Adult Inflammatory Bowel Disease Physician Performance Measures Set

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American Gastroenterological Association

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Purpose of Measures

These clinical performance measures were developed by the American Gastroenterological Association (AGA) Institute, 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:

Measure # 1: Inflammatory bowel disease (IBD): type, anatomic location and activity all assessed

Measure # 2: IBD preventive care: corticosteroid sparing therapy

Measure # 3: IBD preventive care: corticosteroid related iatrogenic injury – bone loss assessment

Measure # 4: IBD preventive care: influenza immunization

Measure # 5: IBD preventive care: pneumococcal immunization

Measure # 6: Testing for latent TB before initiating anti-TNF therapy

Measure # 7: Assessment of hepatitis B virus before initiating anti-TNF therapy

Measure # 8: Testing for *Clostridium difficile* – inpatient measure

Measure # 9: Prophylaxis for venous thromboembolism — inpatient measure

Measure # 10: IBD preventive care: tobacco user – screening and cessation intervention

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 current procedural terminology (CPT®).[1] 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.

[1] CPT® is a registered trademark of the American Medical Association.

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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 include:
  - Not indicated (absence of organ/limb, already received/performed, other).
  - Contraindicated (patient allergy history, potential adverse drug interaction, other).
- Patient reasons include:
  - Patient declined.
  - Social or religious reasons.
  - Other patient reasons.
- System reasons include:
  - Resources to perform the services not available.
  - Insurance coverage/payor-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.

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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 System (PQRS). 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.
- Numerator exclusion (B) includes: number of patients not meeting numerator eligibility.
- Performance denominator (PD) includes: number of patients meeting criteria for denominator inclusion.
- Denominator exclusions (C) includes: number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure).

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Performance Calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)}}{\text{PD (\# patients in denominator)} - \text{C (\# patients with valid denominator exclusions)} - \text{B (\# of patients not meeting numerator eligibility)}}$$

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

Overall Exclusion Calculation

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

OR

Exclusion Calculation by Type

$$\frac{\text{C1 (\# patients with medical reason)}}{\text{PD (\# patients in denominator)}} \quad \frac{\text{C2 (\# patients with patient reason)}}{\text{PD (\# patients in denominator)}} \quad \frac{\text{C3 (\# patients with system reason)}}{\text{PD (\# patients in denominator)}}$$

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 components, where applicable. There may be instances where there are no patients to include in A, B, C, D or E.

A	Number of patients meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9-CM and CPT Category I coding alone) AND numerator criteria.
B	Number of patients not meeting numerator eligibility.
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.
E	All other patients not meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9-CM and CPT Category I coding alone).

Reporting Denominator (RD) Includes:

RD	Denominator criteria (identifiable through ICD-9-CM and CPT Category I coding).

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Reporting Calculation

$$\frac{\text{A (\# of patients meeting additional denominator criteria AND numerator criteria) + B (\# of patients not meeting numerator eligibility) + C (\# of patients with valid exclusions) + D (\# of patients NOT meeting numerator criteria) + E (\# of patients not meeting additional denominator criteria)}}{\text{RD (\# of patients in denominator)}}$$

Burden of Illness (Mortality and Morbidity)

The two 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 percent of whom are diagnosed in their childhood years.

The Centers 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."[2]

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.

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]

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[2] CDC, DACH, 2007, http://www.cdc.gov/nccdphp/dach/ibd.htm.

[3] Everhart JE, editor. The burden of digestive diseases in the United States. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office, 2008; NIH Publication No. 09-6443 pp. 97.

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Prevalence/Incidence

The annual incidence rate per 100,000 persons was 6.3 for Crohn's disease (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 Crohn's disease (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 Crohn's disease 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 (sic) 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 (sic) 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]

Potential of IBD Performance Measurement Set to Improve Health Outcomes

IBD is a complex chronic condition associated with significant health, life style 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 health-care 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 decrease 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.

Health-care 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.

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[4] Herrinton LJ, Liu L, Lewis JD. Incidence and Prevalence of Inflammatory Bowel Disease in a Northern California Managed Care Organization, 1996-2002. Am J Gastro. 2008;103(9):1998-2006.

[5] Crohn's and Colitis Foundation of America. About Crohn's Disease and Ulcerative Colitis. http://www.ccfa.org/about/press/ibdfacts. Accessed March 3, 2010.

[6] Ruhl, CE, Sayer B, Byrd-Holt DD and Brown DM. Costs of Digestive Diseases. The burden of digestive diseases in the United States. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office, 2008; NIH Publication No. 09-6443 pp. 142.

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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 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.

Glossary:

The two inflammatory bowel diseases 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

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Measure # 1

Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Assessed

This measure may be used as an accountability measure

Clinical Performance Measure

Numerator: Patients with documented assessment of:

a. Type of inflammatory bowel disease (Crohn's, ulcerative colitis or IBD-unclassified).
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.

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

Denominator Exclusions: Documentation of patient reason(s) for not performing assessments (e.g., patient refuses endoscopic and/or radiologic assessment).

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who were assessed for disease type, anatomic location and activity, at least once during the reporting year.

Evidence Base

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. (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.)

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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:

- Patients with documented assessment of:
  a. Type of inflammatory bowel disease (Crohn's, UC or IBD-unclassified).
  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 patients age 18 years and older with a diagnosis of inflammatory bowel disease.

Denominator exclusions (C) include:

- Documentation of patient reason for not performing assessments type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations in the medical record.

Performance Calculation

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

Components for this performance measure are defined as:

A	# of patients with documented assessment of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations documented in the medical record.
PD	# of patients age 18 years and older with a diagnosis of inflammatory bowel disease
C	# of patients with valid patient reason(s) for not performing assessment of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations in medical record.

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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 documented assessment of:

a. Type of inflammatory bowel disease (Crohn's, UC or IBD-unclassified).

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. Patients with documentation of patient reason for not performing assessment of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations.

D. Patients with no documentation of assessment 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 patients age 18 years and older with a diagnosis of inflammatory bowel disease.

Reporting Calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{C (\# of patients with valid exclusions)} + \text{D (\# of patients NOT meeting numerator criteria)}}{\text{RD (\# of patients in denominator)}}$$

Components for this reporting measure are defined as:

A	# of patients with documented assessment of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations documented in the medical record.
C	# of patients with documentation of patient reason for not performing assessment of the type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations.
D	# of patients with no documentation of assessment of type of IBD, anatomic location, disease activity and presence of extraintestinal manifestations.
RD	# of patients age 18 years and older with a diagnosis of inflammatory bowel disease.

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Measure Specifications — Inflammatory bowel disease: type, anatomic location and activity all assessed

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

Administrative Claims Data

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

Denominator (eligible population): All patients 18 years and older with a diagnosis of inflammatory bowel disease.

CPT Service 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

AND

ICD-9 diagnosis codes: 555, 556.

Numerator: Patients with documented assessment of type of IBD, anatomic location, luminal disease activity and presence of extraintestinal manifestations. Report CPT II code: 1052F*: Type, anatomic location, and activity all assessed*.

Denominator exclusion: Documentation of patient reason(s) for not performing assessments (e.g., patient refuses endoscopic and/or radiologic assessment). Append modifier to CPT Category II code: 1052F-2P.

Reporting instruction:

For patients with appropriate exclusion criteria report code 1052F with modifier 2P.

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Measure # 2

IBD Preventive Care: Corticosteroid Sparing Therapy

This measure may be used as an accountability measure.

Clinical Performance Measure

Numerator: Patients managed with corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days AND prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents).

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

Denominator Exclusions:

- Documentation of medical reason(s) for not treating with corticosteroid sparing therapy (e.g., benefits of continuing steroid therapy outweigh the risk of weaning patient off steroids, initiating steroid sparing therapy or patient refuses to initiate steroid sparing therapy).

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroid* greater than or equal to 10mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year.

*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.

Evidence Base

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 [azothioprine] 2.0 to 3.0 mg/kg/day or 6-MP [6-mercaptopurine] 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 in 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.)

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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 Crohn's disease: TREAT registry. Clin Gastroenterol Hepatol. 2006 May;4(5):621-30.)

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, Jan. 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 Medications and Mortality in Inflammatory Bowel Disease. Am J Gastro.2008;103:1428-1435).

Data Capture and Calculations

Calculation for Performance

For performance purposes, this measure is calculated by creating a fraction with the following components: numerators, denominators, and denominator exclusions.

Performance numerator (A) includes:

- Patients managed with corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days AND prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents).

Performance numerator exclusion (B) includes:

- Patients not receiving corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days.

Performance denominator (PD) includes:

- Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

*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.

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Denominator exclusions (C) include:

- Documentation of medical reason(s) for not treating with corticosteroid sparing therapy (e.g.; patient receiving corticosteroids for non-IBD related condition).

Performance Calculation

$$\frac{\text{A (\# of patient meeting measure criteria)}}{\text{PD (\# of patients in denominator)} - \text{C (\# of patient with valid denominator exclusions)} - \text{B (\# of patients not meeting numerator eligibility)}}$$

Components for this performance measure are defined as:

A	# of patients managed with corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days AND prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents).
B	# of patients not receiving corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days.
PD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease.
C	# of patient with documentation of medical reason(s) for not treating with corticosteroid sparing therapy.

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 managed with corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days AND prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents).

B. Patients not receiving corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days.

C. Patients with documentation of medical reason for not treating with corticosteroid sparing therapy.

D. Patients with no documentation of treating with corticosteroid sparing therapy and there is no documented reason for not doing so.

Reporting Denominator (RD) Includes:

RD. Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Reporting Calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{B (\# of patients not meeting numerator eligibility)} + \text{C (\# of patients with valid exclusions)} + \text{D (\# of patients NOT meeting numerator criteria- no documentation)}}{\text{RD (\# of patients in denominator)}}$$

*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.

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Components for this reporting measure are defined as:

A	# Patients managed with corticosteroids* for 60 or greater consecutive days prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents).
B	# of patients not receiving corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days.
C	# of patients with documentation of medical reason(s) for not treating with corticosteroid sparing therapy.
D	# of patients with documented corticosteroids* use in the last calendar year and no documentation of medical reason(s) for not treating with corticosteroid sparing therapy and there is no documented reason for not doing so.
RD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Measure Specifications — IBD Preventive Care: Corticosteroid Sparing Therapy

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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 aged 18 years and older with a diagnosis of inflammatory bowel disease.

CPT Service 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

AND

ICD-9 diagnosis codes: 555, 556.

Numerator:

- Patients managed with corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days AND prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents). Report the CPT Category II 4142F: *Corticosteroid sparing therapy prescribed*.
- Patient not receiving corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days. Report the CPT Category II 3750F, *Patient not receiving corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days*.

Denominator Exclusion: Documentation of medical reason(s) for not treating with steroid sparing therapy. Append modifier to CPT Category II code: 4142F-1P.

Reporting Instructions:

For patients with appropriate exclusion criteria, report code 4142F with modifier 1P.

*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.

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Measure # 3
IBD Preventive Care:
Corticosteroid Related Iatrogenic Injury — Bone Loss Assessment

This measure may be used as an accountability measure.

Clinical Performance Measure

Numerator: Patients who have received dose of corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days who were assessed** for risk of bone loss.

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

Denominator Exclusions: There are no exclusions for this measure.

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days were assessed for risk of bone loss once per the reporting year.

* Prednisone equivalents used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) 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.

** Documentation that an assessment for risk of bone loss has been performed or ordered. This includes, but is not limited to, review of systems and medication history, ordering of DEXA scan.

Evidence Base

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

IBD has only a modest effect on BMD, with a pooled Z score of - 0.5 (level A evidence). (AGA, American Gastroenterological Association Medical Position Statement: Guidelines on Osteoporosis in Gastrointestinal Diseases, 2003).

Corticosteroid use is the variable most strongly associated with osteoporosis (level A evidence). However, it is difficult to distinguish corticosteroid use from disease activity in terms of causal impact on bone density, because the two are closely linked. (AGA, American Gastroenterological Association Medical Position Statement: Guidelines on Osteoporosis in Gastrointestinal Diseases. 2003.)

However there is strong evidence that those on long-term steroids of greater than three 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.)

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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…. 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. (Moscandrew M., Mahadevan U., Kane S. General Health Maintenance in IBD. Inflamm Bowel Dis. 2009;15:1399–1409.)

Markers of greater osteoporosis and fracture risk include older age, hypogonadism, corticosteroid therapy, and established cirrhosis (American Gastroenterological Association. (2003). American Gastroenterological Association Medical Position Statement: Osteoporosis in Hepatic Disorders. *Gastroenterology.* 125: pp 937-940.)

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 two 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:

Patients who have received dose of corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days who were assessed** for risk of bone loss.

Performance numerator exclusion (B) includes:

Patients not receiving dose of corticosteroids greater than or equal to 10mg/day* for 60 or greater consecutive days.

Performance denominator (PD) includes:

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

Denominator exclusions (C) include:

There are no exclusions for this measure.

* Prednisone equivalents used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) 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.

** Documentation that an assessment for risk of bone loss has been performed or ordered. This includes, but is not limited to, review of systems and medication history, ordering of DEXA scan.

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Performance calculation

$$\frac{\text{A (\# of patients meeting measure criteria)}}{\text{PD (\# of patients in denominator)} - \text{B (\# of not meeting eligibility)}}$$

Components for this performance measure are defined as:

A	# of patients who have received dose of corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days who were assessed** for risk of bone loss .
B	# patients not receiving corticosteroids greater than or equal to 10mg/day* for 60 or greater consecutive days.
PD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

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 have received dose of corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days who were assessed** for risk of bone loss.

B. Patients not receiving dose of corticosteroids greater than or equal to 10mg/day* for 60 or greater consecutive days.

D. Patients with no documentation of assessment for risk of bone loss and there is no documented reason for not doing so.

Reporting denominator (RD) includes:

RD. Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Reporting calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{B (\# of patients not meeting eligibility)} + \text{D (\# of patients NOT meeting numerator criteria- no documentation)}}{\text{RD (\# of patients in denominator)}}$$

Components for this reporting measure are defined as:

A	# of patients who have received dose of corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days who were assessed** for risk of bone loss.
B	# patients not receiving corticosteroids greater than or equal to 10mg/day* for 60 or greater consecutive days.
D	# of patients with no documentation of assessing for risk of bone loss (e.g. recent assessment of risk of bone loss) and there is no documented reason for not doing so.
RD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease

* Prednisone equivalents used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) 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.

** Documentation that an assessment for risk of bone loss has been performed or ordered. This includes, but is not limited to, review of systems and medication history, ordering of DEXA scan.

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Measure Specifications — IBD Preventive Care: Corticosteroid Related Iatrogenic Injury — Bone Loss

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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

Denominator (eligible population): All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

CPT Service 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: Patients who have received dose of corticosteroids* greater than or equal to 10mg/day for 60 or greater consecutive days who were assessed** for risk of bone loss

Report the CPT Category II code: 3096F – Central Dual-energy X-Ray Absorptiometry (DXA) ordered.

OR

Report the CPT Category II code: 3095F – Central Dual-energy X-Ray Absorptiometry (DXA) results documented.

OR

Report the CPT Category II code: 4005F – Pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed.

OR

Report the CPT Category II code: 3750F – *Patient not receiving corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days*.

Denominator exclusion: There are no exclusions for this measure.

Reporting instructions:

There are no exclusions for this measure; modifiers 1P,2P and 3P may not be used for this measure.

* Prednisone equivalents used expressly for the treatment of IBD and not for other indications (including premedication before anti-TNF therapy, non-IBD indications) 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.

** Documentation that an assessment for risk of bone loss has been performed or ordered. This includes, but is not limited to, review of systems and medication history, ordering of DEXA scan.

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Measure # 4

IBD Preventive Care: Influenza Immunization

This measure may be used as an accountability measure

Clinical Performance Measure

Numerator: Patients for whom influenza immunization was recommended, administered or previously received.

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

Denominator exclusions:

- Documentation of medical reason(s) for not recommending, administering or having previously received influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction).
- Documentation of patient reason(s) for not recommending, administering or having previously received influenza immunization (e.g., patient refusal).
- Documentation of system reason(s) for not recommending, administering or having previously received influenza immunization (e.g., vaccine not available).

Measure: Percentage of patients aged 18 years and older with inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year.

Evidence Base

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

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 (including diabetes mellitus);
- adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV); and
- residents of nursing homes and other long-term–care facilities.

(Prevention & Control of Seasonal Influenza with Vaccines - Recommendations of the Advisory Committee on Immunization Practices (ACIP) 2009. MMWR 2009 Jul 24; Early Release: 1-52.)

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.)

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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.10; 5: 677-692.)

Rationale for the Measure:

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

Patients with inflammatory bowel disease often rely on their gastroenterologist for health-care 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. (Moscandrew M., Mahadevan U., Kane S. General Health Maintenance in IBD. Inflamm Bowel Dis. 2009;15:1399–1409.)

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 influenza immunization was recommended, administered or previously received.

Performance denominator (PD) includes:

- Patients age 18 years or older with a diagnosis of inflammatory bowel disease.

Denominator exclusions (C) include:

- Documentation of patient or medical or systems reason(s) not recommending, administering or having previously received influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction).

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Performance Calculation

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

Components for this performance measure are defined as:

A	# of patients for whom influenza immunization was recommended, administered or previously received and documented during the reporting year.
PD	# of patients age 18 years or older with a diagnosis of inflammatory bowel disease.
C	# of patients with patient or medical or system reason(s) for not recommending, administering or having previously received influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction).

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 that influenza immunization was recommended, administered or previously received during the reporting year.

C. Patients with documentation of patient or medical or system reason(s) for not recommending, administering or having previously received influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction).

Reporting denominator (RD) includes:

RD. All patients age 18 years and older with a diagnosis of inflammatory bowel disease.

Reporting Calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{C (\# of patients with valid exclusions)} + \text{D (\# of patients NOT meeting numerator criteria)}}{\text{RD (\# of patients in denominator)}}$$

Components for this reporting measure are defined as:

A	# of patients for whom influenza immunization was recommended, administered or previously received and documented during the reporting year.
C	# of patients with patient or medical or system reason(s) for not recommending, administering or having previously received influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction).
RD	# of patients age 18 years or older with a diagnosis of inflammatory bowel disease.

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Measure Specifications — IBD Preventive Care: Influenza Immunization

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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

Denominator (Eligible Population): Patients 18 years or older with a diagnosis of inflammatory bowel disease.

CPT Service 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:

- Patients for whom influenza immunization recommended, report the CPT Category II 4035F: *Influenza immunization recommended*.
- Patients for whom influenza immunization administered or previously received, report the CPT Category II 4037F: *Influenza immunization administered or previously received*.

Denominator Exclusion:

- Documentation of medical reason(s) for not recommending influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction); append modifier to CPT Category II code: 4035F -1P.
- Documentation of medical reason(s) for not administering or having previously received influenza immunization (e.g., patient allergic reaction, potential adverse drug reaction); append modifier to CPT Category II code: 4037F -1P.
- Documentation of patient reason(s) for not recommending influenza immunization (e.g., patient refusal); append modifier to CPT Category II code: 4035F -2P.
- Documentation of patient reason(s) for not administering or having previously received influenza immunization (e.g., patient refusal); append modifier to CPT Category II code: 4037F -2P.
- Documentation of system reason(s) for not recommending influenza immunization (e.g., vaccine not available); append modifier to CPT Category II code: 4035F -3P.
- Documentation of system reason(s) for not administering or having previously received influenza immunization (e.g., vaccine not available); append modifier to CPT Category II code: 4037F -3P.

Reporting Instructions:

For patients with appropriate exclusion criteria, report code 4037F or 4035F with modifier 1P, 2P or 3P.

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Measure # 5

IBD Preventive Care: Pneumococcal Immunization

This measure may be used as an accountability measure.

Clinical Performance Measure

Numerator: Patients for whom pneumococcal vaccine was administered or previously received.

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

Denominator exclusions:

- Documentation of medical reason(s) for not administering pneumococcal immunization (e.g., patient allergic reaction, potential adverse drug reaction).
- Documentation of patient reason(s) for not recommending pneumococcal immunization (e.g., patient refusal).

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received.

Evidence Base

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 greater than or equal to 2 years, including persons with HIV infection, leukemia, lymphoma, Hodgkins 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. (Centers for Disease Control and Prevention. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP).MMWR 1997;46(No. RR-8): [13].)

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.)

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. 10; 5. 677-692.)

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Rationale for the Measure

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

Patients with IBD often rely on their gastroenterologist for health-care 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.(Moscandrew M., Mahadevan U., Kane S. General Health Maintenance in IBD. Inflamm Bowel Dis. 2009;15:1399–1409.)

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 for whom pneumococcal vaccine was administered or previously received are documented during the reporting year.

Performance denominator (PD) includes:

- All patients age 18 years and older with a diagnosis of inflammatory bowel disease.

Denominator exclusions (C) include:

- Documentation of medical reason(s) for not administering pneumococcal immunization (e.g., patient allergic reaction, potential adverse drug reaction). Documentation of patient reason(s) for not recommending pneumococcal vaccination (e.g., patient refusal).

Performance Calculation

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

Components for this performance measure are defined as:

A	# of patients for whom pneumococcal vaccine was administered or previously received are documented during the reporting year.
PD	# of patients age 18 years or older with a diagnosis of inflammatory bowel disease
C	# of patients with medical reason(s) for not administering pneumococcal immunization (e.g., patient allergic reaction) or patient reason(s) for not recommending pneumococcal vaccination (e.g., patient refusal).

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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 pneumococcal vaccine was administered or previously received documented during the reporting year.

C. Patients for whom documentation of medical reason for not administering pneumococcal immunization (e.g., patient allergic reaction) or patient reason(s) for not recommending pneumococcal vaccination (e.g., patient refusal).

D. Patients with no documentation that pneumococcal vaccine was administered or previously received and there is no documented reason for not doing so.

Reporting denominator (RD) includes:

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

Reporting calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{C (\# of patients with valid exclusions)} + \text{D (\# of patients NOT meeting numerator criteria)}}{\text{RD (\# of patients in denominator)}}$$

Components for this reporting measure are defined as:

A	# of patients for whom pneumococcal vaccine was administered or previously received are documented during the reporting year.
C	# of patients with documentation of medical reason for not administering pneumococcal immunization (e.g., patient allergic reaction) or patient reason(s) for not recommending pneumococcal vaccination (e.g., patient refusal).
D	# of patients with no documentation that pneumococcal vaccine was administered or previously received and there is no documented reason for not doing so.
RD	# of patients age 18 years or older with a diagnosis of inflammatory bowel disease.

Measure Specifications — IBD Preventive Care: Pneumococcal Immunization

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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): Patients aged 18 years or older with a diagnosis of inflammatory bowel disease.

CPT Service 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.

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Numerator: Patients for whom pneumococcal vaccine administered or previously received, report the CPT Category II, 4040F *Pneumococcal vaccine administered or previously received* for this numerator.

Denominator exclusion:

- Documentation of medical reason(s) for not administering pneumococcal immunization (e.g., patient allergic reaction, potential adverse drug reaction); append modifier to CPT Category II code: 4040F-1P.
- Documentation of patient reason(s) for not recommending pneumococcal vaccination (e.g., patient refusal); append modifier to CPT Category II code: 4040F-2P.

Reporting Instructions:

- For patients with appropriate exclusion, report code 4040F with modifier 1P or 2P.

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Measure # 6

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 tuberculosis (TB) screening was performed and results interpreted, within six months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.

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

Denominator exclusions:

- Documentation of medical reason(s) 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) within six months prior to first course of anti-TNF therapy.
- Documentation of patient reason(s) for not screening for TB (e.g., patient declined) within six months prior to first course of anti-TNF therapy.

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a TB screening was performed and results interpreted within six months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.

Evidence Base

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. Deighton, 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 TNFa 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 tuberculin skin test (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 (interferon-gamma release assay) 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 IGRAs 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

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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.)

Infliximab can reactivate latent HBV. (Esteve M, Saro C, González-Huix F, Suarez F, Forné M, Viver JM. Chronic hepatitis B reactivation following infliximab therapy in Crohn's disease patients: need for primary prophylaxis. Gut. 2004 Sep;53(9):1363-5.)

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).

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 for whom TB screening was performed and results interpreted, within six months prior to receiving a first course of therapy.

Performance numerator exclusion (B) includes:

- Patients not receiving a first course of anti-TNF.

Performance denominator includes:

- PD. Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Denominator exclusions (C) include:

- Documentation of medical reason(s) 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) within six months prior first course of anti-TNF therapy.
- Documentation of patient reason(s) for not screening for TB (e.g., patient declined) within six months prior first course of anti-TNF therapy.

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Performance calculation

$$\frac{\text{A (\# of patients meeting measure criteria)}}{\text{PDA (\# of patients in denominator)} - \text{B (\# of patients not meeting eligibility)} - \text{C (\# of patients with valid denominator exclusions)}}$$

Components for this performance measure are defined as:

A	# of patients with TB screening performed and results interpreted, within six months prior to receiving a first course of anti-TNF therapy.
C	# of patients not receiving a first course of anti-TNF therapy.
PD	# of patient aged 18 years and older with a diagnosis of inflammatory bowel.
C	# of patients with valid medical or patient reason(s) for not documenting screening for latent TB within six months prior to receiving a first course of anti-TNF therapy.

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.

B. Patients not receiving a first course of anti-TNF therapy.

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

D. Patients with no documentation of performing TB screening, within six months prior to receiving a first course of anti-TNF therapy.

Reporting denominator (RD) includes:

RD. Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Reporting calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{C (\# of patients with valid exclusions)} + \text{B (\# patients not meeting eligibility)} + \text{D (\# of patients NOT meeting numerator criteria- no documentation)}}{\text{RD (\# of patients in denominator)}}$$

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Components for this reporting measure are defined as:

A	# of patients with TB screening performed and results interpreted, within six months prior to receiving a first course of anti-TNF therapy.
B	# of patients not receiving a first course of anti-TNF therapy.
C	# of patients with valid medical or patient reason(s) for not documenting screening for latent TB within six months prior to receiving a first course of anti-TNF therapy.
D	# of patients with no documentation of TB screening, within six months prior to receiving a first course of anti-TNF therapy.
RD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Measure Specifications — Testing for latent TB before initiating anti-TNF therapy

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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

Denominator (eligible population): Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

CPT Service 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:

- Patients who had TB screening performed and results interpreted, within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy. Report the CPT Category II code 3510F: *Documentation that Tuberculosis (TB) screening test performed and results interpreted.*

OR

Report 6150F *Patient not receiving a first course of anti-TNF (tumor necrosis factor) therapy.*

Denominator exclusion:

- Documentation of medical reason(s) 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) within six months prior to receiving a first course of anti-TNF therapy. Append modifier to CPT Category II code: 3510F-1P.
- Documentation of patient reason(s) medical reason(s) 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) within six months prior to receiving a first course of anti-TNF therapy. Append modifier to CPT Category II code: 3510F-2P.

Reporting instructions: For patients with appropriate exclusion criteria, report code 3510F with modifier 1P or 2P.

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Measure # 7

Assessment of Hepatitis B Virus Before Initiating Anti-TNF Therapy

This measure may be used as an accountability measure.

Clinical Performance Measure

Numerator: Patients who had hepatitis B virus (HBV) status assessed* and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.

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

Denominator Exclusions:

- Documentation of medical reason(s) for not assessing for hepatitis B virus (HBV) status(e.g. potential drug interaction, potential for allergic reaction) within one year prior to first course of anti-TNF (tumor-necrosis factor) therapy.
- Documentation of patient reason(s) for not assessing hepatitis B virus (HBV) status (e.g. patient declines) one year prior to first course of anti-TNF (tumor-necrosis factor) therapy.

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.

*Assessed by one of the following: 87340: HBsAG
87341: HBsAG neutralization
86704 HBcAb, total
86705: HBcAB, IgM
86706: HBsAB

Evidence Base

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

Infliximab can reactivate latent HBV. (Esteve M, Saro C, González-Huix F, Suarez F, Forné M, Viver JM. Chronic hepatitis B reactivation following infliximab therapy in Crohn's disease patients: need for primary prophylaxis. Gut. 2004 Sep;53(9):1363-5.)

Rationale for the Measure:

Before initiating biologic anti-TNF therapy for a patient with IBD, it is essential to screen the patient for HBV, as research has documented reactivation of HBV after anti-TNF therapy. 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 documentation of HBV 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.

See FDA package labeling for anti-TNF biological agents — golimumab, certolizumab pegol, infliximab and adalimumab.

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF blocker medicines.

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(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 who had HBV status assessed* and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.

Performance numerator exclusion (B) includes:

- Patient not receiving a first course of anti-TNF (tumor necrosis factor) therapy.

Performance denominator (PD) includes:

- Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Denominator exclusions (C) include:

- Documentation of medical reason(s) for not assessing HBV status (e.g. potential drug interaction, potential for allergic reaction) within one year prior to first course of anti-TNF therapy.
- Documentation of patient reason(s) for not assessing HBV status (e.g. patient declines) one year prior to first course of anti-TNF (tumor-necrosis factor) therapy.

Performance Calculation

A (# of patients meeting measure criteria)

PD (# of patients in denominator) – B (# of patients not meeting eligibility)
– C (# of patients with valid denominator exclusions)

A	# of patients who had HBV status assessed.
B	# of patients not receiving a first course of anti-TNF therapy.
PD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease.
C	# of patients with valid medical or patient reason(s) documented for not assessing HBV status within one year prior to first course of anti-TNF therapy.

Components for this performance measure are defined as:

*Assessed by one of the following: 87340: HBsAG
87341: HBsAG neutralization
86704 HBcAb, total
86705: HBcAB, IgM
86706: HBsAB

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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 HBV status assessed and results interpreted within one year before initiating a first course of anti-TNF therapy.

B. Patients not receiving a first course of anti-TNF therapy.

C. Documentation of medical or patient reason(s) for not assessing HBV status within one year prior to first course of anti-TNF therapy.

D. Patients with no documentation of assessing HBV status within one year before initiating anti-TNF therapy.

Reporting denominator (RD) includes:

RD. Patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

Reporting calculation

$$\frac{\text{A (\# of patients meeting numerator criteria) + B (\# of patients not meeting eligibility) + C (\# of patients with valid exclusions) + D (\# of patients NOT meeting numerator criteria-not documented)}}{\text{RD (\# of patient in denominator)}}$$

Components for this reporting measure are defined as:

A	# of patients who had HBV status assessed.
B	# of patients not receiving a first course of anti-TNF therapy.
C	# of patients with valid medical or patient reason(s) documented for not assessing HBV status within one year prior to first course of anti-TNF therapy.
D	# of patients with no documentation of assessing HBV status within one year prior to first course of anti-TNF therapy.
RD	# of patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

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Measure Specifications — Assessment of Hepatitis B virus status before initiating anti-TNF therapy

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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

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

CPT Service 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:

Report the CPT Category II code 3216F *Patient has documented immunity to hepatitis B.*

OR

Report CPT Category II code 4149F *Hepatitis B vaccine injection administered or previously received.*

OR

Report the CPT Category II code 6150F *Patient not receiving a first course of anti-TNF (tumor necrosis factor) therapy.*

OR

Report the CPT Category II code 3517F *Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.*

Denominator exclusion:

- Documentation of medical reason(s) for not assessing hepatitis B virus (e.g., potential drug interaction, potential for allergic reaction) status within one year prior to receiving first course of anti-TNF therapy. Append modifier to CPT Category II code: 3517F-1P.
- Documentation of patient reason(s) for not assessing hepatitis B virus status (e.g. patient refuses) within one year prior to receiving first course of anti-TNF therapy. Append modifier to CPT Category II code: 3517-2P.

Reporting instructions: For patients with appropriate exclusion criteria, report code 3517 with modifier 1P or 2P.

Assessed is defined as one of the following: 87340: HBsAG
87341: HBsAG neutralization
86704 HBcAb, total
86705: HBcAB, IgM
86706: HBsAB

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Measure # 8

Testing for *Clostridium difficile* — Inpatient Measure

This measure may be used as an accountability measure.

Clinical Performance Measure

Numerator: Patients who are tested for *Clostridium difficile*.

Denominator: All patients aged 18 years and older with a diagnosis of inflammatory bowel disease hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization.

Denominator Exclusions: Documentation of medical reason(s) for not testing for *Clostridium difficile* (e.g., testing completed within two weeks of admission to hospital or patient had resection of colon).

Measure: Percentage of patients aged 18 and older with a diagnosis of inflammatory bowel disease hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization who are tested for *Clostridium difficile*.

Evidence Base

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 (C.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. (Ananthakrishnan AN, McGinley EL, Binion DG. 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. Sixty-seven 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.

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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 who are tested for *Clostridium difficile*.

Performance denominator (PD) includes:

- All patients aged 18 years and older with a diagnosis of inflammatory bowel disease hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization.

Denominator exclusions (C) include:

- Documentation of medical reason(s) for not testing for Clostridium difficile (e.g., testing completed within 2 weeks of admission to hospital or patient had a resection of colon).

Performance calculation

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

Components for this performance measure are defined as:

A	# of patients who are tested for *Clostridium difficile*.
PD	# patients aged 18 years and older with a diagnosis of inflammatory bowel disease hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization.
C	# of patients with valid medical reason(s) for not testing for *Clostridium difficile* (e.g., testing completed within two weeks of admission or patient had a resection of colon).

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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 are tested for *Clostridium difficile*.

C. Patients with medical 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 with a diagnosis of inflammatory bowel disease hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization.

Reporting Calculation

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

Components for this measure are defined as:

A	# of patients with documentation of testing for *Clostridium difficile*.
C	# of patients with documentation of medical reason for not testing for *Clostridium difficile*.
D	# of patients who are not tested for *Clostridium difficile* and without a valid exclusion.
RD	of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization.

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Measure Specifications — Testing for Clostridium difficile — Inpatient Measure

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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

Denominator (Eligible Population): All patients aged 18 years and older with a diagnosis of inflammatory bowel disease hospitalized (for any reason) who have refractory diarrhea at the time of hospitalization or who develop diarrhea during hospitalization.

CPT Service Codes-Hospital: 99218, 99219, 99220,99224, 99225, 99226, 99251-55, 99221, 99222, 99223, 99231, 99232, 99233, 99234, 99235, 99236, 99238, 99239, 99356, 99357

AND

ICD-9 diagnosis codes: 555, 556

AND

ICD-9 diagnosis codes; 008.45, 009.1, 009.2, 009.3.

Numerator: Patient with documentation of testing for *Clostridium difficile*. Report the CPT Category II 3520F, *Clostridium difficile testing performed*.

Denominator Exclusion: Documentation of medical reason(s) for not testing for *Clostridium difficile*. Append modifier to CPT Category II code: 3520F-1P

Reporting Instructions: For patients with appropriate exclusion criteria, report code 3520F with modifier 1P.

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Measure # 9

Prophylaxis for Venous Thromboembolism — Inpatient Measure

This measure may be used as an accountability measure.

Clinical Performance Measure

Numerator: Patients who receive prophylaxis* for venous thromboembolism prevention.

Denominator: All patients aged 18 years and older with a diagnosis of inflammatory bowel disease hospitalized for any reason.

Denominator Exclusions: There are no exclusions for this measure.

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) hospitalized for any reason who receive prophylaxis* for venous thromboembolism prevention.

* Definition: For purposes of this measure, DVT prophylaxis can include low molecular weight heparin (LMWH), low-dose unfractionated heparin (LDUH), intravenous heparin, low-dose subcutaneous heparin, or intermittent pneumatic compression devices when pharmacological prophylaxis is contraindicated. Mechanical prophylaxis does not include anti-embolism stockings, such as TED hose. (See category II code 4070F)

Evidence Base

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

VTE prophylaxis is specifically recommended for IBD inpatients. (M J Carter, A J Lobo, S P L Travis, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. Gut. 2004;53(Suppl V):v1–v16. doi: 10.1136/gut.2004.043372.)

The risk of venous thromboembolism is related to the presence or absence of specific risk factors and it increases if multiple risk factors are present, as is the case in most hospitalized patients. Because decisions regarding prophylaxis depend on the baseline risk, all patients should undergo a risk assessment on admission to the hospital and a reassessment when their status changes….Evidence indicates that prophylaxis for venous thromboembolism is underused in hospitalized patients (Francis CW. Prophylaxis for Thromboembolism in Hospitalized Medical Patients. N Engl J Med. 2007;356:1438-44.)

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. (Grainge MJ, West J, Card TR. Venous thromboembolism during active disease and remission in inflammatory bowel disease: a cohort study. The Lancet. 2010 February; 375, 9715; Pages 657-663.)

All hospitalized patients who are high risk for venous thromboembolism should receive anticoagulation prophylaxis unless contraindicated. (Institute for Clinical Systems Improvement. Health Care Guideline: Venous Thromboembolism Prophylaxis, Seventh Edition. August 2010.)

Mechanical prophylaxis devices available for venous thromboembolism prophylaxis include graduated compression stockings and intermittent pneumatic compression devices. Although mechanical prophylaxis devices have been evaluated extensively in clinical studies,

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their efficacy in venous thromboembolism prevention remains unclear. These studies have often failed to define exactly what device was used, and frequently the devices were used in combination with other prophylaxis methods, making it difficult to demonstrate their efficacy. The 2008 American College of Chest Physicians Clinical Practice Guideline recommends "that mechanical methods of thromboprophylaxis be used primarily in patients at high risk of bleeding (Grade 1A), or possibly as an adjunct to anticoagulant-based thromboprophylaxis (Grade 2A)." (*Geerts*, 2008). The guideline identified both the advantages and the limitations of mechanical thromboprophylaxis modalities. Mechanical prophylaxis devices, particularly thigh-high graduated compression stockings, can have harmful consequences, most commonly related to skin irritation and breakdown. "Antiembolism" stockings such as TEDS, which provide relatively little compression (ankle 15 mm Hg, calf 8 mm Hg), are designed for non-ambulatory patients. The manufacturers of elastic stockings recommend higher compression (minimum ankle 30 mm Hg, minimum calf 20 mm Hg) for ambulatory patients. The tolerance and acceptability of higher compression elastic stockings are unclear. Though the work group understands that, in practice, mechanical means are widely used as an adjunct to pharmaceutical prophylaxis, the work group has not found compelling evidence of efficacy. Mechanical devices as a sole means of prophylaxis have not been demonstrated as efficacious. (Institute for Clinical Systems Improvement. Health Care Guideline: Venous Thromboembolism Prophylaxis, Seventh Edition, August 2010.).

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 prophylaxis* for venous thromboembolism prevention.

Performance denominator (PD) includes:

All patients with IBD aged 18 years and older, hospitalized for any reason.

Performance calculation

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

* Definition: For purposes of this measure, DVT prophylaxis can include low molecular weight heparin (LMWH), low-dose unfractionated heparin (LDUH), intravenous heparin, low-dose subcutaneous heparin, or intermittent pneumatic compression devices when pharmacological prophylaxis is contraindicated. Mechanical prophylaxis does not include anti-embolism stockings, such as TED hose. (See category II code 4070F)

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Components for this performance measure are defined as:

A	# of patient who receive prophylaxis* for venous thromboembolism prevention.
PD	# of patients with IBD (inflammatory bowel disease) aged 18 years and older hospitalized for any reason.

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 prophylaxis* for venous thromboembolism prevention.

D. Patients with no documentation of prophylaxis* for venous thromboembolism prevention.

Reporting denominator (RD) includes:

RD. Patients with IBD (inflammatory bowel disease) aged 18 years and older, hospitalized for any reason.

Reporting Calculation

$$\frac{\text{A (\# of patient visits meeting numerator criteria)} + \text{D (\# of patient visits NOT meeting numerator criteria)}}{\text{RD (\# of patient visits in denominator)}}$$

Components for this reporting measure are defined as:

A	# of patients who receive prophylaxis* for venous thromboembolism prevention.
D	# of patients with no documentation of prophylaxis* for venous thromboembolism prevention.
RD	# of patients with IBD (inflammatory bowel disease) aged 18 years and older, hospitalized for any reason.

* Definition: For purposes of this measure, DVT prophylaxis can include low molecular weight heparin (LMWH), low-dose unfractionated heparin (LDUH), intravenous heparin, low-dose subcutaneous heparin, or intermittent pneumatic compression devices when pharmacological prophylaxis is contraindicated. Mechanical prophylaxis does not include anti-embolism stockings, such as TED hose. (See category II code 4070F)

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Measure Specifications — Prophylaxis for Venous Thromboembolism — Inpatient measure

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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

Denominator (eligible population): All patients with IBD (inflammatory bowel disease) aged 18 years and older, hospitalized for any reason.

CPT Service Codes — Hospital: 99218, 99219, 99220,99224, 99225, 99226,99251-55, 99221, 99222, 99223, 99231, 99232, 99233, 99234, 99235, 99236, 99238, 99239, 99356, 99357

AND

ICD-9 diagnosis codes: 555, 556.

Numerator: Patients who receive prophylaxis for venous thromboembolism prevention. Report the CPT Category II 4069F, *Venous thromboembolism (VTE) prophylaxis received*.

Denominator exclusion: There are no exclusions for this measure.

Reporting instructions: There are no exclusions for this measure: 1P, 2P, and 3P may not be reported for this measure.

For purposes of this measure, DVT prophylaxis can include low molecular weight heparin (LMWH), low-dose unfractionated heparin (LDUH), intravenous heparin, low-dose subcutaneous heparin, or intermittent pneumatic compression devices when pharmacological prophylaxis is contraindicated. Mechanical prophylaxis does not include anti-embolism stockings, such as TED hose. (See category II code 4070F)

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Measure # 10

Tobacco Use: Screening & Cessation Intervention

For purposes of harmonization this measure mirrors the Physician Consortium for Performance Improvement® Preventive Care and Screening Measure.

Clinical Performance Measure

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

Denominator: All 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 (e.g., limited life expectancy)

Measure: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease 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.

*Includes use of any type of tobacco
** Cessation counseling intervention includes brief counseling (three minutes or less), and/or pharmacotherapy.

Evidence Base

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

All patients should be encouraged to quit smoking after surgery for Crohn's disease [EL1b, RG B] (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.)

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).

(Fiore MC, Jaen CR, Baker TB et al. Treating tobacco use and dependence: 2008 update. Clinical practice guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 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.

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There is an opportunity for improvement. For example, from 1998-2000:

- 43 percent of patients had smoking status documented at least once.
- 61 percent of patients that were documented smokers had their smoking status indicated on more than 50 percent of office visits.
- 12 percent 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

Performance denominator (PD) includes:

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

Denominator exclusions (C) Include:

Documentation of medical reason(s) for not screening for tobacco use (e.g., limited life expectancy)

Performance Calculation

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

Components for this performance measure are defined as:

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
PD	# of patients age 18 years or older with a diagnosis of inflammatory bowel disease.
C	# of patients with medical reason(s) for not screening for tobacco use (e.g., limited life expectancy)

*Includes use of any type of tobacco

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

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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

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

D. Patients 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 older with a diagnosis of inflammatory bowel disease.

Reporting Calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)} + \text{C (\# of patients with valid exclusions)} + \text{D (\# of patients NOT meeting numerator criteria)}}{\text{RD (\# of patients in denominator)}}$$

Components for this reporting measure are defined as:

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 .
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 older with a diagnosis of inflammatory bowel disease.

Measure Specifications — Tobacco Use: Screening & Cessation Intervention

Measure specifications for data sources other than administrative claims, incuding electronic health record systems and registration, will be developed at a later date.

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). 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 Service Codes: 99201-99205, 99212-99215, 99241-99245, 99354-99355, 99385-99387, 99395-99397, 99401-99404

AND

ICD-9 diagnosis codes: 555, 556.

*Includes use of any type of tobacco

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

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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.

CPT Category II code:

4004F: Patient screened for tobacco use AND received tobacco cessation counseling, if identified as a tobacco user.

OR

1036F: Current tobacco non-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 three-10 minutes.

99407: Smoking/tobacco counseling greater than 10 minutes.

Documentation of medical reason(s) for screening for tobacco use (e.g., limited life expectancy). Append modifier to CPT Category II code: 4XXXF-1P.

*Includes use of any type of tobacco

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

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Evidence Classification/Rating Schemes

AGA-quality of evidence on which a recommendation is based:

Grade A 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.

Grade B Evidence from at least one large well-designed clinical trial with or without randomization, from cohort or case-control analytical studies, or well-designed meta-analysis.

Grade C Evidence based on clinical experience, descriptive studies, or reports of expert committees.

European Crohn's and Colitis Organisation (ECCO) Definitions of Evidence Level (EL) and Grades of Recommendation

Evidence Levels

EL1a . . . . Systematic review (with homogeneity) of RCTs

EL1b . . . . Individual RCT (with narrow Confidence Interval)

EL1c . . . . All or none — poor quality cohort study

EL2a . . . . Systematic review (with homogeneity) of cohort studies

EL2b . . . . Individual cohort study (including low quality RCT; e.g., <80percent follow-up)

EL2c . . . . Outcomes research; ecological studies

EL3a . . . . Systematic review (with homogeneity) of case-control studies

EL3b . . . . Individual case-control study

EL4 . . . . . Case-series (and poor quality cohort and case-control studies)

EL5 . . . . . Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Grade of Recommendation

Grade A Consistent level I studies

Grade B Consistent level II or III studies or extrapolations from level I studies.

Grade C Level IV studies or extrapolations from level II or III studies.

Grade D Level V evidence or troublingly inconsistent or inconclusive studies of any level.

American College of Gastroenterology — quality of evidence on which a recommendation is based:

Grade A 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.

Grade B Evidence from at least one large well-designed clinical trial with or without randomization, from cohort or case-control analytical studies, or well-designed meta-analysis.

Grade C Evidence based on clinical experience, descriptive studies or reports of expert committees.

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American Society of Colon and Rectal Surgeons Levels/Gradings of Evidence Levels of Evidence and Grade Recommendation

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

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 randomized 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 randomization 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).

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All references are listed within the body of the document. This is not an inclusive listing of all references cited above.

1. American Gastroenterological Association (AGA) Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. Gastroenterology. 2006 Mar; 130(3):935-9. http://www.gastro.org/user-assets/Documents/02_Clinical_Practice/medical_position_statments/corticosteroids_mps.pdf
2. 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.
3. Leighton JA, Shen B, Baron TH, Adler DG, Davila R, Egan JV, Faigel DO, Gan SI, Hirota WK, Lichtenstein D, Qureshi WA, Rajan E, Zuckerman MJ, VanGuilder T, Fanelli RD. Endoscopy in the diagnosis and treatment of inflammatory bowel disease. Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. Gastrointest Endosc. 2006 Apr;63(4):558-65.
4. Lichtenstein GR, Hanauer SB, Sandborn WJ. Management of Crohn's disease in adults; Practice Parameters Committee of American College of Gastroenterology. Am J Gastroenterol. 2009 Feb;104(2):465-83.
5. Practice Parameters for the Surgical Treatment of Ulcerative Colitis (revised). Prepared by The Standards Practice Task Force and The American Society of Colon and Rectal Surgeons. Dis Colon Rectum 2005; 48: 1997–2009.
6. Practice Parameters for the Treatment of Perianal Abscess and Fistula-in-Ano (Revised). Prepared by The Standards Practice Task Force and The American Society of Colon and Rectal Surgeons Dis Colon Rectum. 2005; 48: 1337–1342.
7. J Ledingham and C Deighton, 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 TNFa blockers in adults with rheumatoid arthritis (update of previous guidelines of April 2001. Rheumatology. 2005; 44(2):157-163.
8. Carter MJ, Lobo AJ, Travis SPL on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. Gut. 2004;53:v1-v16
9. Centers for Disease Control and Prevention. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP).MMWR 1997;46(No. RR-8):[13].
10. Fiore MC, Jaen CR, Baker TB et al. Treating tobacco use and dependence: 2008 update. Clinical practice guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.
11. Grainge MJ, West J, Card TR. Venous thromboembolism during active disease and remission in inflammatory bowel disease: a cohort study. The Lancet, 2010 February; 375, 9715, Pages 657 - 663.
12. Institute for Clinical Systems Improvement. Health Care Guideline: Venous Thromboembolism Prophylaxis, Seventh Edition, August 2010.
13. Francis CW Prophylaxis for Thromboembolism in Hospitalized Medical Patients. N Engl J Med. 2007;356:1438-44.

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