INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP OVERVIEW

2016 PQRS OPTIONS FOR MEASURES GROUPS:

2016 PQRS MEASURES IN INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP:

#110 Preventive Care and Screening: Influenza Immunization
#111 Pneumonia Vaccination Status for Older Adults
#226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
#270 Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy
#271 Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment
#274 Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
#275 Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

INSTRUCTIONS FOR REPORTING:

- It is not necessary to submit the measures group-specific intent G-code for registry-based submissions. However, the measures group-specific intent G-code has been created for registry only measures groups for use by registries that utilize claims data.

  **G8899:** I intend to report the Inflammatory Bowel Disease (IBD) Measures Group

- Report the patient sample method:
  **20 Patient Sample Method via registries:** 20 unique patients (a majority of which must be Medicare Part B FFS patients) meeting patient sample criteria for the measures group during the reporting period (January 1 through December 31, 2016).

- Patient sample criteria for the IBD Measures Group are patients aged 18 years and older with a specific diagnosis of IBD accompanied by a specific patient encounter:

  **One of the following diagnosis codes indicating IBD:**

  **Accompanied by:**

  **One of the following patient encounter codes:** 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99406, 99407

  - To satisfactorily report the IBD Measures Group requires reporting a numerator option on all applicable measures, for each patient within the eligible professional's patient sample, a minimum of once during the reporting period.
• Measure #110 only needs to be reported a minimum of once during the reporting period when the patient’s visit included in the patient sample population is between January and March for the 2015-2016 influenza season OR between October and December for the 2016-2017 influenza season. When the patient’s office visit is between April and September, Measure #110 is not applicable and will not affect the eligible provider’s reporting or performance rate.

• Measure #111 should be reported on patients 18 years and older for purposes of this measures group. This measure assesses whether patients have received one or more pneumococcal vaccinations.

• Instructions for qualifying numerator option reporting for each of the measures within the Inflammatory Bowel Disease (IBD) Measures Group are displayed on the next several pages. The following composite Quality Data Code (QDC) has been created for registries that utilize claims data. This QDC may be reported in lieu of individual QDCs when all quality clinical actions for all applicable measures within the group have been performed.

  Composite QDC G8758: All quality actions for the applicable measures in the Inflammatory Bowel Disease (IBD) Measures Group have been performed for this patient

• Measure Group Reporting Calculations:

  Measures groups containing a measure with a 0% performance rate will not be counted as satisfactorily reporting the measures group. The recommended clinical quality action must be performed on at least one patient for each applicable measure within the measures group reported by the eligible professional.

  Performance exclusion QDCs are not counted in the performance denominator. If the eligible professional submits all performance exclusion QDCs, the performance rate would be 0/0 (null) and would be considered satisfactorily reporting.

  If a measure within a measures group is not applicable to a patient, the patient would not be counted in the performance denominator for that measure (e.g., Preventive Care Measures Group - Measure #39: Screening for Osteoporosis for Women Aged 65-85 Years of Age would not be applicable to male patients according to the patient sample criteria). If the measure is not applicable for all patients within the sample, the performance rate would be 0/0 (null) and would be considered satisfactorily reporting.

• NOTE: The detailed instructions in this specification apply exclusively to the reporting and analysis of the included measures under the measures group option.
Measure #110 (NQF 0041): Preventive Care and Screening: Influenza Immunization -- National Quality Strategy Domain: Community/Population Health

DESCRIPTION:
Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization

NUMERATOR:
Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization

Numerator Instructions:
- If reporting this measure between January 1, 2016 and March 31, 2016, quality-data code G8482 should be reported when the influenza immunization is administered to the patient during the months of August, September, October, November, and December of 2015 or January, February, and March of 2016 for the flu season ending March 31, 2016.
- If reporting this measure between October 1, 2016 and December 31, 2016, quality-data code G8482 should be reported when the influenza immunization is administered to the patient during the months of August, September, October, November, and December of 2016 for the flu season ending March 31, 2017.
- Influenza immunizations administered during the month of August or September of a given flu season (either 2015-2016 flu season OR 2016-2017 flu season) can be reported when a visit occurs during the flu season (October 1 - March 31). In these cases, G8482 should be reported.

Definition:
Previous Receipt - Receipt of the current season’s influenza immunization from another provider OR from same provider prior to the visit to which the measure is applied (typically, prior vaccination would include influenza vaccine given since August 1st).

NUMERATOR NOTE: The numerator for this measure can be met by reporting either administration of an influenza vaccination or that the patient reported previous receipt of the current season’s influenza immunization. If the performance of the numerator is not met, a clinician can report a valid performance exclusion for having not administered an influenza vaccination. For clinicians reporting a performance exclusion for this measure, there should be a clear rationale and documented reason for not administering an influenza immunization if the patient did not indicate previous receipt, which could include a medical reason (e.g., patient allergy), patient reason (e.g., patient declined), or system reason (e.g., vaccination not available). The system reason should be indicated only for cases of disruption or shortage of influenza vaccination supply.

Numerator Options:
Performance Met: Influenza immunization administered or previously received (G8482)

OR

Other Performance Exclusion: Influenza immunization was not administered for reasons documented by clinician (e.g., patient allergy or other medical reasons, patient declined or other patient reasons, vaccine not available or other system reasons) (G8483)

OR

Performance Not Met: Influenza immunization was not administered, reason not given (G8484)
Measure #111 (NQF 0043): Pneumonia Vaccination Status for Older Adults -- National Quality Strategy Domain: Community/Population Health

**DESCRIPTION:**
Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine

**NUMERATOR:**
Patients who have **ever** received a pneumococcal vaccination

**NUMERATOR NOTE:** While the measure provides credit for adults 65 years of age and older who have ever received either the PCV13 or PPSV23 vaccine (or both), according to ACIP recommendations, patients should receive both vaccines. The order and timing of the vaccinations depends on certain patient characteristics, and are described in more detail in the ACIP recommendations.

**Numerator Options:**

**Performance Met:**
Pneumococcal vaccine administered or previously received (4040F)

OR

**Performance Not Met:**
Pneumococcal vaccine was not administered or previously received, reason not otherwise specified (4040F with 8P)
**Measure #226 (NQF 0028): Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention -- National Quality Strategy Domain: Community/Population Health**

**DESCRIPTION:**
Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user

**NUMERATOR:**
Patients who were screened for tobacco use at least once within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user

**Definitions:**
- **Tobacco Use** – Includes use of any type of tobacco.
- **Tobacco Cessation Intervention** – Includes brief counseling (3 minutes or less), and/or pharmacotherapy.

**NUMERATOR NOTE:** In the event that a patient is screened for tobacco use and identified as a user but did not receive tobacco cessation intervention report 4004F with 8P.

**Numerator Options:**

- **Performance Met:** Patient screened for tobacco use AND received tobacco cessation intervention (counseling, pharmacotherapy, or both), if identified as a tobacco user (4004F)
- **Performance Met:** Current tobacco non-user (1036F)
- **Medical Performance Exclusion:** Documentation of medical reason(s) for not screening for tobacco use (eg, limited life expectancy, other medical reasons) (4004F with 1P)
- **Performance Not Met:** Tobacco screening OR tobacco cessation intervention not performed, reason not otherwise specified (4004F with 8P)
Measure #270: Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy -- National Quality Strategy Domain: Effective Clinical Care

DESCRIPTION:
Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy within the last twelve months

NUMERATOR:
Prescribed a corticosteroid sparing therapy (e.g., thiopurines, methotrexate, or biologic agents)

Definition:  
Corticosteroids - 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.

Numerator Options:  
Performance Met:  
Corticosteroid sparing therapy prescribed (4142F)  
AND  
Patient who have received or are receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills within the last twelve months (G9467)

OR

Medical Performance Exclusion:  
Documentation of medical reason(s) for not treating with corticosteroid sparing therapy (e.g., benefits of continuing steroid therapy outweigh the risk of continuing steroid therapy or initiating steroid sparing therapy, patient is receiving the first course of corticosteroids for the treatment of IBD)  
(4142F with 1P)

OR

Patient Performance Exclusion:  
Documentation of patient reason(s) for not treating with corticosteroid sparing therapy (eg, patient refuses to initiate steroid sparing therapy)  
(4142F with 2P)

AND  
Patient who have received or are receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills within the last twelve months (G9467)

OR
**Other Performance Exclusion:**

Patient not receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills (G9468)

**OR**

**Performance Not Met:**

Corticosteroid sparing therapy not prescribed, reason not otherwise specified (4142F with 8P)

**AND**

Patient who have received or are receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills within the last twelve months (G9467)
Measure #271: Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment -- National Quality Strategy Domain: Effective Clinical Care

DESCRIPTION:
Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year

NUMERATOR:
Patients who have received dose of corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and who were documented for risk of bone loss during the reporting year or the pervious calendar year

Definitions:
Corticosteroids - 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.
Documented - 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, and ordering of Central Dual-energy X-Ray Absorptiometry (DXA) scan.

Numerator Options:
Performance Met:
Within the past 2 years, Central Dual-energy X-Ray Absorptiometry (DXA) ordered and documented review of systems and medication history or pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed (G8861)

AND
Patients who have received or are receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills (G9469)

OR
Other Performance Exclusion:
Patients not receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills (G9470)

OR
**Performance Not Met:**

Within the past 2 years, Central Dual-energy X-Ray Absorptiometry (DXA) not ordered and documented, no review of systems and no medication history or pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed (G9472)

**AND**

Patients who have received or are receiving corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills (G9469)
Measure #274: Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy -- National Quality Strategy Domain: Effective Clinical Care

**DESCRIPTION:**
Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy

**NUMERATOR:**
Patients who had TB screening performed and results interpreted, within 6 months prior to receiving a first course of anti-TNF therapy

**Definition:**
First Course of anti-TNF therapy - the first (ever) course of anti-TNF therapy

**Numerator Options:**
- **Performance Met:**
  - Documentation that tuberculosis (TB) screening test performed and results interpreted (3510F)
- AND
  - Patients receiving a first course of anti-TNF therapy (G8868)

OR

- **Performance Met:**
  - Patients not receiving a first course of anti-TNF (tumor necrosis factor) therapy (6150F)

OR

- **Medical Performance Exclusion:**
  - Documentation of medical reason(s) for not performing TB screening test within 6 months prior to receiving a first course of anti-TNF therapy (eg, patient positive for TB and documentation of past treatment; patient recently completed course of anti-TB therapy) (3510F with 1P)

OR

- **Patient Performance Exclusion:**
  - Documentation of patient reason(s) for not performing TB screening test within 6 months prior to receiving a first course of anti-TNF therapy (eg, patient declined) (3510F with 2P)
- AND
  - Patients receiving a first course of anti-TNF therapy (G8868)

OR

- **Performance Not Met:**
  - TB screening test not performed within 6 months prior to receiving a first course of anti-TNF therapy, reason not otherwise specified (3510F with 8P)
- AND
  - Patients receiving a first course of anti-TNF therapy (G8868)
Measure #275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy -- National Quality Strategy Domain: Effective Clinical Care

DESCRIPTION:
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

NUMERATOR:
Patients who had HBV status assessed and results interpreted within one year prior to receiving a first course of anti-TNF therapy

Numerator Instructions: HBV status must be assessed by one of the following: HBsAG, HBsAG neutralization, HbcAb total, HbcAB IgM, HBsAB.

Definition:
First Course of anti-TNF therapy: the first (ever) course of anti-TNF therapy

Numerator Options:
Performance Met: 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 (3517F)

OR
Performance Met: Patient has documented immunity to hepatitis B and is receiving a first course of anti-TNF therapy (G8869)

OR
Other Performance Exclusion: Documented reason for not assessing Hepatitis B Virus (HBV) status (e.g. patient not receiving a first course of anti-TNF therapy, patient declined) within one year prior to first course of anti-TNF therapy (G9504)

OR
Performance Not Met: Hepatitis B Virus (HBV) status not assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy, reason not otherwise specified (3517F with 8P)
MEASURE #110 – PREVENTIVE CARE AND SCREENING: INFLUENZA IMMUNIZATION
RATIONALE:
Annual influenza vaccination is the most effective method for preventing influenza virus infection and its complications. Influenza vaccine is recommended for all persons aged ≥ 6 months who do not have contraindications to vaccination.

CLINICAL RECOMMENDATION STATEMENTS:
The following evidence statements are quoted verbatim from the referenced clinical guidelines.

Routine annual influenza vaccination is recommended for all persons aged >=6 months who do not have contraindications. Vaccination optimally should occur before onset of influenza activity in the community. Health care providers should offer vaccination soon after vaccine becomes available (by October, if possible). Vaccination should be offered as long as influenza viruses are circulating. (CDC/ACIP, 2014)

MEASURE #111 - PNEUMONIA VACCINATION STATUS FOR OLDER ADULTS
RATIONALE:
Pneumonia is a common cause of illness and death in the elderly and persons with certain underlying conditions such as heart failure, diabetes, cystic fibrosis, asthma, sickle cell anemia, or chronic obstructive pulmonary disease (NHLBI, 2011). In 1998, an estimated 3,400 adults aged > 65 years died as a result of invasive pneumococcal disease (IPD) (CDC, 2003).

Among the 91.5 million US adults aged > 50 years, 29,500 cases of IPD, 502,600 cases of nonbacteremic pneumococcal pneumonia and 25,400 pneumococcal-related deaths are estimated to occur yearly; annual direct and indirect costs are estimated to total $3.7 billion and $1.8 billion, respectively. Pneumococcal disease remains a substantial burden among older US adults, despite increased coverage with 23-valent pneumococcal polysaccharide vaccine, (PPV23) and indirect benefits afforded by PCV7 vaccination of young children (Weycker, et al., 2011).

Vaccination has been found to be effective against bacteremic cases (OR: 0.34; 95% CI: 0.27–0.66) as well as nonbacteremic cases (OR: 0.58; 95% CI: 0.39–0.86). Vaccine effectiveness was highest against bacteremic infections caused by vaccine types (OR: 0.24; 95% CI: 0.09–0.66) (Vila-Corcoles, et al., 2009).

CLINICAL RECOMMENDATION STATEMENTS:
The Advisory Committee on Immunization Practices’ (ACIP) released recommendations in September, 2014, describing the use of 13-valent pneumococcal conjugate vaccine (PCV13) and 23-valent pneumococcal polysaccharide vaccine (PPSV23) among adults aged ≥65 Years. According to the ACIP, both the PCV13 and PPSV23 should be administered routinely in series to all adults aged ≥65 years. Adults aged ≥65 years with no previous history or an unknown history of pneumococcal vaccination should receive PCV13 before PPSV23. Adults aged ≥65 years with a history of PPSV23 should receive PCV13, after which a second dose of PPSV23 may be administered for those adults with an indication for two doses of PPSV23.

MEASURE #226 – PREVENTIVE CARE AND SCREENING: TOBACCO USE: SCREENING AND CESSATION INTERVENTION
RATIONALE:
This measure is intended to promote adult tobacco screening and tobacco cessation interventions for those who use tobacco products. There is good evidence that tobacco screening and brief cessation intervention (including counseling and/or pharmacotherapy) 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.
CLINICAL RECOMMENDATION STATEMENTS:
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

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 use 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 and Human Services. Public Health Service, 2008)

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

Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention, whether or not he or she is referred to an intensive intervention. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (ie, pregnant women, smokeless tobacco users, light smokers, and adolescents). (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. (A Recommendation) (U.S. Preventive Services Task Force, 2009)

MEASURE #270 - INFLAMMATORY BOWEL DISEASE (IBD): PREVENTIVE CARE: CORTICOSTEROID SPARING THERAPY
RATIONALE:
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). Similar findings were reached after an additional 5 years of follow-up in this patient population using multivariate logistic regression analyses which demonstrated a significant increase in mortality risk associated with chronic corticosteroid therapy, Hazard Ratio-2.14. (Lichtenstein G et al. Serious Infection and Mortality in Patients with Crohn’s Disease: More Than 5 Years of Follow-up in the TREAT Registry. Am J Gastro. 2012: 107:1409-1422.)

CLINICAL RECOMMENDATION STATEMENTS:
Long-term treatment with corticosteroids is undesirable. Patients with chronic active corticosteroid-dependent disease (either CD or UC) should be treated with AZA [azathioprine] 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
Individual patients with either CD or UC who experience a severe flare of disease requiring corticosteroid treatment or require retreatment 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 Organization [ECCO, 2006]. European evidence based consensus on the diagnosis and management of Crohn's disease: current management. Gut. 2006 Mar; 55 Suppl 1:i16-35.)

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

This is the first report from the TREAT Registry, a large, prospective, observational research program designed to address the long term safety of medications, including infliximab, for the treatment of CD. After adjustment for confounding factors including disease severity and the use of other medications, the risk for serious infection or death with infliximab use was similar to that observed with the use of conventional immunomodulators, and was not higher than the overall incidence of serious infections among all CD patients.


**MEASURE #271 - INFLAMMATORY BOWEL DISEASE (IBD): PREVENTIVE CARE: CORTICOSTEROID RELATED IATROGENIC INJURY – BONE LOSS ASSESSMENT**

**RATIONALE:**

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.)

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 bone mineral density 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)


CLINICAL RECOMMENDATION STATEMENTS:

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) DXA screening is recommended in inflammatory bowel disease patients with one or more risk factors: history of vertebral fractures, postmenopausal, male >50 years of age, chronic corticosteroid therapy, or hypogonadism. If the initial DXA is normal, the AGA recommends repeat testing in 2-3 years. If the patient has osteoporosis, or has a history of a low trauma fracture, evaluation for secondary causes should be completed. Suggested studies include a complete blood count, serum concentrations of alkaline phosphatase level, calcium, creatinine, and 25-OH vitamin D, serum protein electrophoresis, serum calcium, and a testosterone level in males. (Bernstein CN, Leslie WD, Leboff MS. AGA technical review on osteoporosis in gastrointestinal diseases. Gastroenterology. 2003;124(3):795-841).

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]. Newer data also support the use of strontium salts [EL2a, RG B]. Patients receiving systemic steroid therapy should receive calcium and vitamin D for prophylaxis [EL5, RG D]. (Assche G et al., Second European evidence-based consensus on ulcerative colitis' diagnosis and management. Journal of Crohn's and Colitis (2013) 7, 1-33.)

Diagnosis of osteoporosis in adults is best made from at T score of less than -2.5 on radiographic bone densitometry [EL1a, RG A], all other diagnostic methods having current limitations [EL2b, RG B]. The presence of osteoporosis identifies patients at above average risk for fracture and who should receive treatment [EL2b, RG B]. Osteopenia
may be a prognostic marker for future osteoporosis, but presents little direct risk [EL2b, RG C]. However if the T score is less than -1.5, treatment with calcium and vitamin D should be recommended [EL4, RG C]. Pre-existing history of fracture is of substantial adverse prognostic significance and patients should be treated for osteoporosis even if the T score is normal [EL4, RG C]. (Assche G et al., Second European evidence-based consensus on ulcerative colitis' diagnosis and management. Journal of Crohn’s and Colitis (2013) 7, 1-33.)

MEASURE #274 - INFLAMMATORY BOWEL DISEASE (IBD): TESTING FOR LATENT TUBERCULOSIS (TB) BEFORE INITIATING ANTI-TNF (TUMOR NECROSIS FACTOR) THERAPY

RATIONALE:
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.)

CLINICAL RECOMMENDATION STATEMENTS:
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 IGRA may be used as described above, there is evidence that the T-SPOT.TB assay may be more sensitive than the QFT-GIT assay in active TB, and this characteristic might be especially relevant in immunocompromised populations. While the approach of accepting either test result (TST or IGRA) as positive will improve the sensitivity of detecting LTBI in immunocompromised populations, there are no data supporting the efficacy of preventive
therapy in TST-negative but IGRA-positive individuals. Thus the ©2010-2011 American Gastroenterological Association. All rights reserved. Page 31 of 52 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.)


MEASURE #275 - INFLAMMATORY BOWEL DISEASE (IBD): ASSESSMENT OF HEPATITIS B VIRUS (HBV) STATUS BEFORE INITIATING ANTI-TNF (TUMOR NECROSIS FACTOR) THERAPY

RATIONALE:
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. (Kaiser T, Moessner J, McHutchison JG, Tillmann HG. Life threatening liver disease during treatment with monoclonal antibodies. BMJ. 2009;338:b508)

CLINICAL RECOMMENDATION STATEMENTS: