions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients whom physicians have identified as meeting the criteria for exclusion.

Please refer to the documentation for each individual measure for information on acceptable exclusion categories and the codes and modifiers to be used for reporting.

**Data Capture and Measure Calculation**

The intent of this measurement set is to encourage physicians to collect data on each patient eligible for a measure. Physicians should receive feedback on measures both at the patient level to facilitate patient management and in the aggregate to identify opportunities for improvement across a physician’s patient population.

Measure calculations will differ depending on whether a rate is being calculated for performance or reporting purposes.

The method of calculation for performance follows three steps. First, identify the patients who meet the eligibility criteria for the denominator (PD); second, identify which of those patients meet the numerator criteria (A); and third, for those patients who do not meet the numerator criteria, determine whether an appropriate exclusion applies and then subtract those patients from the denominator (C) (see examples below).

The methodology also enables implementers to calculate the rates of exclusions and to analyze further both low rates and high rates, as appropriate (see examples below).

The method of calculation for reporting differs. One program that currently focuses on reporting rates is the Centers for Medicare and Medicaid Services’ (CMS) Physician Quality Reporting Initiative (PQRI). Under that program’s current design, there is a reporting denominator determined solely from claims data (CPT and ICD-9), which in some cases results in a reporting denominator that is much larger than the eligible population for the performance denominator. Additional components of the reporting denominator are explained below.

The components that make up the numerator for reporting include all patients from the eligible population for which the physician has reported, including the number of patients who meet the numerator criteria (A), the number of patients for whom valid exclusions apply (C), and the number of patients who do not meet the numerator criteria (D). These components, where applicable, are summed to make up the inclusive reporting numerator. The calculation for reporting will be the reporting numerator divided by the reporting denominator (see examples below).

Examples of calculations for reporting and performance are provided for each measure.
**Calculation for Performance**

For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

- **Numerator (A)** Includes: Number of patients meeting numerator criteria
- **Performance Denominator (PD)** Includes: Number of patients meeting criteria for denominator inclusion
- **Denominator Exclusion (C)** Includes: Number of patients with valid medical, patient, or system exclusions (where applicable; will differ by measure)

**Performance Calculation**

It is also possible to calculate the percentage of patients either excluded overall or excluded by medical, patient, or system reason where applicable:

- **Overall Exclusion Calculation**
- **Exclusion Calculation by Type**

**Calculation for Reporting**

For reporting purposes, this measure is calculated by creating a fraction with two components: Reporting Numerator and Reporting Denominator.

- **Reporting Numerator** includes each of the following components, where applicable. (There may be instances where there are no patients to include in A, C, D, or E.)
  - A. Number of patients meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9 and CPT Category I coding alone) AND numerator criteria
  - C. Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)
  - D. Number of patients not meeting numerator criteria and without a valid exclusion

\[
\frac{A \text{ (# of patients meeting numerator criteria)}}{PD \text{ (# of patients in denominator)}} - \frac{C \text{ (# of patients with valid denominator exclusions)}}{PD \text{ (# of patients in denominator)}}
\]

\[
\frac{C \text{ (# of patients with any valid exclusion)}}{PD \text{ (# of patients in denominator)}}
\]

\[
\frac{C1 \text{ (# patients with medical reason)}}{PD \text{ (# patients in denominator)}}
\]

\[
\frac{C2 \text{ (# patients with patient reason)}}{PD \text{ (# patients in denominator)}}
\]

\[
\frac{C3 \text{ (# patients with system reason)}}{PD \text{ (# patients in denominator)}}
\]
E. All other patients not meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9 and CPT Category I coding alone)

**Reporting Denominator (RD) Includes:**
- RD. Denominator criteria (identifiable through ICD-9 and CPT Category I coding)

**Reporting Calculation**

\[
A \left( \text{# of patients meeting additional denominator criteria AND numerator criteria} \right) + C \left( \text{# of patients with valid exclusions} \right) + D \left( \text{# of patients NOT meeting numerator criteria} \right) + E \left( \text{# of patients not meeting additional denominator criteria} \right) \\
------------------------
RD \left( \text{# of patients in denominator} \right)
\]

**Burden of Illness (Mortality and Morbidity)**

The two inflammatory bowel disease (IBD) conditions are Crohn's disease (also known as regional enteritis) and ulcerative colitis (UC). Indeterminate colitis (IC) is the diagnosis assigned when it is unclear if a patient has Crohn's or UC.

Crohn's disease and ulcerative colitis (collectively known as inflammatory bowel diseases) are chronic disorders of the gastrointestinal tract which afflict approximately 1.4 million Americans, 30% of whom are diagnosed in their childhood years.

The Center for Disease Control notes “IBD is one of the five most prevalent gastrointestinal disease burdens in the United States, with an overall health care cost of more than 1.7 billion. This chronic condition is without a medical cure and commonly requires a lifetime of care. Each year in the United States, IBD accounts for over 700,000 physician visits, 100,000 hospitalizations, and disability in 119,000 patients. Over the long term, up to 75% of patients with Crohn's disease and 25% of those with ulcerative colitis will require surgery.

“The most common complication of Crohn’s disease is blockage of the intestine due to swelling and scar tissue. Symptoms of blockage include cramping pain, vomiting and bloating. Another complication is sores or ulcers within the intestinal tract. Sometimes these deep ulcers turn into tracts—called fistulas. In 30% of people with Crohn’s disease, these fistulas become infected. Patients may also develop a shortage of proteins, calories, or vitamins. They generally do not develop unless the disease is severe and of long duration. Until recently an increased risk of cancer was thought to exist mainly for ulcerative colitis patients, but it is now known that Crohn's patients have an increased risk of colon cancer as well.”

The five groups of drugs used to treat Crohn’s disease today are aminosalicylates (5-ASA), steroids, immune modifiers (azathioprine, 6-MP, and methotrexate), antibiotics (metronidazole, ampicillin, ciprofloxin, others) and biologic therapies (inflixamab, adalimumab, certolizumab, natalizumab). Two-thirds to three-quarters of patients with Crohn's disease will require surgery at some point during their lives. Surgery becomes necessary in Crohn’s disease when medications can no longer control the symptoms.

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Complications of ulcerative colitis are less frequent than in Crohn’s disease. Complications can include bleeding from deep ulcerations, rupture of the bowel or failure of the patient to respond to the usual medical treatments. Patients with ulcerative colitis are at increased risk of colon cancer.

The four major classes of medication used today to treat ulcerative colitis are: aminosalicylates (5-ASA), steroids, immune modifiers (azathioprine and 6-MP) and biologics (infliximab). In one-quarter to one-third of patients with ulcerative colitis, medical therapy is not completely successful or complications arise. Under these circumstances, surgery may be considered. This operation involves the removal of the colon (colectomy). Unlike Crohn’s disease, which can recur after surgery, ulcerative colitis is "cured" once the colon is removed.

Most care for these chronic diseases occurs in the outpatient setting, with hospitalizations reserved for complications that might require surgery. Mortality is relatively uncommon, such that death due to GERD is more common than death due to IBD. The significant suffering from IBD is not captured well in such statistics.³

### Prevalence/Incidence

The annual incidence rate per 100,000 persons was 6.3 for CD (95% confidence interval [CI], 5.6-7.0) and 12.0 for UC (CI, 11.0-13.0). The point prevalence per 100,000 on December 31, 2002 was 96.3 for CD (95% CI, 89.6-103.0) and 155.8 for UC (95% CI, 146.6-164.9), increasing to 100.3 and 205.8 per 100,000, respectively, when hospital discharge data from 1985 to 1995 were included. The age-specific incidence of CD was bimodal, while UC incidence rose in early adulthood and remained elevated with advancing age. Herrinton and colleagues concluded “The incidence we estimated for CD was similar to the previous U.S. estimate. Our incidence estimate for UC was much higher than the previous U.S. estimate, but similar to that of recent Canadian and European studies. The prevalence we estimated for CD was somewhat lower than previous estimates.”⁴

### Burden of Illness (Cost)

The Crohn’s and Colitis Foundation (CCFA) notes “According to a 1990 study, the medical costs of IBD in the U.S. totaled $1.4-$1.8 billion annually. Surgery and inpatient care were estimated to account for roughly one-half of this amount. The disability costs of illness (lost labor productivity) were estimated to be $0.4-$0.8 billion, making the total estimated annual cost of IBD $1.8-$2.6 billion.”⁵ In 2004 the combined direct and indirect costs of IBD were 2,166.9 million dollars.⁶

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Potential of IBD Performance Measurement Set to Improve Health Outcomes

IBD is a complex chronic condition associated with significant health, lifestyle and cost burdens on patients and their families. Management of Crohn’s and UC require medications with major side effects which also must be considered by physicians and other healthcare professionals caring for them. Many endure episodes of long term corticosteroid use potentially resulting in infections and glaucoma. Those with IBD are at risk for developing osteoporosis; additionally treatment with corticosteroids can contribute to this complication. As immunomodulators and biologics are now treatment options, it is important that providers attempt to shift treatment of individual patients to steroid sparing alternatives, thereby limiting their exposure to corticosteroids. A performance measurement set for IBD has the potential to increase patient safety, improve treatment, increase the use of steroid sparing treatments, and complications of various treatments.

The AGA and the CCFA worked collaboratively in the development of these measures. AGA members also are participating with the CCFA to develop practice quality indicators for practices caring for those with IBD. The difference in these measures sets is that the CCFA set is geared towards quality improvement, while those presented here are designed to be used for accountability and performance measurement.

Variability in Clinical Practice

Management of IBD is a complex and dynamic process as patients move in and out of remission. As flare ups occur, treatments and their potential complications require prompt attention and adjustments to treatment protocols. Treatment can occur in a variety of settings, and it is not uncommon to require multiple specialists including gastroenterologists, surgical specialists, internal medicine / family practice / pediatrics, infectious disease, endocrinologists, behavioral health professionals, and dieticians / nutritionists.

Healthcare professionals vary in their skill and approach to treatment and management of inflammatory bowel disease including risk assessment for occult infections and preventive maintenance monitoring. A uniform performance measurement set is needed to clarify these roles and to determine how best to establish evidence-based standards of care.

Available Evidence

Numerous recommendations for performance measures exist that could easily be applied by gastroenterologists and other health professionals. In addition, there are multiple sources of nationally and internationally accredited guidelines available. The major guideline-producing entities are the American Gastroenterological Association (AGA), American College of Gastroenterology (ACG) and Crohn’s and Colitis Foundation of America (CCFA). The performance measures found in this document have been developed using these guidelines, enabling the physician to track his or her performance in individual patient care across patient populations. Please note that the provision of inflammatory bowel disease care must be based on individual patients’ needs and the clinician’s professional judgment. Performance measures are not to be used as a substitute for clinical guidelines or individual physician clinical judgment. There may be instances where the age of an individual patient lies beyond the age range identified for the performance measure(s); however, this does not preclude the patient from receiving the service. Whether or not a patient should receive specific care is a decision that needs to be made between the patient and the physician while weighing the risks and benefits of the service with individual patient preference.

A major goal for the development of these measures is to help health care professionals to transition from measures of processes to measures around improving outcomes.
The two inflammatory bowel diseases (IBD) are Crohn’s disease (also known as regional enteritis) and ulcerative colitis (UC).

Indeterminate colitis is the diagnosis assigned when it is unclear if a patient has Crohn’s or UC.

IBD ...................... Inflammatory Bowel Disease
CD  ...................... Crohn’s Disease
UC  ...................... Ulcerative Colitis
CDC ....................... Centers for Disease Control
CMS  ....................... Centers for Medicare and Medicaid Services
AMA ....................... American Medical Association
CPT ....................... Current Procedural Terminology
ICD ....................... International Classification of Diseases
AGA ....................... American Gastroenterological Association
ACG ....................... American College of Gastroenterology
ASGE ..................... American Society for Gastrointestinal Endoscopy
CCFA ..................... Crohn’s and Colitis Foundation of America
CDAD .................... *Clostridium difficile* associated disease
CRC ....................... Colorectal cancer
PSC ....................... Primary sclerosing cholangitis
TB  ....................... Tuberculosis
TST  ....................... Tuberculin skin test
LTBI ....................... Latent tuberculosis infection
IGRA ..................... Interferon gamma release assay
T-SPOT.TB .......... *In vitro* diagnostic test that measures T cells specific to *Mycobacterium tuberculosis* (MTB) antigens
TNF ....................... Tumor-necrosis factor
LMWH  .................... Low molecular weight heparin
LDUH  .................... Low dose unfractionated heparin
VTE  ....................... Venous thromboembolism
Measure #1: Assessment of inflammatory bowel disease activity and severity

This measure may be used as an Accountability measure

**Clinical Performance Measure**

<table>
<thead>
<tr>
<th>Numerator:</th>
<th>Patient visits with documented assessment of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a. Type of Inflammatory Bowel Disease (Crohn’s, UC or Indeterminate Colitis);</td>
</tr>
<tr>
<td></td>
<td>b. Anatomic location of disease based on current or historic endoscopic and/or radiologic data;</td>
</tr>
<tr>
<td></td>
<td>c. Luminal Disease activity (quiescent, mild, moderate, severe) and presence of extraintestinal manifestations</td>
</tr>
</tbody>
</table>

| Denominator: | All patient visits of patients age 18 years or over with a diagnosis of inflammatory bowel disease. |

<table>
<thead>
<tr>
<th>Denominator Exclusions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation of patient reason(s) for not documenting any or all assessments (e.g., patient refuses on endoscopic and/or radiologic assessment)</td>
</tr>
</tbody>
</table>

**Measure:** Percentage of visits of patients aged 18 years and older with a diagnosis of inflammatory bowel disease with a documented assessment of disease type, anatomic location, and activity.

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

After the diagnosis of UC or CD has been confirmed, the disease extent should be defined, because it determines the best route for therapy. For UC the extent is defined as the proximal margin of macroscopic inflammation, because this is most clearly related to the risk of complications, including dilatation and cancer. The implications of limited macroscopic disease with extensive microscopic inflammation remain unclear. For CD both small bowel and colon should be assessed. (Carter MJ, Lobo AJ, Travis SPL. Guidelines for the management of inflammatory bowel disease in adults. Gut 2004;53:v1-v16; doi:10.1136/gut.2004.043372)

Therapeutic options are determined by an assessment of the disease location, severity, and extraintestinal complications. In the absence of a “gold standard” for the measurement of disease activity, severity is established on clinical parameters, systemic manifestations, and the global impact of the disease on the individual’s quality of life (44,78,79). (Lichtenstein, GR et al. Management of Crohn’s Disease in Adults. Am J Gastro 2009)

After the diagnosis of UC is confirmed, the anatomic extent is assessed endoscopically. The key question to be addressed at this point is whether the inflammation is “distal” (i.e., limited to below the descending colon and hence within reach of topical therapy) or extends proximal to the descending colon, requiring systemic medication. Therefore, a delineation of the proximal margin of inflammation, if not achieved on initial evaluation, is desirable at some point once the patient’s condition permits. From a practical standpoint, the endoscopic extent and clinical severity of an acute attack determine the approach to therapy. Importantly, a flare-up during which distal disease extends proximally is often a severe episode with the need for early aggressive therapy (51). Although therapeutic decisions are rarely based on histologic severity of inflammation, histology may well be taken into account when planning a surveillance regimen (see below). Based on clinical and endoscopic findings, the severity and extent of the disease are characterized. Severity may be classified as mild, moderate, severe, or fulminant (52,53). (Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters for Committee. Am J Gastro, 2010)

In addition to the evaluation of colitis extent and activity, a global assessment of the patient should include
attention to general health concerns, and quality of life issues that may be influenced by colitis activity as well as by extraintestinal manifestations (EIMs) of the disease. (Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters for Committee. Am J Gastro, 2010)

Rationale for the Measure:
Therapeutic options are determined by an assessment of the disease location, severity, and extraintestinal complications. In the absence of a “gold standard” for the measurement of disease activity, severity is established on clinical parameters, systemic manifestations, and the global impact of the disease on the individual’s quality of life (44,78,79). (Lichtenstein, GR et al. Management of Crohn’s Disease in Adults. Am J Gastro 2009)

Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
Patient visits with documented assessment of:
  a. Type of Inflammatory Bowel Disease (Crohn’s, UC or Indeterminate Colitis);
  b. Anatomic location of disease based on current or historic endoscopic and/or radiologic data;
  c. Luminal Disease activity (quiescent, mild, moderate, severe) and presence of extraintestinal manifestations

Performance Denominator (PD) Includes:
All patient visits of patients age 18 years or over with a diagnosis of inflammatory bowel disease.

Denominator Exclusions (C) Include:
  • Documentation of patient reason for not documenting type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations in the medical record

Performance Calculation
\[
A \left( \text{# of patient visits meeting measure criteria} \right) / \left( \text{PD (} \text{# of patients visits in denominator)} – C \left( \text{# of patient visits with valid denominator exclusions} \right) \right)
\]

Components for this measure are defined as:
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient visits with type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations documented in the medical record</td>
</tr>
<tr>
<td>PD</td>
<td># of patient visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease</td>
</tr>
<tr>
<td>C</td>
<td># of patient visits for patients with valid patient reason(s) for not documenting type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations</td>
</tr>
</tbody>
</table>

**Calculation for Reporting**

For reporting purposes, this measure is calculated by creating a fraction with the following components: **Reporting Numerator** and **Reporting Denominator**.

**Reporting Numerator includes each of the following instances:**

A. Patient visits with documented assessment of:
   a. Type of Inflammatory Bowel Disease (Crohn’s, UC or Indeterminate Colitis);
   b. Anatomic location of disease based on current or historic endoscopic and/or radiologic data;
   c. Luminal Disease activity (quiescent, mild, moderate, severe) and presence of extraintestinal manifestations

C. Patient visits with documentation of patient reason for not documenting type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations.

D. Patient visits with no documentation of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations and there is no documented reason for not doing so.

**Reporting Denominator (RD) Includes:**

RD. All visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease.

**Reporting Calculation**

\[
\text{Sample calculation: } \frac{A + C + D}{RD}
\]

**Components for this measure are defined as:**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient visits with type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations documented in the medical record</td>
</tr>
<tr>
<td>C</td>
<td># of patients visits with documentation of patient reason for not documenting the type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations</td>
</tr>
<tr>
<td>D</td>
<td># of patients visits with no documentation of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations</td>
</tr>
<tr>
<td>RD</td>
<td># of patient visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease.</td>
</tr>
</tbody>
</table>
Measure Specifications - Assessment of inflammatory bowel disease activity and severity
Measure specifications for data sources other than administrative claims will be developed at a later date.

A. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).
(Note: The specifications listed below are those needed for performance calculation.)
Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

CPT® Procedure Codes: 99201, 99202, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99251, 99252, 99253, 99254, 99255, 99354, 99355, 99356, 99357, G0406, G0407, G0408, G0425, G0426, G0427

AND

ICD-9 diagnosis codes: 555, 556

Numerator: Patient with documentation of type of IBD, anatomic location, luminal disease activity and presence of extraintestinal manifestations

Report the CPT Category II, Assessment of inflammatory bowel disease activity and severity in development designated for this numerator XXXX.

Denominator Exclusion: Documentation of patient reason(s) for not recording type of IBD, anatomic location, luminal disease activity and presence of extraintestinal manifestations

Append modifier to CPT Category II code: XXXX-2P

B. Electronic Health Record System and Registry (to be developed at a later date)
Measure #2: Counseling for steroid sparing therapy

This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Clinical Performance Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator:</strong> All patients with documented steroid use (defined as oral steroids (prednisone and budesonide) and/or intravenous steroids (methylprednisolone and hydrocortisone) used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) in the last year with documentation of counseling regarding steroid sparing therapy.</td>
</tr>
<tr>
<td><strong>Denominator:</strong> All patients aged 18 years and older with inflammatory bowel disease.</td>
</tr>
<tr>
<td><strong>Denominator Exclusions:</strong> Documentation of medical reason(s) for not counseling regarding steroid sparing therapy (e.g., when the benefits of continuing steroid therapy outweigh the risk of weaning patient off steroids)</td>
</tr>
</tbody>
</table>

Prednisone equivalents can be determined using the following: 1 mg of prednisone = 1 mg of prednisolone; 5 mg of cortisone; 4 mg of hydrocortisone; 0.8 mg of triamcinolone; 0.8 mg of methylprednisolone; 0.15 mg of dexamethasone; 0.15 mg of betamethasone

**Measure:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been treated with steroids in the last year that have been counseled regarding steroid sparing therapy.

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Long-term treatment with corticosteroids is undesirable. Patients with chronic active corticosteroid-dependent disease (either CD or UC) should be treated with AZA 2.0 to 3.0 mg/kg/day or 6-MP 1.0 to 1.5 mg/kg/day in an effort to lower or preferably eliminate corticosteroid use. Infliximab is another option in this situation, as is combination infliximab/antimetabolite therapy. (Grade A) (American Gastroenterological Association Institute. American Gastroenterological Association Institute Medical Position Statement on Corticosteroids, Immunomodulators, and Infliximab in Inflammatory Bowel Disease. Gastroenterology, 2006;130:935–939.)

Individual patients with either CD or UC who experience a severe flare of disease requiring corticosteroid treatment or require re-treatment during the year with another course of corticosteroids should be considered for initiation of therapy with AZA 2.0 to 3.0 mg/kg/day or 6-MP 1.0 to 1.5 mg/kg/day in an effort to avoid future corticosteroid use. Infliximab is another option in this situation, as is combination infliximab/antimetabolite therapy. (Grade C) (American Gastroenterological Association Institute. American Gastroenterological Association Institute Medical Position Statement on Corticosteroids, Immunomodulators, and Infliximab in Inflammatory Bowel Disease. Gastroenterology, 2006;130:935–939.)

Conventional corticosteroids are not efficacious in maintenance treatment of patients with CD (Grade A) or patients with UC (Grade B). (American Gastroenterological Association Institute. American Gastroenterological Association Institute Medical Position Statement on Corticosteroids, Immunomodulators, and Infliximab Inflammatory Bowel Disease. Gastroenterology, 2006;130:935–939.)

Corticosteroids should not be used to maintain remission (EL1a, RG A) (European Crohn's and Colitis Organisation (ECCO, 2006). European evidence based consensus on the diagnosis and management of Crohn's disease: current management. Gut. 2006 Mar; 55 Suppl 1:i16-35.)

Conventional corticosteroids should not be used as long-term agents to prevent relapse of CD (Grade A). Budesonide at a dose of 6 mg / day reduces the time to relapse in ileal and / or right colonic disease, but
does not provide significant maintenance benefits after 6 months (Grade A). Azathioprine / 6-
mercaptopurine (Grade B) and methotrexate (Grade B) have demonstrable maintenance benefits after
inductive therapy with corticosteroids. (Lichtenstein, GR et al. Management of Crohn’s Disease in Adults.
Am J Gastro 2009)

This is the first report from the TREAT Registry, a large, prospective, observational research program
designed to address the long-term safety of medications, including infliximab, for the treatment of CD.
After adjustment for confounding factors including disease severity and the use of other medications, the
risk for serious infection or death with infliximab use was similar to that observed with the use of
conventional immunomodulators, and was not higher than the overall incidence of serious infections
among all CD patients. The use of prednisone was a strong independent risk factor for both serious
infection and death. Likewise, the use of narcotic analgesics also was associated with a significantly
increased risk for serious infection. (Lichtenstein GR, Feagan BG, Cohen RD, Salzberg BA, Diamond RH,
Chen DM, Pritchard ML, Sandborn WJ. Serious infections and mortality in association with therapies for

Rationale for the Measure:

Thirty to forty percent of patients with moderate to severe IBD have steroid dependent disease. That
means that they are unable to taper off steroids without experiencing a flare up. (Crohn’s and Colitis
Foundation of America, Corticosteroids, Special Considerations. www.ccfa.org, January 16, 2009).

A retrospective study examined whether the treatment of Crohn’s disease (CD) and ulcerative colitis
(UC) with immunosuppressant medications was associated with an increased risk of death prior to
antitumor necrosis factor therapies. The authors found that patients with both CD and UC are at
increased risk of death during periods of current Corticosteroid use. In contrast, current treatment with
thiopurines was not associated with an increased risk of death. (Lewis J, et al Immunosuppressant
Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
All patients with documented steroid use (defined as oral steroids (prednisone and budesonide) and/or intravenous steroids (methylprednisolone and hydrocortisone) used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) in the last measurement year with documentation of counseling regarding steroid sparing therapy.

Performance Denominator (PD) Includes:
All patients age 18 years or over with a diagnosis of inflammatory bowel disease
Denominator Exclusions (C) Include:
• Documentation of medical reason(s) for not counseling regarding steroid sparing therapy

Performance Calculation

\[
\frac{A \ (# \ of \ patient \ meeting \ measure \ criteria)}{PD \ (# \ of \ patients \ in \ denominator) - C \ (# \ of \ patient \ with \ valid \ denominator \ exclusions)}
\]

Components for this measure are defined as:

<table>
<thead>
<tr>
<th>A</th>
<th># of patient with documented steroid use in the last year with documentation of counseling regarding steroid sparing therapy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD</td>
<td># of patient for patients age 18 years or over with a diagnosis of inflammatory bowel disease.</td>
</tr>
<tr>
<td>C</td>
<td># of patient with documentation of medical reason(s) for not counseling regarding steroid sparing therapy.</td>
</tr>
</tbody>
</table>

Calculation for Reporting
For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

Reporting Numerator includes each of the following instances:

A. All patients with documented steroid use (defined as oral steroids (prednisone and budesonide) and/or intravenous steroids (methylprednisolone and hydrocortisone) used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) in the last measurement year with documentation of counseling regarding steroid sparing therapy.

C. Patients with documentation of medical reason for not counseling regarding steroid sparing therapy

D. Patients with no documentation of counseling regarding steroid sparing therapy and there is no documented reason for not doing so.

Reporting Denominator (RD) Includes:
RD. All patients age 18 years or over with a diagnosis of inflammatory bowel disease.

### Reporting Calculation

A (# of patient meeting numerator criteria) + C (# of patient with valid exclusions) + D (# of patient NOT meeting numerator criteria)

RD (# of patient in denominator)

### Components for this measure are defined as:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patients with documented steroid use in the last year with documentation of counseling regarding steroid sparing therapy.</td>
</tr>
<tr>
<td>C</td>
<td># of patients with documentation of medical reason(s) for not counseling regarding steroid sparing therapy.</td>
</tr>
<tr>
<td>D</td>
<td># of patients with documented steroid use in the last calendar year and no documentation of counseling regarding steroid sparing therapy.</td>
</tr>
<tr>
<td>RD</td>
<td># of patients for patients age 18 years or over with a diagnosis of inflammatory bowel disease.</td>
</tr>
</tbody>
</table>
Measure Specifications - Counseling for steroid sparing therapy
Measure specifications for data sources other than administrative claims will be developed at a later date.

### C. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

- CPT® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99251, 99252, 99253, 99254, 99255, 99256, 99257, G0406, G0407, G0408, G0425, G0426, G0427
- AND
  - ICD-9 diagnosis codes: 555,556

Numerator: Patient with documentation of counseling regarding steroid sparing therapy

Report the CPT Category II, *Counseling for steroid sparing therapy* in development designated for this numerator XXXX.

Denominator Exclusion: Documentation of medical reason(s) for not counseling regarding steroid sparing therapy.

Append modifier to CPT Category II code: XXX-1P

| Electronic Health Record System and Registry (to be developed at a later date) |
Measure #3: Inflammatory Bowel Disease Preventive Care Composite

This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Numerator:</th>
<th>Patients for which:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>current/up to date influenza and pneumococcal immunizations as recommended by current CDC immunization guidelines are documented; and</td>
</tr>
<tr>
<td>b.</td>
<td>discussion about avoidance of live vaccines in IBD patients receiving immunosuppression therapy is documented; and</td>
</tr>
<tr>
<td>c.</td>
<td>assessment of risk for bone loss is documented once per measurement year.</td>
</tr>
</tbody>
</table>

| Denominator: | Patients aged 18 years and older with a diagnosis of inflammatory bowel disease. |

<table>
<thead>
<tr>
<th>Denominator Exclusions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation of medical reason(s) for not documenting any or all preventive care components (e.g., patient not receiving immunosuppression therapy)</td>
</tr>
<tr>
<td>Documentation of patient reason(s) for not documenting any or all preventive care components (e.g., patient refusal)</td>
</tr>
</tbody>
</table>

| Measure: | Percentage of patients aged 18 years and older with inflammatory bowel disease for whom current influenza and pneumococcal immunizations are documented; and discussion about avoidance of live vaccines is documented in patients receiving immunosuppression therapy; and assessment of risk for bone loss is documented once per measurement year. |

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Persons who have conditions associated with decreased immunologic function that increase the risk for severe pneumococcal disease or its complications should be vaccinated. Although the vaccine is not as effective for immunocompromised patients as it is for immunocompetent persons, the potential benefits and safety of the vaccine justify its use.

The vaccine is recommended for persons in the following groups: immunocompromised persons aged ≥2 years, including persons with HIV infection, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression (e.g., organ or bone marrow transplantation); and persons receiving immunosuppressive chemotherapy, including long-term systemic corticosteroids. If earlier vaccination status is unknown, immunocompromised persons should be administered pneumococcal vaccine.


Vaccination to prevent influenza is particularly important for the following persons, who are at increased risk for severe complications from influenza, or at higher risk for influenza-related outpatient, ED, or hospital visits:

- all children aged 6 months--4 years (59 months);
- all persons aged 50 years;
- children and adolescents (aged 6 months--18 years) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- women who will be pregnant during the influenza season;
- adults and children who have chronic pulmonary (including asthma) or cardiovascular (except hypertension), renal, hepatic, neurological/neuromuscular, hematologic, or metabolic disorders

Routine vaccination status should be reviewed (62). In patients on immunosuppressants, live vaccines are contraindicated, so if these are required they should be administered at the time of UC diagnosis. However, patients on immunosuppressant drugs can and should be vaccinated routinely for influenza and pneumococcal infection, and for tetanus and meningococcus in the appropriate settings (63 – 65). (Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters for Committee. Am J Gastro 2010)

IBD has only a modest effect on BMD, with a pooled Z score of _0.5 (level evidence). Corticosteroid use is the variable most strongly associated with osteoporosis (level evidence). However, it is difficult to distinguish corticosteroid use from disease activity in terms of causal impact on bone density, because the 2 are closely linked. (AGA, American Gastroenterological Association Medical Position Statement: Guidelines on Osteoporosis in Gastrointestinal Diseases, 2003)

As noted above, patients with IBD would not be considered to be immune compromised in the absence of severe malnutrition or medical immune suppression. High dose prednisone therapy may be considered a contraindication in the use of live-virus vaccines. Most patients with steroid dependent or refractory IBD respond well to other immunosuppressive agents and are weaned effectively off of corticosteroids.

However, recent trends in the use of steroid-sparing agents such as azathioprine and 6-mercaptopurine are to use higher, more effective doses, whereas the doses of methotrexate used in IBD are often higher than those used for rheumatoid arthritis, psoriasis, or asthma. Consequently, one may not assume the safety of live vaccines in patients treated with these agents. Sands BE, Cuffari C, Katz J, et al Guidelines for Immunizations in Patients With Inflammatory Bowel Disease. Inflammatory Bowel Diseases, Volume 10, Issue 5. 677-692.

However there is strong evidence that those on long-term steroids of greater than 3 months have a significant increase risk of fracture (Papaioannou A. et al. All Patients with Inflammatory Bowel Disease Should Have Bone Density Assessment: Pro. Inflammatory Bowel Diseases. 2001. 7(2): 158-162)

Data on the treatment of osteoporosis in Crohn’s disease depend on studies that are not specific to IBD. The evidence levels and recommendation grades are accordingly marked down. Weight bearing, isotonic exercise [EL2b, RG B], stopping smoking [EL3b, RG C], avoiding alcohol excess [EL4, RG D], and maintaining adequate dietary calcium (>1 g/day) [EL2b, RG B] are beneficial. Hormone replacement treatment is no longer generally advised in post-menopausal women with osteoporosis [EL2b, RG B], but regular use of bisphosphonates, calcitonin and its derivatives, and raloxifene may reduce or prevent further bone loss [EL2b, RG C]. Data in men with osteoporosis are less secure but bisphosphonates are probably of value, [EL3b, RG C], and those with low testosterone may benefit from its therapeutic administration [EL3b, RG C]. Routine administration of vitamin D is not warranted [EL3b, RG C] (Caprilli R. et al. European evidence based consensus on the diagnosis and management of Crohn’s disease: special situations. Gut 2006;55(Supplement 1):i36-i58;.)
Rationale for the Measure:
“Patients with inflammatory bowel disease (IBD) often rely on their gastroenterologist for healthcare maintenance. In addition, the gastroenterologist also provides guidance to the patient’s primary care physician on a broad range of issues such as vaccinations, osteoporosis screening, and cancer/dysplasia surveillance. Appropriate vaccinations should be administered to patients with IBD, particularly those likely to receive immunosuppression.

Live virus vaccines are not appropriate for patients on immunosuppressive therapy, and therefore should be anticipated and given prior to initiating immunosuppression.

Screening for osteoporosis is based on a combination of individual risk factors, but a history of prolonged (>3 months) steroid use over 10 mg is reason enough to obtain dual-energy x-ray absorptiometry scanning. Smoking cessation also falls within the realm of the gastroenterologist, as current smoking has a negative impact on Crohn’s disease and cessation can be related to exacerbation in ulcerative colitis.” (Moscandrew M., Mahadevan U., Kane S. General Health Maintenance in IBD. Inflamm Bowel Dis 2009;15:1399–1409)


The decision to measure bone density should follow an individualized approach. It should be considered when it will help the patient decide whether to institute treatment to prevent osteoporotic fracture. It should also be considered in patients receiving glucocorticoid therapy for 2 months or more and patients with other conditions that place them at high risk for osteoporotic fracture. (NIH)

The most commonly used measurement to diagnose osteoporosis and predict fracture risk is based on assessment of BMD by dual-energy X-ray absorptiometry (DXA). (NIH)

Measurements of BMD made at the hip predict hip fracture better than measurements made at other sites while BMD measurement at the spine predicts spine fracture better than measures at other sites. (NIH) (National Institutes of Health. Osteoporosis Prevention, Diagnosis and Therapy. NIH Consensus Statement. March 2000;17:1-45)

Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
# of patients with:
  a. current/up to date influenza and pneumococcal immunizations as recommended by current CDC immunization guidelines are documented, and
  b. discussion about avoidance of live vaccines is documented in patients receiving immunosuppression therapy; and
  c. assessment of risk for bone loss is documented one per measurement year

Performance Denominator (PD) Includes:
All patient visits of patients age 18 years or over with a diagnosis of inflammatory bowel disease.

Denominator Exclusions (C) Include:
• Documentation of patient or medical reason(s) for not documenting any or all preventive care components
Performance Calculation

\[ \frac{A}{PD} - \frac{C}{PD} \]

Components for this measure are defined as:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patients with current/up to date influenza and pneumococcal immunizations as recommended by current CDC immunization guidelines, discussion about avoidance of live vaccines in immunosuppressed patients and assessment of risk for bone loss documented one per measurement year</td>
</tr>
<tr>
<td>PD</td>
<td># of patients age 18 years or over with a diagnosis of inflammatory bowel disease</td>
</tr>
<tr>
<td>C</td>
<td># of patients with patient or medical reason(s) for not documenting any or all preventive care components</td>
</tr>
</tbody>
</table>

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

**Reporting Numerator** includes each of the following instances:

A. Patients with:
   a. current/up to date influenza and pneumococcal immunizations as recommended by current CDC immunization guidelines are documented; and
   b. discussion about avoidance of live vaccines is documented in immunosuppressed patients; and
   c. assessment of risk for bone loss is documented one per measurement year

C. Patients with documentation of patient or medical reason for not documenting any or all preventive care components.

D. Patients with no documentation of any or all preventive care components and there is no documented reason for not doing so.

**Reporting Denominator (RD)** includes:

RD. All patients age 18 years or over with a diagnosis of inflammatory bowel disease.

Reporting Calculation

\[ \frac{A + C + D}{RD} \]

Components for this measure are defined as:
Measure Specifications - Inflammatory Bowel Disease Preventive Care Composite

Measure specifications for data sources other than administrative claims will be developed at a later date.

D. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).
(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

CPT ® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99251, 99252, 99253, 99254, 99255, 99354, 99355, 99356, 99357, G0406, G0407, G0408, G0425, G0426, G0427, 99401, 99402, 99403, 99404, 99406, 99407

AND

ICD-9 diagnosis codes: 555, 556

Numerator: Patient with documentation of current/up to date influenza and pneumococcal immunizations as recommended by current CDC immunization guidelines, discussion about avoidance of live vaccines in immunosuppressed patients, and assessment of risk for bone loss documented in the medical record one per measurement year.

Report the CPT Category II, IBD Preventive Care Composite in development designated for this numerator XXXX.

Denominator Exclusion: Documentation of medical reason(s) for not recording any or all preventive care components.
Append modifier to CPT Category II code: XXXX-1P

Documentation of patient reason(s) for not recording any or all preventive care components.
Append modifier to CPT Category II code: XXXX-2P

Electronic Health Record System and Registry (to be developed at a later date)
**Measure #4: Tobacco Use: Screening & Cessation Intervention**

This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Clinical Performance Measure</th>
</tr>
</thead>
</table>
| **Numerator:** Patients who were screened for tobacco use* at least once during the one-year measurement period AND who received tobacco cessation counseling intervention** if identified as a tobacco user  
*Includes use of any type of tobacco  
**Cessation counseling intervention includes brief counseling (3 minutes or less), and/or pharmacotherapy |
| **Denominator:** Patients aged 18 years and older with a diagnosis of inflammatory bowel disease. |
| **Denominator Exclusions:** Documentation of medical reason(s) for not screening for tobacco use (eg, limited life expectancy) |
| **Measure:** Percentage of patients aged 18 years and older who were screened for tobacco use at least once during the one year measurement period AND who received cessation counseling intervention if identified as a tobacco user |

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:


The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products. (A Recommendation) (USPSTF, 2003)

All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco status or the use of other reminder systems such as chart stickers or computer prompts, significantly increase rates of clinician intervention. (Strength of Evidence = A) (U.S. Department of Health & Human Services-Public Health Service, 2008)

All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. (Strength of Evidence = A) (U.S. Department of Health & Human Services-Public Health Service, 2008)

Rationale for the Measure:
There is good evidence that tobacco screening and brief cessation intervention (including counseling and pharmacotherapy) in the primary care setting is successful in helping tobacco users quit. Tobacco users who are able to stop smoking lower their risk for heart disease, lung disease, and stroke.

There is an opportunity for improvement. For example, from 1998-2000,
- 43% of patients had smoking status documented at least once
- 61% of patients that were documented smokers had their smoking status indicated on more than 50% of office visits
- 12% of patients identified as smokers had documentation that advice to quit smoking was given at least once during the year

Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
Patients who were screened for tobacco use* at least once during the one-year measurement period AND who received tobacco cessation counseling intervention** if identified as a tobacco user
*Includes use of any type of tobacco
**Cessation counseling intervention includes brief counseling (3 minutes or less), and/or pharmacotherapy

Performance Denominator (PD) Includes:
All patient visits of patients age 18 years or over with a diagnosis of inflammatory bowel disease.

Denominator Exclusions (C) Include:
Documentation of medical reason(s) for not screening for tobacco use (eg, limited life expectancy)

Performance Calculation

\[
\frac{A}{PD - C} = \frac{\text{# of patients meeting measure criteria}}{\text{# of patients in denominator} - \text{# of patients with valid denominator exclusions}}
\]

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patients who were screened for tobacco use* at least once during the one-year measurement period AND who received tobacco cessation counseling intervention** if identified as a tobacco user</td>
</tr>
<tr>
<td></td>
<td>*Includes use of any type of tobacco</td>
</tr>
<tr>
<td></td>
<td>**Cessation counseling intervention includes brief counseling (3 minutes or less), and/or pharmacotherapy</td>
</tr>
<tr>
<td>PD</td>
<td># of patients age 18 years or over with a diagnosis of inflammatory bowel disease</td>
</tr>
</tbody>
</table>
# of patients with medical reason(s) for not screening for tobacco use (eg, limited life expectancy)

**Calculation for Reporting**

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

**Reporting Numerator** includes each of the following instances:

A. Patients with documentation of being screened for tobacco use* at least once during the one-year measurement period **AND** who received tobacco cessation counseling intervention** if identified as a tobacco user

*Includes use of any type of tobacco

** Cessation counseling intervention includes brief counseling (3 minutes or less), and/or pharmacotherapy

C. Patient visits with documentation of medical reason for not screening for tobacco use

D. Patient visits with no documentation of screening for tobacco use and there is no documented reason for not doing so.

**Reporting Denominator (RD) Includes:**

RD. All patients age 18 years or over with a diagnosis of inflammatory bowel disease.

### Reporting Calculation

A (# of patients meeting numerator criteria) + C (# of patients with valid exclusions) + D (# of patients NOT meeting numerator criteria)

RD (# of patients in denominator)

**Components for this measure are defined as:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **A** | # of patients who were screened for tobacco use* at least once during the one-year measurement period **AND** who received tobacco cessation counseling intervention** if identified as a tobacco user  
*Includes use of any type of tobacco  
** Cessation counseling intervention includes brief counseling (3 minutes or less), and/or pharmacotherapy |
| **C** | # of patients with documentation of medical reason for not screening for tobacco use |
| **D** | # of patients with no documentation of screening for tobacco use |
| **RD** | # of patients age 18 years or over with a diagnosis of inflammatory bowel disease. |
Measure Specifications- Tobacco Use: Screening & Cessation Intervention

Measure specifications for data sources other than administrative claims will be developed at a later date.

E. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).
(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population):

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).
(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

CPT ®Procedure Codes:
- 99201, 99202, 99203, 99204, 99205 (Office/other outpatient services-new patient)
- 99212, 99213, 99214, 99215 (Office/other outpatient services-established patient)
- 96150, 96152 (Health and Behavior Assessment/Intervention)
- 99385, 99386, 99387 (Initial comprehensive preventive medicine-new patient)
- 99395, 99396, 99397 (Initial comprehensive preventive medicine-established patient)
- 99401, 99402, 99403, 99404 (Preventive medicine, Individual Counseling)
- 99411, 99412 (Preventive medicine, Group Counseling)
- 99420 (Other preventive medicine services-administration and interpretation of health risk assessment)
- 99429 (Unlisted preventive)

AND

ICD-9 diagnosis codes: 555,556

Numerator:

Patients who were screened for tobacco use* at least once during the one-year measurement period AND who received tobacco cessation counseling intervention** if identified as a tobacco user
*Includes use of any type of tobacco
**Cessation counseling intervention includes brief counseling (3 minutes or less), and/or pharmacotherapy

CPT Category II code:
- 4XXXF: Patient screened for tobacco use AND received tobacco cessation counseling, if identified as a tobacco user

OR

CPT Category I code-Smoking and tobacco-use cessation counseling
*The following codes are applicable if the patient screened positive for smoking/tobacco use and counseling was provided..
- 99406: Smoking/tobacco counseling 3-10 minutes
- 99407: Smoking/tobacco counseling greater than 10 minutes

Denominator Exclusion: Documentation of medical reason(s) for not screening for tobacco use (eg, limited life expectancy)
Append modifier to CPT Category II code: XXXX-1P
| Electronic Health Record System and Registry (to be developed at a later date) |
Measure #5  Testing for latent TB before initiating anti-TNF therapy

This measure may be used as an Accountability measure

**Clinical Performance Measure**

**Numerator:**
Patients for whom a TB screening was performed and results interpreted within six months prior to receiving a first course* of therapy using a biologic anti-TNF drug.

**Denominator:**
Patients aged 18 years and older with a diagnosis of inflammatory bowel disease and receiving a first course of therapy using a biologic disease-modifying anti-TNF drug

**Denominator Exclusions:** Documentation of medical reason for not screening for TB (i.e. patient positive for TB and documentation of past treatment; patient who has recently completed a course of anti-TB therapy)

**Measure:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-TNF drug.

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Prior to commencing treatment with anti-TNF, all patients should be screened for TB in accordance with the British Thoracic Society (BTS) guidelines. Active TB needs to be adequately treated before anti-TNF therapy can be started. Prior to commencing anti-TNF therapy, consideration of prophylactic anti-TB therapy (as directed by the BTS guidelines) should be given to patients with evidence of potential latent disease (past history of TB treatment or abnormal chest X-ray raising the possibility of TB) after consultation with a local TB specialist. All patients commenced on anti-TNF therapies need to be closely monitored for TB. (Level of Evidence C) (J. Ledingham and C. Deighton1, on behalf of the British Society for Rheumatology Standards, Guidelines and Audit Working Group (SGAWG) Update on the British Society for Rheumatology guidelines for prescribing TNFα blockers in adults with rheumatoid arthritis (update of previous guidelines of April 2001)Rheumatology 2005 44(2):157-163)

In an immunocompromised person (adult or child), the TST should be the initial test used to detect LTBI. If the TST is positive, the person should be considered to have LTBI. However, in light of the known problem with false-negative TST results in immunocompromised populations, a clinician still concerned about the possibility of LTBI in an immunocompromised person with a negative initial TST result may perform an IGRA test. If the IGRA result is positive, the person might be considered to have LTBI. If the IGRA result is indeterminate, the test should be repeated to rule out laboratory error. If the repeat test is also indeterminate, the clinician should suspect anergy and rely on the person’s history, clinical features, and any other laboratory results to make a decision as to the likelihood of LTBI. Although both IGRA may be used as described above, there is evidence that the T-SPOT.TB assay may be more sensitive than the QFT-GIT assay in active TB, and this characteristic might be especially relevant in immunocompromised populations. While the approach of accepting either test result (TST or IGRA) as positive will improve the sensitivity of detecting LTBI in immunocompromised populations, there are no data supporting the efficacy of preventive therapy in TST-negative but IGRA-positive individuals. Thus the clinician must weigh the potential benefit of detecting more persons with positive test results against the lack of evidence for the benefit of preventive therapy in such persons. (Canada Communicable Disease Report, October 2008)
Rationale for the Measure:
Before initiating biologic anti-TNF therapy for a patient with IBD, it is essential to screen the patient for tuberculosis, as research has documented a higher incidence of TB after anti-TNF therapy. All patients being considered for biologic anti-TNF therapy should receive a tuberculin skin test, even if the patient has previously received the BCG vaccination. Test results, in addition to patient risk for TB and other tests, should be used to assess the patient’s risk for latent TB infection. This is a patient safety measure.

Opportunity for improvement: While there are a limited number of studies that investigate gaps in care for patients with IBD, the research that does exist identifies opportunities for improvement in care areas: 1) there is a lack of adherence to tuberculosis screening, most noticeably in the use of disease-modifying anti-TNF drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

Golimumab, certolizumab pegol, infliximab and adalimumab may all trigger latent TB. Also all patients should be monitored during therapy for active TB even if the initial latent TB testing is negative. (See FDA package labeling for these anti-TNF biological agents).

Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
Patients for whom a TB screening was performed and results interpreted within six months prior to receiving a first course* of therapy using a biologic anti-TNF drug.

Performance Denominator (PD) Includes:
Patients aged 18 years and older with a diagnosis of inflammatory bowel disease and receiving a first course of therapy using a biologic disease-modifying anti-TNF drug

Denominator Exclusions (C) Include:
Documentation of medical reason(s) for not documenting screening for latent TB prior to beginning anti-TNF therapy.

Performance Calculation

\[
\frac{A}{PD} - \frac{C}{PD} = \frac{\# \text{ of patient visits meeting measure criteria}}{\# \text{ of patients visits in denominator} - \# \text{ of patients visits with valid denominator exclusions}}
\]

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient visits with TB screening performed and results interpreted within six months prior to receiving a first course* of therapy using a biologic anti-TNF drug documented in the medical record</td>
</tr>
<tr>
<td>PD</td>
<td># of patient visits for patients aged 18 years and older with a diagnosis of inflammatory bowel disease and receiving a first course of therapy using a biologic disease-modifying anti-TNF drug</td>
</tr>
<tr>
<td>C</td>
<td># of patient visits for patients with valid medical reason(s) for not documenting screening for latent TB prior to beginning anti-TNF therapy</td>
</tr>
</tbody>
</table>
**Calculation for Reporting**

For reporting purposes, this measure is calculated by creating a fraction with the following components: **Reporting Numerator** and **Reporting Denominator**.

**Reporting Numerator** includes each of the following instances:

A. Patients for whom a TB screening was performed and results interpreted within six months prior to receiving a first course* of therapy using a biologic anti-TNF drug.

C. Documentation of medical reason(s) for not performing TB screening or interpreting results within six months prior to receiving a first course of therapy using a biologic anti-TNF.

D. Patients with no documentation of performing TB screening or interpreting results within six months prior to receiving a first course of therapy using a biologic anti-TNF.

**Reporting Denominator (RD) Includes:**

RD. Patients aged 18 years and older with a diagnosis of inflammatory bowel disease and receiving a first course of therapy using a biologic anti-TNF.

<table>
<thead>
<tr>
<th>Reporting Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (# of patient visits meeting numerator criteria) + C (# of patient visits with valid exclusions) + D (# of patients NOT meeting numerator criteria)</td>
</tr>
<tr>
<td>RD (# of patient visits in denominator)</td>
</tr>
</tbody>
</table>

**Components for this measure are defined as:**

<table>
<thead>
<tr>
<th>A</th>
<th># of patient visits documentation of assessment for TB infection while on anti-TNF therapy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td># of patients for patients with valid medical reason(s) for not documenting screening for latent TB prior to beginning anti-TNF therapy</td>
</tr>
<tr>
<td>D</td>
<td># of patients visits with no documentation of testing for latent TB prior to beginning anti-TNF therapy.</td>
</tr>
<tr>
<td>RD</td>
<td># of patient visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease and on anti-TNF therapy.</td>
</tr>
</tbody>
</table>
Measure Specifications- Testing for latent TB before initiating anti-TNF therapy
Measure specifications for data sources other than administrative claims will be developed at a later date.

F. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

- CPT® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309
- AND
- ICD-9 diagnosis codes: 555,556

Numerator: Patient with documentation of testing for latent TB before initiating anti-TNF therapy.

Report the CPT Category II, Testing for Latent TB in development designated for this numerator XXXX.

Denominator Exclusion: Documentation of medical reason(s) for not recording testing for latent TB before initiating anti-TNF therapy.

Append modifier to CPT Category II code: XXXX-1P

Documentation of system reason(s) for not recording testing for latent TB before initiating anti-TNF therapy.

Append modifier to CPT Category II code: XXXX-3P

G. Electronic Health Record System and Registry (to be developed at a later date)
Measure #6: Assessment for infection while on anti-TNF therapy

This measure may be used as an Accountability measure

**Clinical Performance Measure**

**Numerator:** Patients on anti-TNF therapy who develop signs of an infection and have a TB testing performed and results interpreted

**Denominator:** All visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease receiving anti-TNF therapy.

**Measure:** Percentage of patients 18 years and older with a diagnosis of inflammatory bowel disease (IBD) receiving therapy using a biologic disease-modifying anti-TNF drug who develop signs of an infection and have documentation of tuberculosis (TB) testing performed and results interpreted.

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Prior to commencing treatment with anti-TNF, all patients should be screened for TB in accordance with the British Thoracic Society (BTS) guidelines. Active TB needs to be adequately treated before anti-TNF therapy can be started. Prior to commencing anti-TNF therapy, consideration of prophylactic anti-TB therapy (as directed by the BTS guidelines) should be given to patients with evidence of potential latent disease (past history of TB treatment or abnormal chest X-ray raising the possibility of TB) after consultation with a local TB specialist. All patients commenced on anti-TNF therapies need to be closely monitored for TB. (Level of Evidence C) (British Society for Rheumatology, 2005).

In an immunocompromised person (adult or child), the TST should be the initial test used to detect LTBI. If the TST is positive, the person should be considered to have LTBI. However, in light of the known problem with false-negative TST results in immunocompromised populations, a clinician still concerned about the possibility of LTBI in an immunocompromised person with a negative initial TST result may perform an IGRA test. If the IGRA result is positive, the person might be considered to have LTBI. If the IGRA result is indeterminate, the test should be repeated to rule out laboratory error. If the repeat test is also indeterminate, the clinician should suspect anergy and rely on the person’s history, clinical features, and any other laboratory results to make a decision as to the likelihood of LTBI. Although both IGRA may be used as described above, there is evidence that the T-SPOT.TB assay may be more sensitive than the QFT-GIT assay in active TB, and this characteristic might be especially relevant in immunocompromised populations. While the approach of accepting either test result (TST or IGRA) as positive will improve the sensitivity of detecting LTBI in immunocompromised populations, there are no data supporting the efficacy of preventive therapy in TST-negative but IGRA-positive individuals. Thus the clinician must weigh the potential benefit of detecting more persons with positive test results against the lack of evidence for the benefit of preventive therapy in such persons. (Canada Communicable Disease Report, October 2008)

**Rationale for the Measure:**

Before initiating biologic anti-TNF therapy for a patient with IBD, it is essential to screen the patient for tuberculosis, as research has documented a higher incidence of TB after anti-TNF therapy. All patients being considered for biologic anti-TNF therapy should receive a tuberculin skin test, even if the patient has previously received the BCG vaccination. Test results, in addition to patient risk for TB and other tests, should be used to assess the patient’s risk for latent TB infection. This is a patient safety measure.
Opportunity for improvement: While there are a limited number of studies that investigate gaps in care for patients with IBD, the research that does exist identifies opportunities for improvement in care areas: 1) there is a lack of adherence to tuberculosis screening, most noticeably in the use of disease-modifying anti-TNF drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

Golimumab, certolizumab pegol, infliximab and adalimumab may all trigger latent TB. All patients receiving anti-TNF therapies should be monitored during therapy for active TB even if the initial latent TB testing is negative. (See FDA package labeling for these anti-TNF biological agents).

Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
Patients on anti-TNF therapy who develop signs of an infection and have a TB testing performed and results interpreted

Performance Denominator (PD) Includes:
Patients aged 18 years and older with a diagnosis of inflammatory bowel disease and receiving therapy using a biologic disease-modifying anti-TNF drug

Performance Calculation

\[
\frac{A \text{ (# of patient visits meeting measure criteria)}}{PD \text{ (# of patient visits in denominator)}}
\]

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient visits with signs of infection while on anti-TNF therapy with assessment of TB documented in the medical record</td>
</tr>
<tr>
<td>PD</td>
<td># of patient visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease and on anti-TNF therapy</td>
</tr>
</tbody>
</table>

Calculation for Reporting
For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

Reporting Numerator includes each of the following instances:

A. Patients with IBD with signs of infection while on anti-TNF therapy with assessment of TB.

Reporting Denominator (RD) Includes:
RD. All visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease receiving anti-TNF therapy who have clinical signs of infection.
### Reporting Calculation

<table>
<thead>
<tr>
<th>A (# of patients visits meeting numerator criteria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RD (# of patient visits in denominator)</td>
</tr>
</tbody>
</table>

Components for this measure are defined as:

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patients on anti-TNF therapy who develop signs of an infection and have a TB testing performed and results interpreted in the medical record</td>
</tr>
<tr>
<td>RD</td>
<td># of patients age 18 years or over with a diagnosis of inflammatory bowel disease and on anti-TNF therapy.</td>
</tr>
</tbody>
</table>
Measure Specifications- Assessment for infection while on anti-TNF therapy

Measure specifications for data sources other than administrative claims will be developed at a later date.

### H. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Notes: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

- CPT® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309
- AND
- ICD-9 diagnosis codes: 555, 556

Numerator: Patient with documentation of testing for infection when on anti-TNF therapy.

Report the CPT Category II, Assessment for infection on anti-TNF therapy in development designated for this numerator XXXX.

### I. Electronic Health Record System nd Registry (to be developed at a later date)
Measure #7: Hepatitis B Risk Assessment

This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Clinical Performance Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator:</strong> Patients with IBD who have documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF therapy</td>
</tr>
<tr>
<td><strong>Denominator:</strong> Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.</td>
</tr>
</tbody>
</table>

**Denominator Exclusions:**
- Documentation of medical reason(s) for not documenting assessment for hepatitis B infection prior to beginning anti-TNF therapy.
- Documentation of patient reason(s) for not having received assessment for hepatitis B infection prior to beginning anti-TNF therapy (eg, patient declined).

**Measure:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who were evaluated for prior evidence of HBV infection before initiating anti-TNF.

**The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:**

**Rationale for the Measure:** Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF blocker medicines. (Kaiser T, Moessner J, McHutchison JG, Tillmann HG. Life threatening liver disease during treatment with monoclonal antibodies. BMJ 2009;338:b508)
Data Capture and Calculations:

**Calculation for Performance**
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

**Performance Numerator (A) Includes:**
Patients with documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF

**Performance Denominator (PD) Includes:**
All patient visits of patients age 18 years or over with a diagnosis of inflammatory bowel disease.

**Denominator Exclusions (C) Include:**
Documentation of medical reason(s) for not documenting assessment of risk for hepatitis B infection prior to beginning anti-TNF therapy

**Performance Calculation**

\[
\frac{A}{PD - C}
\]

Components for this measure are defined as:

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient visits with documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF</td>
</tr>
<tr>
<td>PD</td>
<td># of patient visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease</td>
</tr>
<tr>
<td>C</td>
<td># of patient visits for patients with medical reason(s) for not documenting assessment of risk for hepatitis B infection prior to beginning anti-TNF therapy</td>
</tr>
</tbody>
</table>

**Calculation for Reporting**
For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

**Reporting Numerator includes each of the following instances:**

A. Documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF therapy.
C. Patient visits with documentation of medical reason for not documenting evaluation for prior evidence of HBV infection before initiating anti-TNF therapy.

**Reporting Denominator (RD) Includes:**
RD. All visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease.
### Reporting Calculation

\[
A \text{ (# of patient visits meeting numerator criteria)} + C \text{ (# of patient visits with valid exclusions)} + D \text{ (# of patient visits NOT meeting numerator criteria)} \quad \frac{\text{RD (# of patient visits in denominator)}}{}
\]

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td># of patient visits with documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF therapy</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td># of patients visits with documentation of medical reason for not documenting evaluation for prior evidence of HBV infection before initiating anti-TNF therapy</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td># of patients visits with no documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF therapy</td>
</tr>
<tr>
<td><strong>RD</strong></td>
<td># of patient visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease.</td>
</tr>
</tbody>
</table>
Measure Specifications - Hepatitis B Risk Assessment
Measure specifications for data sources other than administrative claims will be developed at a later date.

### J. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Note: The specifications listed below are those needed for performance calculation.)

**Denominator (Eligible Population):** All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

- CPT® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309
- AND
- ICD-9 diagnosis codes: 555, 556

- **Numerator:** Patient with documentation of evaluation for prior evidence of HBV infection before initiating anti-TNF
  
  Report the CPT Category II, *Hepatitis B Risk Assessment* in development designated for this numerator XXXX.

- **Denominator Exclusion:** Documentation of medical reason(s) for not documenting evaluation for prior evidence of HBV infection before initiating anti-TNF
  
  Append modifier to CPT Category II code: XXXX-1P

### K. Electronic Health Record System and Registry (to be developed at a later date)
**Measure #8: Testing for Clostridium difficile - Inpatient Measure**

This measure may be used as an Accountability measure.

<table>
<thead>
<tr>
<th>Clinical Performance Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator:</strong> Patients with inflammatory bowel disease (IBD) aged 18 and older who are hospitalized, develop diarrhea, and who are tested for Clostridium difficile.</td>
</tr>
<tr>
<td><strong>Denominator:</strong> All patients aged 18 years and older hospitalized for IBD with diarrhea (includes IBD patients with intact colons, patients with end ileostomies, and patients with ileal pouch anal anastomoses).</td>
</tr>
<tr>
<td><strong>Denominator Exclusions:</strong> none</td>
</tr>
<tr>
<td><strong>Measure:</strong> Percentage of IBD patients aged 18 years and older hospitalized, who develop diarrhea that are tested for Clostridium difficile.</td>
</tr>
</tbody>
</table>

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Primarily, patients who have recently been hospitalized or treated with antibiotics should have stools examined for *Clostridium difficile*, although antibiotic-associated diarrhea may be present in the absence of *C. difficile* toxin. (Kornbluth A., Sachar DB. Ulcerative Colitis Practice Guidelines in Adults (Update): American College of Gastroenterology, Practice Parameters for Committee. American Journal of Gastroenterology, 2004, 1371-1385)

*C difficile* colitis is associated with a significant healthcare burden in hospitalised patients with IBD and carries a higher mortality than in patients with *C difficile* without underlying IBD. ¹ A N Ananthakrishnan, E L McGinley², D G Binion¹ Excess hospitalisation burden associated with *Clostridium difficile* in patients with inflammatory bowel disease. Gut, Feb 2008; 57: 205 – 210)

Rationale for the Measure:

Several studies have demonstrated that *Clostridium difficile* (*C. difficile*) infections in inflammatory bowel disease (IBD) have increased dramatically. The number of patients hospitalized with Crohn’s disease (CD) and ulcerative colitis (UC) who tested positive for *C. difficile* doubled and tripled, respectively, in a seven-year span.

The highest risk for infection occurs primarily in UC, less so in patients with Crohn’s small bowel disease. Thus, the focus is on UC and on the subset of CD patients with a predominance of colitis. 67 percent of the *C. difficile*-affected IBD patients tested positive within the first two days of hospitalization, suggesting that the infection was acquired not as a classic nosocomial infection, but rather in the community. Hence, the majority of these hospitalizations are due to *C. difficile* infection directly, a secondary exacerbation of the underlying IBD or a combination of both. When a UC patient hospitalized for worsening diarrhea tests positive for *C. difficile*, clinicians grapple with whether true *C. difficile*-associated disease (CDAD) exists, whether the infection has been properly treated and when to begin an induction regimen for presumed flare of the underlying chronic colitis. (Rodemann JF, Dubberke ER, Reske KA, Seo D, Stone CD. Incidence of *Clostridium difficile* infection in inflammatory bowel disease. Clin Gastroenterol Hepatol. 2007; 5(3): 339-44.)

In a hospitalized UC patient presenting with diarrhea, one cannot distinguish between causes of diarrhea on clinical grounds alone. And unlike the non-IBD patient, in whom pseudomembranes revealed during colonoscopy can help confirm true CDAD, the IBD patient with CDAD exhibits neither gross nor histological features of *C. difficile* infection. The second pitfall in the IBD-CDAD scenario is delay in the treatment of the underlying chronic colitis. This typically stems from an assumption that CDAD has not been fully treated and a fear of worsening the infection by adding immunosuppression to treat the IBD. It
is common to see UC patients treated for C. difficile for days or weeks with persistent but not worsening diarrhea, yet no change in the outpatient IBD regimen. This tends to result in a longer hospital stay than necessary. Therefore, in patients without signs or symptoms of severe CDAD, after two to three days of antibiotics, proper management is to start medications to induce remission of the IBD and to overlap this treatment with antibiotics. (Issa M, Vijayapal A, Graham MB, Beaulieu DB, Otterson MF, Lundeen S, Skaros S, et al. Impact of Clostridium difficile on inflammatory bowel disease. Clin Gastroenterol Hepatol. 2007; 5(3): 345-51.)

Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
Patients with IBD who are hospitalized, who develop diarrhea and who are tested for Clostridium difficile.

Performance Denominator (PD) Includes:
All patients aged 18 years and older hospitalized for IBD with diarrhea.

Performance Calculation

\[
\frac{A (\text{# of patient visits meeting measure criteria})}{PD (\text{# of patients visits in denominator})}
\]

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient with IBD aged 18 years and older who hospitalized, develop diarrhea, and are tested for Clostridium difficile</td>
</tr>
<tr>
<td>PD</td>
<td># of patient aged 18 years and older hospitalized for IBD with diarrhea (includes IBD patients with intact colons, patients with end ileostomies, and patients with ileal pouch anal anastomoses). Visits for patients age 18 years or over with a diagnosis of inflammatory bowel disease</td>
</tr>
</tbody>
</table>

Calculation for Reporting
For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

Reporting Numerator includes each of the following instances:

A. IBD patients who are hospitalized, develop diarrhea, and are tested for Clostridium difficile.
C. # of patients with medical or system reason(s) for not testing for Clostridium difficile

D. Patients who are not tested for Clostridium difficile and without a valid exclusion

Reporting Denominator (RD) Includes:
RD. All patients aged 18 years and older hospitalized for IBD, who develop diarrhea (includes IBD patients with intact colons, patients with end ileostomies, and patients with ileal pouch anal anastomoses).

<table>
<thead>
<tr>
<th>Reporting Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (# of patient visits meeting numerator criteria) + C (# of patient visits with valid exclusions) + D (# of patient visits NOT meeting numerator criteria)</td>
</tr>
<tr>
<td>RD (# of patient visits in denominator)</td>
</tr>
</tbody>
</table>

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient with documentation of testing for Clostridium difficile</td>
</tr>
<tr>
<td>C</td>
<td># of patients with documentation of medical or system reason for not testing for Clostridium difficile</td>
</tr>
<tr>
<td>RD</td>
<td># of patients age 18 years or over hospitalized for IBD who develop diarrhea (includes IBD patients with intact colons, patients with end ileostomies, and patients with ileal pouch anal anastomoses).</td>
</tr>
</tbody>
</table>
L. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

- CPT® Procedure Codes: 99251-55, 99221, 99222, 99223,
  99231, 99232, 99233, 99234, 99235, 99236, 99238, 99239, 99356, 99357

- AND
- ICD-9 diagnosis codes: 008.45, 555, 556

Numerator: Patient with documentation of testing for Clostridium difficile.

- Report the CPT Category II, Testing for Clostridium difficile in development designated for this numerator XXXX.

M. Electronic Health Record System and Registries (to be developed at a later date)
Measure #9: Surveillance Colonoscopy Interval for patients with Colitis
This measure may be used as an Accountability measure

**Clinical Performance Measure**

**Numerator:** Patients aged 18 years and older with a diagnosis of colitis and a disease duration of 8 years or more who had an interval of no less than 12 months and no more than 3 years since their last colonoscopy.

**Denominator:** All patients aged 18 years and older with a diagnosis of colitis (UC or Crohn’s), excluding ulcerative proctitis, and a disease duration of 8 years or more who have undergone a colonoscopy for surveillance without a history of flat dysplasia in a previous colonoscopy.

**Denominator Exclusions:**
- Documentation of medical reason(s) for not performing colorectal cancer (CRC) surveillance between every 12 months and 3 years (e.g., Patients with concomitant primary sclerosing cholangitis [PSC] – these patients should have an annual surveillance colonoscopy)
- Documentation of a system reason(s) for an interval of less than 12 months since the last colonoscopy (e.g., unable to locate previous colonoscopy report)
- Documentation of patient reason(s) for not performing CRC surveillance between every 12 months and 3 years (e.g., patient refusal)

**Measure:** Percentage of patients aged 18 years and older with colitis (UC or Crohn’s) with a disease duration of at least 8 years that have undergone colonoscopy for surveillance: In the absence of flat dysplasia, CRC surveillance should not be performed more frequently than every 12 months and no less than every 3 years.

**The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:**

Patients with ulcerative colitis and Crohn’s disease of the colon have an increased risk of developing colorectal cancer. (AGA Institute Medical Position Statement on: Diagnosis and Management of Colorectal Neoplasia in Inflammatory Bowel Disease. Gastroenterology 2010;138:738-745)

All patients, regardless of the extent of disease at initial diagnosis, should undergo a screening colonoscopy a maximum of 8 years after onset of symptoms, with multiple biopsy specimens obtained throughout the entire colon to assess the true microscopic extent of inflammation. (AGA Institute Medical Position Statement on: Diagnosis and Management of Colorectal Neoplasia in Inflammatory Bowel Disease. Gastroenterology 2010;138:738-745)

The optimal surveillance interval has not been clearly defined. After 2 negative examinations (no dysplasia or cancer), further surveillance examinations should be performed every 1 to 3 years. Recent data suggests that increasing the frequency of surveillance colonoscopy to every 1 to 2 years after 20 years of disease is not needed for all patients but should be individualized according to the presence or absence of other risk factors. (AGA Institute Medical Position Statement on: Diagnosis and Management of Colorectal Neoplasia in Inflammatory Bowel Disease. Gastroenterology 2010;138:738-745)

After 8-10 yr of colitis, annual or biannual surveillance colonoscopy with multiple biopsies at regular intervals should be performed (evidence B). The findings of high grade dysplasia in flat mucosa, confirmed by expert pathologists’ review, is an indication for colectomy, while finding of low-grade dysplasia in flat mucosa may also be an indication for colectomy to prevent progression to a high grade of neoplasia (Evidence B). (Kornbluth A., Sachar DB. Ulcerative Colitis Practice Guidelines in Adults (Update): American College of Gastroenterology, Practice Parameters for Committee. Am J Gastro, 2004, 1371-1385)

CRC risk is increased in both UC and extensive Crohn’s colitis and surveillance colonoscopy with multiple
biopsies should be performed every 1-2 years beginning after 8-10 years of disease (B). (ASGE guideline: endoscopy in the diagnosis and treatment of inflammatory bowel disease. Gastrointestinal Endoscopy 2006, 63:558-565.)

**Rationale for the Measure:**
Patients with colonic IBD are at increased risk for developing colorectal cancer. Surveillance is not only useful to reduce CRC mortality and morbidity but potentially could minimize unnecessary colon resections.

**Data Capture and Calculations:**

**Calculation for Performance**
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

**Performance Numerator (A) Includes:**
Patients who had an interval of no less than 12 months and no more than 3 years since their last colonoscopy

**Performance Denominator (PD) Includes:**
All patients aged 18 years and older with a diagnosis of colitis (CUC or Crohn’s), excluding ulcerative proctitis, and a disease duration of 8 years or more who have undergone a colonoscopy for surveillance without a history of flat dysplasia in a previous colonoscopy.

**Denominator Exclusions (C) Include:**
- Documentation of medical reason(s) for not performing CRC surveillance between every 12 months and 3 years (e.g., Patients with concomitant PSC – these patients should have an annual surveillance colonoscopy)
- Documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (e.g., unable to locate previous colonoscopy report)
- Documentation of patient reason(s) for not performing CRC surveillance between every 12 months and 3 years (e.g., patient refusal)

**Performance Calculation**
Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient who had an interval of no less than 12 months and no more than 3 years since their last colonoscopy</td>
</tr>
<tr>
<td>PD</td>
<td># of patient aged 18 years and older with a diagnosis of colitis (CUC or Crohn’s), excluding ulcerative proctitis, and a disease duration of 8 years or more who have undergone a colonoscopy for surveillance without a history of flat dysplasia in a previous colonoscopy.</td>
</tr>
<tr>
<td>C</td>
<td># of patients with medical or patient or system reason(s) for not performing CRC surveillance between every 12 months and 3 years</td>
</tr>
</tbody>
</table>

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

**Reporting Numerator includes each of the following instances:**

A. **Patients** who had an interval of no less than 12 months and no more than 3 years since their last colonoscopy
B. **Patients** who did not have an interval of no less than 12 months and no more than 3 years since their last colonoscopy and without valid exclusion.
C. **Patients** with medical or system or patient reason(s) for not performing CRC surveillance between every 12 months and 3 years

**Reporting Denominator (RD) Includes:**
RD. patient aged 18 years and older with a diagnosis of colitis (UC or Crohn’s), excluding ulcerative proctitis, and a disease duration of 8 years or more who have undergone a colonoscopy for surveillance without a history of flat dysplasia in a previous colonoscopy.

**Reporting Calculation**

\[
\frac{A \text{ (# of patient visits meeting numerator criteria)} + C \text{ (# of patient visits with valid exclusions)} + D \text{ (# of patient visits NOT meeting numerator criteria)}}{RD \text{ (# of patient visits in denominator)}}
\]
**Measure Specifications - Surveillance Colonoscopy Interval for patients with Colitis**

Measure specifications for data sources other than administrative claims will be developed at a later date.

### N. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Note: The specifications listed below are those needed for performance calculation.)

**Denominator (Eligible Population):** All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

**CPT® Procedure Codes:**

99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99251, 99252, 99253, 99254, 99255, 99256, 99354, 99355, 99356, 99357, 99406, 99407, 99408, G0406, G0407, G0408, G0425, G0426, G0427, 45378, 45380, 45385, G0121, G0105, 45330, 45331, 45333, 44380, 44382, 44385, 44386, 44388, 44389, 44392, 44393, 44394

**AND**

ICD-9 diagnosis codes: 555, 556

**Numerator:** Patient with documentation of having an interval of no less than 12 months and no more than 3 years since their last colonoscopy

Report the CPT Category II, *Surveillance Colonoscopy Interval for patients with Colitis* in development designated for this numerator XXXX.

**Denominator Exclusion:** Documentation of medical reason(s) for not having an interval of no less than 12 months and no more than 3 years since their last colonoscopy

Append modifier to CPT Category II code: XXXX-1P

**Denominator Exclusion:** Documentation of patient reason(s) for not performing CRC surveillance between every 12 months and 3 years (e.g., patient refusal)

Append modifier to CPT Category II code: XXXX-2P

**Denominator Exclusion:** Documentation of system reason(s) for not having an interval of no less than 12 months and no more than 3 years since their last colonoscopy

Append modifier to CPT Category II code: XXXX-3P

### O. Electronic Health Record System and Registry (to be developed at a later date)
Measure #10: Treatment Management
This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Clinical Performance Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator:</strong></td>
</tr>
<tr>
<td>• The patient's diagnosis, if known;</td>
</tr>
<tr>
<td>• The nature and purpose of a proposed treatment or procedure;</td>
</tr>
<tr>
<td>• The risks and benefits of a proposed treatment or procedure;</td>
</tr>
<tr>
<td>• Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);</td>
</tr>
<tr>
<td>• The risks and benefits of the alternative treatment or procedure; and</td>
</tr>
<tr>
<td>• The risks and benefits of not receiving or undergoing a treatment or procedure.</td>
</tr>
</tbody>
</table>

In turn, the patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

| Denominator: | All patients aged 18 years and older with a diagnosis of inflammatory bowel disease. |

| Denominator Exclusions: |
| • Documentation of medical reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment. |
| • Documentation of systems reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment. |
| • Documentation of patient reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment (e.g. patient refusal to discuss) |

| Measure: | Percentage of patients aged 18 years and older with inflammatory bowel disease with documentation of medication reconciliation and shared decision making-discussion of risks and benefits of treatment. |

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Adverse events occurred frequently in the peridischarge period, and many could potentially have been prevented or ameliorated with simple strategies. (Forster AJ, Murff HJ, Peterson JF, Tejal GK, Bates DW. The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital. Ann Intern Med. 2003;138:161-167).

The treatment of inflammatory bowel disease (IBD) is becoming more complex due to the introduction of new medications and evolving treatment algorithms. Data suggest that more aggressive treatment will yield improved clinical results. To increase patients' participation in medical decisions, it is critical to fairly present the tradeoffs of risks versus benefits of treatment. Tools are being developed to more clearly present clinical trial data, risks of medication side effects and for calculating individualized risks of disease complications and response to therapy. (Siegel C. Making therapeutic decisions in inflammatory bowel disease: the role of patients. Current Opinion in Gastroenterology: July 2009 - Volume 25 - Issue 4 - p 334-338)
Rationale for the Measure:
Shared decision-making is gaining favor in clinical practice, although the extent to which patients want to be involved in choosing their treatment varies substantially. Adult IBD patients were asked to anonymously complete an online survey on their preferences. Non-parametric tests ($^2$) were used to determine the relationship between responses and respondents. Results: The questionnaire was completed by 1,067 patients, 617 with Crohn’s disease and 450 with ulcerative colitis. Patients’ mean age was 43 (SD 13.7) years; the majority were female (66%). In total, 866 patients (81%) reported it as ‘very important’ to be actively involved in the decision-making process, and another 177 (17%) rated it as ‘quite important’. When asked how their treatment could be improved, 537 patients (50%) wanted close, equitable collaboration with their physician. This preference was significantly associated with a disease duration of 8 years ($p = 0.03$). Gender and type of IBD were not significantly associated with patients’ preferences. Conclusions: This study demonstrates IBD patients’ desire to be actively involved in the decision-making process (Baars JE, Markus T, Kuipers EJ, van der Woude CJ. Patients’ Preferences regarding Shared Decision-Making in the Treatment of Inflammatory Bowel Disease: Results from a Patient-Empowerment Study Digestion 2010;81:113-119)
Data Capture and Calculations:

**Calculation for Performance**
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

**Performance Numerator (A) Includes:**
Patients with documentation of medication reconciliation and shared decision making-discussion of risks and benefits of treatment

**Performance Denominator (PD) Includes:**
All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

**Denominator Exclusions (C) Include:**
- Documentation of medical reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment.
- Documentation of systems reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment.
- Documentation of patient reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment.

**Performance Calculation**

\[
\frac{A}{PD - C} \]

Components for this measure are defined as:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient visits meeting measure criteria</td>
</tr>
<tr>
<td>PD</td>
<td># of patients visits in denominator</td>
</tr>
<tr>
<td>C</td>
<td># of patient visits with valid denominator exclusions</td>
</tr>
</tbody>
</table>

**Calculation for Reporting**

For reporting purposes, this measure is calculated by creating a fraction with the following components: **Reporting Numerator** and **Reporting Denominator**.

**Reporting Numerator includes each of the following instances:**

A. # of patient with documentation of medication reconciliation and shared decision making-discussion of risks and benefits of treatment

C. # of patients with medical or patient or system reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment

D. # of patients visits with no documentation of medication reconciliation and shared decision making-
discussion of risks and benefits of treatment and without valid exclusion 

**Reporting Denominator (RD) Includes:**
RD. All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

<table>
<thead>
<tr>
<th>A</th>
<th># of patient visits meeting numerator criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td># of patient visits with valid exclusions</td>
</tr>
<tr>
<td>D</td>
<td># of patient visits NOT meeting numerator criteria</td>
</tr>
<tr>
<td>RD</td>
<td># of patient visits in denominator</td>
</tr>
</tbody>
</table>

**Components for this measure are defined as:**

<table>
<thead>
<tr>
<th>A</th>
<th># of patient with documentation of medication reconciliation and shared decision making-discussion of risks and benefits of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td># of patients with medical or patient or system reason(s) for not documenting medication reconciliation and shared decision making-discussion of risks and benefits of treatment</td>
</tr>
<tr>
<td>D</td>
<td># of patients visits with no documentation of medication reconciliation and shared decision making-discussion of risks and benefits of treatment</td>
</tr>
<tr>
<td>RD</td>
<td>All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.</td>
</tr>
</tbody>
</table>
Measure Specifications- Treatment management
Measure specifications for data sources other than administrative claims will be developed at a later date.

P. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).

(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All visits for patients 18 years or older with a diagnosis of inflammatory bowel disease.

- CPT® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309

- AND
- ICD-9 diagnosis codes: 555, 556


Report the CPT Category II, Treatment Management in development designated for this numerator XXXX.

Denominator Exclusion: Documentation of medical reason(s) for not documenting of medication reconciliation and shared decision making-discussion of risks and benefits of treatment

- Append modifier to CPT Category II code: XXXX-1P
- Documentation of patient reason(s) for not documenting of medication reconciliation and shared decision making-discussion of risks and benefits of treatment
- Append modifier to CPT Category II code: XXXX-2P
- Documentation of system reason(s) for not documenting of medication reconciliation and shared decision making-discussion of risks and benefits of treatment
- Append modifier to CPT Category II code: XXXX-3P

Q. Electronic Health Record System and Registry (to be developed at a later date)
### Measure #11: Prophylaxis for Thromboembolism-Inpatient measure

This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Numerator:</th>
<th>Patients with IBD who are hospitalized, who receive LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator:</td>
<td>All patients aged 18 years and older hospitalized with IBD</td>
</tr>
<tr>
<td>Denominator Exclusions:</td>
<td>Documentation of medical reason(s) for not providing prophylaxis against venous thromboembolism</td>
</tr>
<tr>
<td>Measure:</td>
<td>Percentage of IBD patients aged 18 years and older hospitalized that receive prophylaxis against venous thromboembolism.</td>
</tr>
</tbody>
</table>

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:


For acutely ill medical patients admitted to hospital with congestive heart failure, or severe respiratory disease, or are confined to bed and have one or more additional risk factors, including active cancer, previous VTE, sepsis, acute neurologic disease, or inflammatory bowel disease, we recommend thromboprophylaxis LMWH (Grade 1A), LDUH (Grade 1A), or fondaparinux(Grade 1A). (Geerts WH, Bergqvist D, Pineo GF, Heit JA, Samama CM, Lassen M R, Colwell CW. Prevention of Thromboembolism. Chest 2008;133;381S-453S).

Inflammatory bowel disease was associated with a roughly three-fold increase in the risk of venous thromboembolism. Compared with the general population while ambulatory, the risk of venous thromboembolism was increased about 16-fold for non-hospitalised patients with active inflammatory bowel disease. Despite the low absolute risks during non-hospitalised periods, these results suggest that active inflammatory bowel disease in ambulatory patients might be a far greater risk factor for venous thromboembolism than previously recognised. Reference: Grainge MJ, West J, Card TR. Venous thromboembolism during active disease and remission in inflammatory bowel disease: a cohort study. Lancet 2010; published online Feb 9. DOI:10.1016/S0140-6736(09)61963-2.

**Rationale for the Measure:**

IBD patients are at increased risk for venous thromboembolism when experiencing a flare up as well as when non-ambulatory. Those that are having a flare up need to be assessed for thromboembolism and counseled regarding signs and symptoms and action they should take. Likewise those IBD patients who are non-ambulatory need to be on thromboembolism prophylaxis to minimize the development or effects of thromboembolism.
Data Capture and Calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

Performance Numerator (A) Includes:
Patients who receive LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis.

Performance Denominator (PD) Includes:
All patients aged 18 years and older hospitalized with IBD

Denominator Exclusions (C) Include:
- Documentation of medical reason(s) for not providing prophylaxis against venous thromboembolism.

Performance Calculation

\[
\frac{A}{PD} - C
\]

Components for this measure are defined as:

<table>
<thead>
<tr>
<th>A</th>
<th># of patient who receive LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD</td>
<td># of patients (admissions) aged 18 years and older hospitalized with IBD</td>
</tr>
<tr>
<td>C</td>
<td># of patients with medical reason(s) for not providing prophylaxis against venous thromboembolism</td>
</tr>
</tbody>
</table>

Calculation for Reporting
For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

Reporting Numerator includes each of the following instances:

A. Patients who receive LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis

C. # of patients with medical reason(s) for not providing prophylaxis against venous thromboembolism

D. # of patients with no documentation of prophylaxis against venous thromboembolism and without a valid exclusion.

Reporting Denominator (RD) Includes:
RD. # of patients (admissions) aged 18 years and older hospitalized with IBD
### Reporting Calculation

\[
\text{RD} \times \frac{A \times C + D}{RD} 
\]

- **A** (# of patient visits meeting numerator criteria) + **C** (# of patient visits with valid exclusions) + **D** (# of patient visits NOT meeting numerator criteria)

- **RD** (# of patient visits in denominator)

### Components for this measure are defined as:

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td># of patient who receive LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td># of patients with medical reason(s) for not providing prophylaxis against venous thromboembolism</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td># of patients with no documentation of receiving LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis</td>
</tr>
<tr>
<td><strong>RD</strong></td>
<td># of patients (admissions) aged 18 years and older hospitalized with IBD</td>
</tr>
</tbody>
</table>
Measure Specifications - Prophylaxis for Thromboembolism-Inpatient measure
Measure specifications for data sources other than administrative claims will be developed at a later date.

R. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).
(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All patient admissions of those aged 18 years and older hospitalized with IBD

CPT Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 96372

AND

ICD-9 diagnosis codes: 555,556

Numerator: Patient with documentation of receiving LMWH, LDUH, or fondaparinux for venous thromboembolism prophylaxis

Report the CPT Category II, Prophylaxis for Thromboembolism in development designated for this numerator XXXX.

Denominator Exclusion: medical reason(s) for not providing prophylaxis against venous thromboembolism

Append modifier to CPT Category II code: XXXX-1P

S. Electronic Health Record System or Registry (to be developed at a later date)
**Measure # 12: Assessment and Counseling for venous thromboembolism during IBD flare**

This measure may be used as an Accountability measure

<table>
<thead>
<tr>
<th>Clinical Performance Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator:</strong></td>
</tr>
<tr>
<td><strong>Denominator:</strong></td>
</tr>
<tr>
<td><strong>Denominator Exclusions:</strong></td>
</tr>
<tr>
<td><strong>Measure:</strong></td>
</tr>
</tbody>
</table>

The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:

Inflammatory bowel disease was associated with a roughly three-fold increase in the risk of venous thromboembolism. Compared with the general population while ambulatory, the risk of venous thromboembolism was increased about 16-fold for non-hospitalised patients with active inflammatory bowel disease. Despite the low absolute risks during non-hospitalised periods, these results suggest that active inflammatory bowel disease in ambulatory patients might be a far greater risk factor for venous thromboembolism than previously recognised. Reference: Grainge MJ, West J, Card TR. Venous thromboembolism during active disease and remission in inflammatory bowel disease: a cohort study. *Lancet* 2010; published online Feb 9. DOI:10.1016/S0140-6736(09)61963-2.

**Rationale for the Measure:**

IBD patients are at increased risk for venous thromboembolism when experiencing a flare up as well as when non-ambulatory. Those that are having a flare up need to be assessed for thromboembolism and counseled regarding signs and symptoms and action they should take. Likewise those IBD patients who are non-ambulatory need to be on thromboembolism prophylaxis to minimize the development or effects of thromboembolism.
Data Capture and Calculations:

**Calculation for Performance**
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerators, Denominator, and Denominator Exclusions.

**Performance Numerator (A) Includes:**
Patient visits with documented assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism

**Performance Denominator (PD) Includes:**
All patients visits of patients aged 18 years during an acute flare of IBD

**Denominator Exclusions (C) Include**
Documentation of medical reason(s) for not assessing for, and counseling regarding, signs and symptoms of venous thromboembolism.

**Performance Calculation**

\[
\frac{A}{PD - C}
\]

Components for this measure are defined as:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td># of patient who receive assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism</td>
</tr>
<tr>
<td>PD</td>
<td># of patients (visits) aged 18 years during an acute flare of IBD</td>
</tr>
<tr>
<td>C</td>
<td># of patients with medical reason(s) for not providing assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism</td>
</tr>
</tbody>
</table>

**Calculation for Reporting**
For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator.

**Reporting Numerator includes each of the following instances:**

A. Patient visits with documented assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism

C. # of patients with medical reason(s) for not providing assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism

D. # of patients with no documentation of receiving assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism
**Reporting Denominator (RD) Includes:**
RD. # of patients visits of  patients aged 18 years during an acute flare of IBD

<table>
<thead>
<tr>
<th><strong>Reporting Calculation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>A (# of patient visits meeting numerator criteria) + C (# of patient visits with valid exclusions) + D (# of patient visits NOT meeting numerator criteria)</td>
</tr>
<tr>
<td>RD (# of patient visits in denominator)</td>
</tr>
</tbody>
</table>

**Components for this measure are defined as:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td># of patient visits with documented assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td># of patients with medical reason(s) for not providing assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td># of patients with no documentation of receiving assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism</td>
</tr>
<tr>
<td><strong>RD</strong></td>
<td># of patients visits of  patients aged 18 years during an acute flare of IBD</td>
</tr>
</tbody>
</table>
Measure Specifications - Assessment and Counseling for venous thromboembolism during IBD flare
Measure specifications for data sources other than administrative claims will be developed at a later date.

T. Administrative Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper).
(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All patients visits of patients aged 18 years during an acute flare of IBD admissions of those aged 18 years and older hospitalized with IBD
  CPT® Procedure Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241,
  99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 96372
  AND
  ICD-9 diagnosis codes: 555, 556

Numerator: Patient visits with documented assessment of signs and symptoms of venous thromboembolism and counseling regarding signs and symptoms of venous thromboembolism
  Report the CPT Category II, Assessment and Counseling for venous thromboembolism in development designated for this numerator XXXX.

Denominator Exclusion: medical reason(s) for not assessing patients of signs and symptoms of venous thromboembolism
  Append modifier to CPT Category II code: XXXX-1P

U. Electronic Health Record System or Registry (to be developed at a later date)
### American Gastroenterological Association (AGA)-Quality of Evidence on which a Recommendation is Based:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade A</td>
<td>Homogenous evidence from multiple well-designed randomized (therapeutic) or cohort (descriptive) controlled trials, each involving a number of participants to be of sufficient statistical power</td>
</tr>
<tr>
<td>Grade B</td>
<td>Evidence from at least 1 large well-designed clinical trial with or without randomization, form cohort or case-control analytical studies, or well-designed meta-analysis</td>
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### European Crohn’s and Colitis Organisation (ECCO) Definitions of Evidence Level (EL) and Grades of Recommendation

<table>
<thead>
<tr>
<th>Evidence Levels</th>
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<tbody>
<tr>
<td>EL1a</td>
<td>systematic review (with homogeneity) of RCTs</td>
</tr>
<tr>
<td>EL1b</td>
<td>Individual RCT (with narrow Confidence Interval)</td>
</tr>
<tr>
<td>EL1c</td>
<td>All or none- poor quality cohort study</td>
</tr>
<tr>
<td>EL2a</td>
<td>systematic review (with homogeneity) of cohort studies</td>
</tr>
<tr>
<td>EL2b</td>
<td>Individual cohort study (including low quality RCT; e.g., &lt;80% follow-up)</td>
</tr>
<tr>
<td>EL2c</td>
<td>Outcomes Research; Ecological studies</td>
</tr>
<tr>
<td>EL3a</td>
<td>systematic review (with homogeneity) of case-control studies</td>
</tr>
<tr>
<td>EL3b</td>
<td>Individual Case-Control Study</td>
</tr>
<tr>
<td>EL4</td>
<td>Case-series (and poor quality cohort and case-control studies)</td>
</tr>
<tr>
<td>EL5</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
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<tbody>
<tr>
<td>A</td>
<td>consistent level 1 studies</td>
</tr>
<tr>
<td>B</td>
<td>consistent level 2 or 3 studies or extrapolations from level 1 studies</td>
</tr>
<tr>
<td>C</td>
<td>level 4 studies or extrapolations from level 2 or 3 studies</td>
</tr>
<tr>
<td>D</td>
<td>level 5 evidence or troublingly inconsistent or inconclusive studies of any level</td>
</tr>
</tbody>
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### American College of Gastroenterology -Quality of Evidence on which a Recommendation is Based:

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### American Society of Colon and Rectal Surgeons Levels/Gradings of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Source of Evidence</th>
<th>Grade</th>
<th>Grade of Recommendation</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>Meta-analysis of multiple well-designed, controlled studies, randomized trials with low-false positive and low-false negative errors (high power)</td>
<td>A</td>
<td>Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV</td>
</tr>
<tr>
<td>II</td>
<td>At least one well-designed experimental study; randomized trials with high false-positive or high-false negative errors or both (low power)</td>
<td>B</td>
<td>Evidence of Type II, II, or IV and generally consistent findings</td>
</tr>
<tr>
<td>III</td>
<td>Well-designed, quasi experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series</td>
<td>C</td>
<td>Evidence of Type II, III, or IV but inconsistent findings</td>
</tr>
<tr>
<td>IV</td>
<td>Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies</td>
<td>D</td>
<td>Little or no systematic empirical evidence</td>
</tr>
<tr>
<td>V</td>
<td>Case reports and clinical examples</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### British Society of Gastroenterology

The guidelines conform to the North of England evidence based guidelines development project. The grading of each recommendation is dependent on the category of evidence supporting it:

- **Grade A**—requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence categories Ia and Ib).

- **Grade B**—requires the availability of clinical studies without randomisation on the topic of consideration (evidence categories IIa, IIb, and III).

- **Grade C**—requires evidence from expert committee reports or opinions or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV).
All references are listed within the body of the document. This is not an inclusive listing of all references cited above.


