NATIONAL QUALITY FORUM

Stage 1 Concept Submission and Evaluation Worksheet 1.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's concept evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: C 2059 NQF Project: GI and GU Project

Date Submitted: Jul 16, 2012

CONCEPT SPECIFICATIONS

De.1 Concept Title: IBD preventive care: corticosteroid sparing therapy

Co.1.1 Concept Steward: American Gastroenterological Association

De.2 Brief Description of Concept: 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.

2a1.1 Numerator Statement: 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).

2a1.4 Denominator Statement: All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

2a1.8 Denominator Exclusions: PQRS: Documentation of medical reason(s) for not treating with corticosteroid sparing therapy (e.g., toxicity,allergy,loss of effectiveness).
In the AGA Digestive Health Recognition Program (TM) because of the use of clinical data those that have not received a dose of corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days are excluded from the denominator. We have also been able to include a patient exclusion for example if the patient refuses steroid sparing therapy.

1.1 Concept Type: Process
2a1. 25-26 Data Source: Electronic Clinical Data : Registry
2a1.33 Level of Analysis: Clinician : Individual

1.2-1.4 Is this concept paired with another measure? No

2a1.1 Numerator Statement *(Brief, narrative description of the concept focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
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).

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the numerator.
CPT Category II codes have been assigned for purposes of PQRS. Subsequently the AGA Digestive Health Recognition Program (TM)has been launched. In this program an online data collection form to record clinical data for each patient will be submitted to a registry.
Related definition: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.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.

2a1.5 Target Population Category *(Check all the populations for which the concept is specified and tested if any)*: Adult/Elderly Care, Populations at Risk : Individuals with multiple chronic conditions

2a1.7 Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the denominator.
For PQRS: Age and ICD9 /ICD10 codes in combination with CPT Service Codes.
AGA Digestive Health Recognition Program (TM): Uses an online data collection form to record age and diagnosis data for each patient (in sample) will be submitted to a registry. In the AGA Digestive Health Recognition Program (TM) because of the use of clinical data those that have not received a dose of corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days are excluded from the denominator.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
PQRS: Documentation of medical reason(s) for not treating with corticosteroid sparing therapy (e.g., toxicity,allergy,loss of effectiveness).
In the AGA Digestive Health Recognition Program (TM) because of the use of clinical data those that have not received a dose of corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days are excluded from the denominator. We have also been able to include a patient exclusion for example if the patient refuses steroid sparing therapy.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the exclusions.
PQRS: Add a P1 modifer to the CPT Category II code that identifies that corticosteroid sparing therapy prescribed.
AGA Digestive Health Recognition Program: Addressed with specfic questions in the data collection form regarding these exclusions.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, if you plan to stratify the measure results, describe the plans for stratification.

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)*
For new concepts, if an outcome, describe how you plan to adjust for differences in case mix/risk across measured entities.

2a1.25 Data Source *(Check all the sources for which the concept is specified and tested)*. If other, please describe:
Electronic Clinical Data : Registry

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): The AGA Digestive Health Recognition Program(TM)

2a1.33 Level of Analysis (*Check the levels of analysis for which the concept is specified and tested*): Clinician : Individual

2a1.34 Care Setting *(Check all the settings for which the concept is specified and tested)*: Ambulatory Care : Clinician Office/Clinic

IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is the criterion that must be met in order to recommend a concept for approval. All three

subcriteria must be met to pass this criterion. See guidance on evidence.

1a. High Impact: H☐ M☐ L☐ I ☐
(*The concept directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Gastrointestinal (GI), Prevention
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Prevention, Safety : Complications, Safety : Medication Safety

1a.1 Demonstrated High Impact Aspect of Healthcare: Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Steroids are required in 40% of patients with inflammatory bowel disease (1). Initial therapy with corticosteroids is associated with a poorer prognosis, including steroid dependence (inability to taper off steroids without experiencing a disease flare), disabling disease and surgery (1-3). Population-based studies have shown that steroid dependence occurs in one third of patients (1-2). A recent study from the Keiser health care organization in California compared therapy trends between 1998-1999 and 2004-2005 (4). Prolonged steroid exposure (continuous use of steroid for >120 days) during 1998-1999 and 2004-2005 occurred in 14% and 9% of Crohn's disease (CD) patients respectively. The corresponding percentages among ulcerative colitis (UC) patients were 11% and 14% (4). Despite advances in the therapy of IBD, a considerable subset of IBD patients receive prolonged steroid therapy. Findings of a comprehensive literature review and analysis (publications range 1966-2006) show that, although
the majority of patients with active Crohn's disease respond rapidly to steroid treatment, about a half will
be either steroid resistant or steroid dependent at 1 year. (5)
Major steroid -related side effects for adult patients with Crohn's disease are metabolic bone disease and infectious complications. Steroid sparing drugs (immunosuppressants and biologics) provide alternatives to treating with corticosteroids alone. Introduction of these steroid sparing therapies into a patient' treatment provides the opportunity to minimize exposure to corticosteroids and their side effects. (5)
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.(6)
Long-term steroids are associated with an osteoporotic fracture rate of 30–50%, mostly at sites of high
abecular bone content such as the vertebrae, hips and pelvis.78 Attempts to minimize bone loss by using
alternate day therapy failed to reduce fracture rates(5)
In a 2006 study, use of the TREAT Registry permitted multivariate analyses, the results indicated that the increased rate of infection likely is attributed to disease severity and the concomitant use of corticosteroids. The use of prednisone was a strong independent risk factor for both serious infection and death. Increased risk for infection with infliximab use, multivariate logistic regression analysis
suggested that infliximab was not an independent predictor of serious infections (OR, .99; 95% CI, .64 –
1.54). Factors independently associated with serious infections included prednisone use (OR, 2.21; 95% CI, 1.46 –3.34; P < .001), narcotic analgesic use (OR,2.38; 95% CI, 1.56 –3.63; P < .001), and moderate to-severe disease activity (OR, 2.11; 95% CI, 1.10 – 4.05; P _ .024). (7)

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Faubion WA Jr, Loftus EV Jr, Harmsen WS, Zinsmeister AR, Sandborn WJ. The natural history of corticosteroid therapy for inflammatory bowel disease: a population-based study. Gastroenterology. 2001 Aug;121(2):255-60.
2. Peyrin-Biroulet L, Loftus EV Jr, Colombel JF, Sandborn WJ. The natural history of adult Crohn´s disease in population-based cohorts. Am J Gastroenterol. 2010 Feb;105(2):289-97.
3. Beaugerie L, Seksik P, Nion-Larmurier I, Gendre JP, Cosnes J. Predictors of Crohn´s disease. Gastroenterology. 2006 Mar;130(3):650-6
4. Herrinton LJ, Liu L, Fireman B, Lewis JD, Allison JE, Flowers N, Hutfless S, Velayos FS, Abramson O, Altschuler A, Perry GS. Time trends in therapies and outcomes for adult inflammatory bowel disease, Northern California, 1998-2005. Gastroenterology. 2009 Aug;137(2):502-11.

5. Irving PM, Gearry RB, Sparrow MP, Gibson PR. Review article: appropriate use of corticosteroids in Crohn´s disease. Aliment Pharmacol Ther. 2007 Aug 1;26(3):313-29.
6.Lewis J et al. Immunosuppressant Medications and Mortality in Inflammatory Bowel Disease. Am J Gastro.2008;103:1428-1435
7. 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. Erratum in: Clin Gastroenterol Hepatol. 2006 Jul;4(7):931.

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this concept:
The risk of co-morbidities including sepsis and fracture are associated with long term/ high dose corticosteroid. Additionally,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. 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). By increasing the tranistion of IBD patients to steroid sparing therapy their use and dependency on corticostreoid decreases along with risk of associated co-morbidities.

1b.2 Provide data demonstrating performance gap/opportunity for improvement *(Variation or overall less than optimal performance across providers).* List citations in 1b.3.
For endorsement maintenance, provide performance data on the measure as specified *(mean, std dev, distribution of scores by decile, min, max).* Describe who was included in the performance data in 1b.3.Study of patients with luminal IBD under the care of a gastroenterologist who sought a a second opinion at Brigham and Women´s Hospital between January 2001 and April 2003.Clinical information was obtained by direct patient interview at the time of initial patient visit and by a review of prior records. Of the 65 patients with confirmed IBD, 56 patients had symptoms of active disease and 9 were asymptomatic. All analyses were carried out on the 56 patients with active disease. Within 6 months of their clinic visit, 35 patients had received corticosteroid therapy, and 27 (77%) patients had been treated with corticosteroids for greater than 3 months. In 16 of 27 (59%) there was no attempt to start steroid sparing medications such as 6-mercaptopurine (6MP), azathioprine, or infliximab.

1b.3 Citations for Data on Performance Gap provided in 1b.2.
For endorsement maintenance, describe who was included in the performance results reported in lb.2 *(number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include)*
Reddy SI, Friedman S, Telford JJ, Strate L, Ookubo R, Banks PA. Are patients with inflammatory bowel disease receiving optimal care? Am J Gastroenterol. 2005 Jun;100(6):1357-61. PMID: 15929770.

1b.4 Provide data on disparities by population group. List citations in 1b.5.
For endorsement maintenance, provide performance data by population group on the measure as specified *(e.g., mean, std dev)*. Describe who was included in the performance data in 1b.5.
Several studies have shown disparities by race and insurance status in the management of IBD. In addition, racial and socioeconomic disparities have been identified in osteoporosis screening and treatment.
A body of data suggests racial disparities in the utilization of specialist care, medical therapies and surgery in IBD.
For example, Nguyen et al (1)found that blacks were less likely than whites to be under the regular care (defined as at least annual visit) of a gastroenterologist (adjusted odds ratio (aOR) 0.43; 95% confidence interval (CI): 0.25-0.75) or IBD specialist (aOR 0.37; 95% CI: 0.22-0.61). Over the preceding 12 months, blacks were more likely than whites to have at least one visit to the ED (aOR 2.02; 95% CI: 1.22-3.35), but there was no difference in hospitalization. Among CD patients with prolonged steroid use, blacks were less likely than whites to have been on infliximab (aOR 0.41; 95% CI: 0.21-0.77).
Nguyen et al found that, among IBD inpatients with malnutrition, parenteral nutrition use was lower among African Americans compared with whites. (2)
Using data from the Nationwide Inpatient Sample, and after adjusting for age, sex, health insurance, comorbidity, median neighborhood income, and hospital characteristics, Nguyen et al found that the relative rate ratios of undergoing bowel resection for CD for were 0.68 (95% CI: 0.61-0.76), 0.70 (95% CI: 0.60-0.83), and 0.31 (95% CI: 0.16-0.59) for African Americans, Hispanics, and Asians respectively compared to whites. Compared to those with private insurance, the relative risk of surgery for those with Medicare, those with Medicaid, and those who were "self-pay" was 0.48 (95% CI: 0.44-0.54), 0.52 (95% CI: 0.46-0.59), and 0.67 (95% CI: 0.58-0.77), respectively. (3)

Similar disparities were seen in hospitalized patients with UC. Using data from the Nationwide Inpatient Sample, and after adjusting for age, gender, health insurance, comorbidity, and hospital characteristics, Nguyen et al found the colectomy rate ratios for African Americans and Hispanics compared with whites were 0.46 (95% CI, 0.35-0.60) and 0.74 (95% confidence interval, 0.59-0.93), respectively. African Americans experienced a longer interval between admission and colectomy than whites (8.8 vs 5.6 days, P=.02). Between 1998 and 2003, the colectomy rate decreased among whites but not African Americans and Hispanics. (4)
Disparities in osteoporosis screening and treatment have been documented in numerous studies.
In a population-based cohort study (5), and after multivariable adjustment for fracture-related risk factors, the likelihood of receiving osteoporosis therapy among African Americans was lower than among Caucasians [OR 0.44, 95% CI, 0.37-0.53].
Neuner et al (6) aimed to determine whether racial and socioeconomic disparities in osteoporosis screening diminish after hip fracture. The population consisted of female Medicare recipients aged 65-89 years old with hip fractures between January 2001 and June 2003. In a logistic regression model adjusted for age, state, and comorbidity, women of black race were about half as likely (RR 0.52 [0.43, 0.62]) and Hispanic women about 2/3 as likely (RR 0.66 [0.54, 0.80]) as white women to undergo testing before their fracture. They remained less likely (RR 0.66 [0.50, 0.88] and 0.58 [0.39, 0.87], respectively) to undergo testing after fracture. Women residing in zip codes in the lowest tertile of income and education were less likely than those in higher-income and educational tertiles to undergo testing before fracture, but were no less likely to undergo testing in the 6 months after fracture.
In a cross-sectional survey of a random sample of 400 women aged 45 years and older enrolled in a family medicine community-based research network, compared with black women, white women had 5.96 (95% CI 3.01, 11.79) times the adjusted odds of having a past bone density test, 2.97 (95% CI 1.57, 5.60) times the odds of discussing osteoporosis with their doctor, and 2.42 (95% CI 1.30, 4.50) times the odds of a physician recommendation to take calcium (7).

1b.5 Citations for Data on Disparities Cited in 1b.4:

1.Nguyen GC, LaVeist TA, Harris ML, Wang MH, Datta LW, Brant SR.Racial disparities in utilization of specialist care and medications in inflammatory bowel disease. Am J Gastroenterol. 2010 Oct;105(10):2202-8. Epub 2010 May 18.
2. Nguyen GC, Munsell M, Brant SR, LaVeist TA. Racial and geographic disparities in the use of parenteral nutrition among inflammatory bowel disease inpatients diagnosed with malnutrition in the United States. JPEN J Parenter Enteral Nutr. 2009 Sep-Oct;33(5):563-8. Epub 2009 Jun 29.
3.Nguyen GC, Bayless TM, Powe NR, Laveist TA, Brant SR. Race and health insurance are predictors of hospitalized Crohn´s disease patients undergoing bowel resection. Inflamm Bowel Dis. 2007 Nov;13(11):1408-16.
4.Nguyen GC, Laveist TA, Gearhart S, Bayless TM, Brant SR. Racial and geographic variations in colectomy rates among hospitalized ulcerative colitis patients. Clin Gastroenterol Hepatol. 2006 Dec;4(12):1507-1513.
5.Curtis JR, McClure LA, Delzell E, Howard VJ, Orwoll E, Saag KG, Safford M, Howard G. Population-based fracture risk assessment and osteoporosis treatment disparities by race and gender. J Gen Intern Med. 2009 Aug;24(8):956-62.
6.Neuner JM, Zhang X, Sparapani R, Laud PW, Nattinger AB. Racial and socioeconomic disparities in bone density testing before and after hip fracture. J Gen Intern Med. 2007 Sep;22(9):1239-45.
7.Gourlay ML, Callahan LF, Preisser JS, Sloane PD. Osteoporosis preventive care in white and black women in community family medicine settings. South Med J. 2007 Jul;100(7):677-82.

1c. Evidence (*Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the concept focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I ☐ Quality: H☐ M☐ L☐ I ☐ Consistency: H☐ M☐ L☐ I ☐

Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the concept pass subcriterion1c? Yes☐ IF rationale supports relationship

Please see the attached Evidence Submission Worksheet for evidence specifications.

Was the concept approval criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

3. USABILITY

4.1 Current and Planned Use
Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).
(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)
Current Use:
Planned Use:

5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:
C 2062 : IBD preventive care: corticosteroid related iatrogenic injury – bone loss assessment

5a.1 If this concept has EITHER the same focus OR the same target population as NQF-endorsed measure(s): Are the specifications completely harmonized?

5a.2 If the specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s):
Describe why this concept is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:

CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): American Gastroenterological Association, 4930 Del Ray Ave. | Bethesda | Maryland | 20814

Co.2 Point of Contact: Debbie | Robin, Senior Director for Quality | drobin@gastro.org | 301-941-2615-

Co.3 Concept Developer if different from Concept Steward: American Gastroenterological Association | 4930 Del Ray Ave. | Bethesda | Maryland, 20814

Co.4 Point of Contact: Debbie | Robin, Senior Director for Quality | drobin@gastro.org | 301-941-2615-

Co.5 Submitter: Debbie | Robin, Senior Director for Quality | drobin@gastro.org | 301-941-2615- | American Gastroenterological Association

Co.6 Additional organizations that sponsored/participated in concept development:
This measure was developed via the Physician Consortium for Physician Improvement (PCPI)(R)Independent Measures Development Process. In addition to a PCPI representative there were representatives from the Crohn´s and Colitis Foundation of America (CCFA) and American Society of Colon and Rectal Surgeons.

Co.7 Public Contact: Debbie | Robin, Senior Director for Quality | drobin@gastro.org | 301-941-2615- | American Gastroenterological Association

ADDITIONAL INFORMATION
Concept Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the concept was first released: Ad.4 Month and Year of most recent revision: Ad.5 What is your frequency for review/update of this measure? Ad.6 When is the next scheduled review/update for this measure?
Ad.7 Copyright statement: © 2010-2011 American Gastroenterological Association. All Rights Reserved. Limited proprietary coding is contained in the measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The AGA, AMA the PCPI and its members disclaim all liability for use or accuracy of any current procedural terminology (CPT®) or other coding contained in the specifications. CPT® contained in the Measure specifications is copyright 2004- 2010 American Medical Association. LOINC® is copyright 2004-2010 Regenstrief Institute, Inc. This material contains SNOMED Clinical Terms® (SNOMED CT®) copyright 2004-2010 International Health Terminology Standards Development Organisation. All Rights Reserved.
Ad.8 Disclaimers: Physician performance measures (measures) and related data specifications have been developed by the American Gastroenterological Association (AGA) Institute. These performance measures are not clinical guidelines and do not establish a standard of medical care, nor have been tested for all potential applications. Neither the AGA, the American Medical Association (AMA), the Physician Consortium for Performance Improvement® (PCPI™), nor its members shall be responsible for any use of the measures. THE MEASURES AND SPECIFICATIONS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND.
Ad.9 Additional Information/Comments:
Date of Submission (*MM/DD/YY*): Jul 16, 2012

NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

Measure Title: IBD preventive care: corticosteroid sparing therapy
Date of Submission: 7/16/2012

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages incudes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the evidence criterion (1c) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- See NQF guidance on evaluating evidence. Contact NQF staff for examples, resources, or questions.

STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

1c.1.This is a measure of:

Outcome

☐ Health outcome: 3T

☐ Intermediate clinical outcome: 3T

X Process: prescribed a corticosteroid sparing therapy (e.g. thiopurines, methotrexate, or anti-TNF agents).

☐ Structure: 3T

☐ Other: 3T

HEALTH OUTCOME MEASURE *If not a health outcome, skip to 1c.3*

If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.

1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

1c.2.1. **State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service**.

Note: For health outcome measures, no further information is required

STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).

1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. *(Do not summarize the evidence here.)*

Long term use of corticosteroids by patients with inflammatory bowel disease increases the risk of serious infection and other health complications including death.

Introducing steroid sparing (SS) therapies to IBD patients on corticosteroids can lead to decreased corticosteroid use and a decrease in related side effects such as sepsis and fractures. Steroid sparing drugs also decrease IBD flares/exacerbations (true).

Prescription of such drugs is a proxy for knowing that SS therapies have been considered by the physician.

Prescription of steroid sparing (SS) therapies >>>Decrease in steroid dose >>>Deceased complication (decreased bone loss sepsis, death)

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? YesX No☐
If no, skip to #1c.6

If yes, *answer 1c.4.1-1c.5.*
1c.4.1. **Guideline citation** (*including date*): 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.)

1c.4.2. **URL** (*if available online*): http://download.journals.elsevierhealth.com/pdfs/journals/0016-5085/PIIS0016508506000734.pdf
1c.4.3. **Identify guideline number and/or page number**: Page 936, second column , 2nd and 3rd bullets.

1c.4.4. **Quote verbatim, the specific guideline recommendation**:
Long-term treatment with corticosteroids is undesirable. Patients with chronic active corticosteroid-dependent disease (either CD or UC) should be treated with AZA 2.0–3.0 mg · kg^{-1} · day^{-1} or 6-MP 1.0–1.5 mg · kg^{-1} · day^{-1} 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)
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)
1c.4.5. **Grade assigned to the recommendation with definition of the grade**:
Recommendations are based on evidence quality Grade A: Homogeneous 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 C: Evidence based on clinical experience, descriptive studies, or reports of expert committees

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes☐ Nox *If no, skip to #1c.6*

If yes, *answer 1c.5.1. (**Note:** Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*
1c.5.1. **Grade assigned to the body of evidence with definition of the grade**:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? *(other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)*
Yesx No☐ *If no, skip to #1c.7*

If yes, *answer 1c.6.1-1c.6.3. (**Note:** Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)*
1c.6.1. **Citation** (*including date*):

- Khan KJ, Dubinsky MC, Ford AC, Ullman TA, Talley NJ, Moayyedi P. Efficacy of immunosuppressive therapy for inflammatory bowel disease: a systematic review and meta-analysis. [Review]. American Journal of Gastroenterology 2011;106:630-642

- Ford AC, Sandborn WJ, Khan KJ, Hanauer SB, Talley NJ, Moayyedi P. Efficacy of biological therapies in inflammatory bowel disease: systematic review and meta-analysis. [Review]. American Journal of Gastroenterology 2011;106:644-659.
- Alfadhli AA, McDonald JW, Feagan BG. Methotrexate for induction of remission in refractory Crohn's disease. Cochrane database of systematic reviews (Online) 2005:2005.

1c.6.2. **URL** (*if available online*):
http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003459.pub2/abstract

1c.6.3. **Grade assigned to the body of evidence with definition of the grade**:

FORD et al: MEDLINE, EMBASE, and the Cochrane central register of controlled trials were searched (through to December 2010). Trials recruiting adults with active or quiescent CD or UC and comparing biological therapies (anti-tumor necrosis factor- (TNF) antibodies or natalizumab) with placebo were eligible.
Dichotomous symptom data were pooled to obtain relative risk (RR) of failure to achieve remission in active disease and RR of relapse of activity in quiescent disease once remission had occurred, with a 95 % confidence interval (CI).
Alfadhli et al used Cochrane

Additionally, an ongoing systematic review of the evidence (AGA technical review) has examined the quality of the body of evidence for each outcome across studies that have been summarized from the systematic reviews cited above (system used: GRADE):

- Thiopurines vs. placebo to reduce failure to achieve remission off steroids (or tapering doses of steroids) (5 RCTs): moderate quality evidence
- Anti-TNF vs. placebo to reduce failure to achieve remission off steroids (or tapering doses of steroids) (10 RCTs): moderate quality evidence
- Thiopurines vs. placebo to reduce disease relapse off steroids (or tapering doses of steroids) (2 RCTs): low quality evidence
- Anti-TNF vs. placebo to reduce disease relapse off steroids (or tapering doses of steroids) (5 RCTs): high quality evidence

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identifed and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes☐ No☐

If yes, *answer 1c.7.1-1c.7.3. (**Note:** Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*
1c.7.1. **Who conducted the measure developer's systematic review of the body of evidence**?

1c.7.2. **Grade assigned to the body of evidence with definition of the grade**:

1c.7.3. **Describe the process used for the systematic review**:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS
(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: Kahn: 1966 to 2010; Ford: 1966 to 2010; Alfadhli: 1966 to 2004

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are inlcuded in the body of evidence? (*e.g., 3 randomized controlled trials and 1 observational study*)

- Thiopurines vs. placebo to reduce failure to achieve remission off steroids (or tapering doses of steroids) (5 RCTs): moderate quality evidence
- Anti-TNF vs. placebo to reduce failure to achieve remission off steroids (or tapering doses of steroids) (10 RCTs): moderate quality evidence
- Thiopurines vs. placebo to reduce disease relapse off steroids (or tapering doses of steroids) (2 RCTs): low quality evidence
- Anti-TNF vs. placebo to reduce disease relapse off steroids (or tapering doses of steroids) (5 RCTs): high quality evidence

1c.10. What is the overall quality of evidence across studies in the body of evidence? (*discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

There is moderate to high certainty in the estimate of effect (quality of evidence) that the use of immunomodulators and/or anti-TNF is effective in inducing and maintaining remission in IBD to the degree that patients can successfully taper or be off steroids.

Immunomodulators:
The overall body of evidence regarding the use of immunomodulators (thiopurines) for steroid-free (or steroid taper) remission includes 5 RCTs that looked at failure to achieve remission (induction studies) and 2 RCTs that were aimed at examining disease relapse (maintenance studies). The overall body of evidence for the 5 RCTs was moderate as there was no significant risk of bias (i.e. there was adequate blinding, randomization, allocation concealment, intention to treat analysis) no inconsistency or indirectness and no publication bias. There was, however, concern about imprecision since the CI

included substantial benefit but also potential harm, thus leading to a moderate rating for the overall quality of the evidence.
The overall certainty on the estimate of effect for the 2 RCTs that examined maintenance of remission was low because there were serious limitations in inconsistency (or heterogeneity) as well as imprecision with a wide confidence interval that crossed 1.

Anti-TNFS
The overall body of evidence for the use of anti-TNF agents in inducing and maintain remission allowing for successful taper and steroid free treatment is moderate to high. Among the 10 RCTs that examined induction of remission, there were limitations with imprecision (the CI crossed the 20% threshold of range minimally important difference) that lowered our confidence in the certainty of effect to moderate quality. Across the 5 RCTs that examined the role of anti_TNF agents in inducing remission, there was no risk of bias and no limitations with respect to inconsistency, indirectness, imprecision, or publication bias therefore, our confidence in the certainty of the effect was high.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) <u>across studies</u> in the body of evidence? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

The pooled effect estimates of anti-TNF therapy are of larger magnitude and more consistent than with immunmodulators:

- Thiopurines vs. placebo to reduce failure to achieve remission off steroids (or tapering doses of steroids) (5 RCTs): RR 0.87 (0.71, 1.06)
- Anti-TNF vs. placebo to reduce failure to achieve remission off steroids (or tapering doses of steroids) (10 RCTs): RR 0.87 (0.8, 0.94)
- Thiopurines vs. placebo to reduce disease relapse off steroids (or tapering doses of steroids) (2 RCTs): RR 0.64 (0.34, 1.23)
- Anti-TNF vs. placebo to reduce disease relapse off steroids (or tapering doses of steroids) (5 RCTs): RR 0.71 (0.65, 0.76)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

- Thiopurines vs. placebo to reduce failure to achieve remission: serious infections: OR 0.78 (0.52, 1.18)
- Anti-TNF vs. placebo to reduce failure to achieve remission: serious infections: RR 1.49 (1.17, 1.9)
- Thiopurines vs. placebo to reduce disease relapse: serious infections: OR 0.78 (0.52, 1.18); lymphoma risk: HR 5.28 (2, 13.9)
- Anti-TNF vs. placebo to reduce disease relapse: serious infections: RR 1.49 (1.17, 1.9); lymphoma risk: OR 0.53 (0.17; 1.66)

Assessment of the balance between benefits vs. harms showed a consistent net benefit as the absolute risk increase for serious infection and lymphoma is small.

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes☐ Nox *If no, stop*

If yes,

1c.13.1. **For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

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Patient ID[01-1000]:	PQRS Only[01-1005]: ☐	Encounter Date[01-1010]:	Age[01-2000]:	Sex[01-2050]: O Male O Female
Race(s)[01-2100]: ☐ White ☐ Black/African American ☐ Asian ☐ American Indian/Alaska Native ☐ Native Hawaiian/Pacific Islander				Hispanic Ethnicity[01-2150]: O Yes O No
Treating Clinician:	Under care of this clinician for at least 1 year[01-3000]: O Yes O No			Dx of IBD for at least 1 year[01-3100]: O Yes O No
Insurer[01-4000/4100]:	**PQRS ONLY** E&M[01-5000]:	ICD-9[01-5100]:		Billed to Medicare in 2012[01-5200]: O Yes O No

Disease Assessment

Was IBD type, anatomic location, luminal disease activity, and external manifestations assessments **within the past year**[02-1000]:

IBD Type[02-1100]: O Crohn's Disease O Ulcerative Colitis O Indeterminate Colitis O Not Assessed Within Past Year			Date Assessed[02-1101]:
Crohn's:	Location[02-2000]: O Ileitis O Ileocolitis O Colitis O Isolated Upper GI O Not Assessed Within Past Year		Date Assessed[02-2001]:
	Phenotype[02-2010]: O Inflammatory Only O Stricturing O Fistulizing O Stricturing & Fistulizing O Not Assessed Within Past Year		
	Perianal Disease[02-2020]: O Yes O No O Not Assessed Within Past Year		
UC:	Location[02-3000]: O Proctitis O Left Side Colitis O Pancolitis O Not Assessed Within Past Year		Date Assessed[02-3001]:
Answer for All Types:	Luminal Disease Activity[02-4000]: O Quiescent O Mild O Moderate O Severe O Not Assessed Within Past Year		Date Assessed[02-4001]:
	External Manifestations[02-4100]: *(Check All That Apply)*	☐ Dermatologic ☐ Ocular ☐ Biliary ☐ Thromboembolic ☐ Arthritis ☐ None ☐ Not Assessed Within Past Year	Date Assessed[02-4101]:
IF IBD TYPE, LOCATION, ACTIVITY, AND PRESENCE OF EXTERNAL MANIFESTATIONS NOT **ALL** ASSESSED:	Documented reason for not assessing **all** within the past year[02-1000]:		O Patient Reason O Other Reason/No Documented Reason

Corticosteroid-Sparing Therapies

Corticosteroids >10mg per day for 60 or more consecutive days **within the past year**[03-1000]? *If No, go to next section*

Documented assessment for risk of bone loss in the past year[03-2000]?		O Yes O No	Date Assessed[03-2001]:
One or more corticosteroid-sparing therapies prescribed or administered in the past year[03-3000]?		O Yes O No, Patient Reason O No, Medical Reason O No, Other Reason/No Documented Reason	
IF NO →	Documented **MEDICAL** reason for not prescribing or administering[03-3010]:	O Allergy/Intolerance O Toxicity O **Lack** of Effectiveness O **Loss** of Effectiveness O Other O No Documented Medical Reason	
	Documented **PATIENT** reason for not prescribing or administering[03-3020]:	O Patient Concerns O Expense O Noncompliant w/Monitoring O Other O No Documented Patient Reason	

Anti-TNF Therapy

First course (ever) of anti-TNF therapy initiated **within the past year**[04-1000] *If No, go to next section*

Documented TB screening performed and results interpretation w/in 6 months prior to initiation[04-2000]:	O Yes O No, Patient Reason	O No, Medical Reason O No, Other Reason/No Documented Reason	Date Assessed[04-2001]:
Documented hepatitis B status assessment and results interpretation w/in 1 year prior to initiation[04-3000]:	O Yes O No, Patient Reason	O No, Medical Reason O No, Other Reason/No Documented Reason	Date Assessed[04-3001]:

TPMT

First course (ever) of 6MP or azathioprine received **within the past year**[05-1000]? *If No, go to next section*

Documented TPMT genotype or enzyme activity assessment performed prior to first dose[05-2000]:	O Yes O No, Patient Reason	O No, Medical Reason O No, Other Reason/No Documented Reason	Date Assessed[05-2001]:

Vaccinations

Answer for all patients:

Influenza immunization recommended, administered, or received during the previous year[06-1000]:	O Yes O No, System Reason	O No, Medical Reason O No, Other Reason/No Documented Reason O No, Patient Reason	Date Recom/Adm/Rec[06-1001]:
Pneumococcal immunization ever performed[06-2000]?	O Yes O No, Patient Reason	O No, Medical Reason O No, Other Reason/No Documented Reason	Date Received[06-2001]:

Tobacco Use

Patient screened for tobacco use within the past 24 months[07-1000]?

Type of tobacco user[07-2000]:	O Does not use O Tobacco smoker O Smokeless tobacco user		Date Assessed[07-2001]:
Tobacco cessation counseling received within previous 24 months[07-3000]?		O Yes O No	Date Counseled[07-3001]:
IF PATIENT WAS NOT SCREENED FOR TOBACCO USE:	Documented reason for not screening[07-1000]:	O Medical Reason O Other Reason/No Documented Reason	

ALL INFORMATION PROVIDED MUST BE FULLY DOCUMENTED WITHIN THE MEDICAL RECORD. ALL DATA ARE SUBJECT TO AUDIT, AND SUBMISSION OF INACCURATE OR UNSUPPORTED INFORMATION IS IN VIOLATION OF RECOGNITION PROGRAM POLICIES AND CAN RESULT IN REVOCATION OF RECOGNITION STATUS.

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Patient ID:	Most Recent Encounter Date:	Treating Clinician:

Pharmacotherapy History

Indicate all medications that were administered or prescribed during the previous year. If a medication was discontinued at any time, mark the reason.

Medication	Usage in Past Year	Reason for Discontinuing
Balsalazide[08-1000]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Olsalazine[08-1100]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Sulfasalazine[08-1200]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Mesalamine[08-1300]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Azathioprine[08-1400]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Methotrexate[08-1500]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
6MP[08-1600]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Cyclosporine[08-1700]	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Infliximab[08-1800] (Remicade™)	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Adalimumab[08-1900] (Humira™)	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Certolizumab[08-2000] (Cimzia™)	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented
Natalizumab[08-2100] (Tysabri™)	O Therapy Active as of Most Recent Encounter O Therapy Used and Discontinued O Therapy Not Used	O No Longer Needed/Remission O **Lack** of Effectiveness O **Loss** of Effectiveness O Allergy/Intolerance O Patient Concerns O Toxicity O Expense O Noncompliance w/Monitoring O Other O Not Documented