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 2062 NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
CONCEPT SPECIFICATIONS
De.1 Concept Title: IBD preventive care: corticosteroid related iatrogenic injury – bone loss assessment
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 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.
2a1.1 Numerator Statement: 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.
2a1.4 Denominator Statement: All patients aged 18 years and older with a diagnosis of inflammatory bowel disease.
2a1.8 Denominator Exclusions: There are no exclusions as specified for PQRS purposes. 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.
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 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. 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 definitions are: 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. Assessed is defined as documentation that an assessment for risk of bone loss has been performed or ordered. Including review of systems and medication history and/or ordering of DEXA scan.
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 which is submitted to a registry.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
There are no exclusions as specified for PQRS purposes.
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.

2a1.9 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.
The AGA Digestive Health Recognition Program data collection form specifically askes if : Corticosteroids >10mg per day for 60 or more consecutive days within the past year.

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.*): AGA BTE IBD Care Recognition Program using the online AGA BTE IBD Care Recognition Data Collection Form.

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), Musculoskeletal : Osteoporosis, Prevention
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Prevention, Safety : Complications

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. Osteoporosis is a recognized complication of IBD and steroid therapy contributes to the increased risk osteoporosis observed in IBD. In a recent population-based cohort study from the United Kingdom (5), the unadjusted relative risk of hip fracture was 1.62 (95% confidence interval (CI) 1.24–2.11) for all IBD, 1.49 (1.04–2.15) for UC and 2.08 (1.36–3.18) for CD. Multivariate modeling showed that fracture risk correlated with current use of corticosteroids (relative risk 1.22 (0.58–2.57) for UC and 1.38 (0.59–3.23) for CD) and IBD itself (relative risk 1.41 (0.94– 2.11) for UC and 1.68 (1.01–2.78) for CD). Cumulative corticosteroids use correlated with increased fracture risk in the CD patients (but not in the UC patients) in a dose dependent manner (relative risk 2.77 (0.95–8.09) in CD patients with >25 steroid courses vs. none). A population-based study form Canada also found that corticosteroids were a risk factor for fracture in CD (6).

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. Card T, West J, Hubbard R, et al. Hip fractures in patients with inflammatory bowel disease and their relationship to corticosteroid use: a population based cohort study. Gut 2004; 53: 251–5.
6. Bernstein CN, Blanchard JF, Metge C, Yogendran M. The association between corticosteroid use and development of fractures among IBD patients in a population-based database. Am J Gastroenterol. 2003 Aug;98(8):1797-801.

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:
As noted above, most IBD patients require steroids and are therefore at significantly increased risk from osteoporotic fractures. Osteoporotic fractures represent a significant burden to the US health care system (7). The prevention and treatment of osteoporosis affords an opportunity to decrease the morbidity and health care costs of osteoporosis in the high risk group of steroid-treated IBD patients.
Utilization of guidelines should increase the number of screened patients and lead to earlier diagnosis and treatment. Kornbluth et al (8) found that in 100 consecutive patients that met the AGA criteria for initial DXA, osteoporosis was found in 12%, and osteopenia in another 44%. Pharmacologic therapy was initiated in 89% of these patients, with 69 patients receiving calcium and vitamin D, and 20 patients receiving bisphosphonates. Kane and Reddy found that clinicians who read the AGA osteoporosis guidelines ordered more DXA scans within the next 6 months (9).

References:
7. Burge R, Dawson-Hughes B, Solomon DH, Wong JB, King A, Tosteson A. Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. J Bone Miner Res. 2007 Mar;22(3):465-75.
8. Kornbluth A, Hayes M, Feldman S, et al. Do guidelines matter? Implementation of the ACG and AGA osteoporosis screening guidelines in inflammatory bowel disease (IBD) patients who meet the guidelines' criteria. Am J Gastroenterol 2006;101(7):1546–1550.
9. Kane S, Reddy D. Guidelines do help change behavior in the management of osteoporosis by gastroenterologists. Am J Gastroenterol. 2006 Aug;101(8):1841-4.

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.There are significant opportunities in improving the rates of detection and treatment of osteoporosis in the IBD population.
A study from the UK found that of women with IBD aged 65 years or older with an osteoporotic fracture (hip, vertebral, or radius/ulna), only 13.1% were treated with bone-active therapy in the year following the fracture: 7.3% with bisphosphonates, 6.6% with vitamin D, and 1.5% with hormone replacement therapy (10).
Kane and Reddy found that 65% of surveyed clinicians had not read the ACG osteoporosis guidelines after these had been disseminated to them (11).
Wagnon et al performed a survey inquiring into awareness and implementation of the AGA guidelines on osteoporosis in IBD patients (12). Of 1000 AGA members approached, 304 responded and 258 were the subject of analysis. Slightly less than half of the responders used the guidelines in decision-making (49%) or in the management (42%) of their IBD patients. The physicians who self-reported utilizing the guidelines adhered to the recommendations.
Etzel at al reviewed the records all IBD patients at seven medical facilities from 1996 through 2006. A total of 2035 patients had 317 bone density tests performed. Osteopenia was found in 48% of patients, and osteoporosis in 26%. Among patients meeting guideline criteria for BMD testing and =1 year of follow-up, only 23.3% underwent testing. The strongest predictors of testing were menopause (adjusted hazard ratio [AHR] 3.02) and receiving care at a tertiary center (AHR 2.56). Testing rates were low in patients with age =60 years, ulcerative colitis, and a history of inpatient IBD treatment. Osteoporotic patients received calcium/vitamin D and bisphosphonates in 59% and 75% of cases, respectively.(13)

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)*

10. van Staa TP, Cooper C, Brusse LS, Leufkens H, Javaid MK, Arden NK. Inflammatory bowel disease and the risk of fracture. Gastroenterology. 2003 Dec;125(6):1591-7.
11.Kane S, Reddy D. Guidelines do help change behavior in the management of osteoporosis by gastroenterologists. Am J Gastroenterol. 2006 Aug;101(8):1841-4.
12.Wagnon JH, Leiman DA, Ayers GD, Schwartz DA. Survey of gastroenterologists´ awareness and implementation of AGA guidelines on osteoporosis in inflammatory bowel disease patients: are the guidelines being used and what are the barriers to their use? Inflamm Bowel Dis. 2009 Jul;15(7):1082-9.
13.Etzel JP, Larson MF, Anawalt BD, Collins J, Dominitz JA. Assessment and management of low bone density in inflammatory bowel disease and performance of professional society guidelines. Inflamm Bowel Dis. 2011 Oct;17(10):2122-9.

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.
To date our knowledge, there have been no studies assessing for disparities in the diagnosis and treatment of osteoporosis among steroid-treated patients with IBD. However, 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:

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 representaives 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:
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 related iatrogenic injury – bone loss assessment
Date of Submission: 7/16/12

- 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: Click here to name the health outcome

☐ Intermediate clinical outcome: Click here to name the intermediate outcome

X Process: Bone loss assessment

☐ Structure: Click here to name the structure

☐ Other: Click here to name what is being measured

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.)*

Corticosteroid use in patients with IBD is associated with bone loss, making these individuals susceptible to osteoporotic fractures, including spine and hip fractures, and associated disability, morbidity and death. Assessment of bone density in steroid-treated individuals leads to timely diagnosis and preventive and therapeutic interventions. The most commonly used measurement to diagnose osteoporosis and predict fracture risk is based on assessment of bone mineral density by Dual-energy X-ray absorptiometry (DXA).

Steroids → bone loss → bone loss assessment by DXA → interventions to prevent bone loss and restore bone health

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*): (*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, first column, 4th bullet.

1c.4.4. **Quote verbatim, the specific guideline recommendation**:
Periodic bone mineral density assessment is recommended for patients on long-term corticosteroid therapy (>3 months). (Grade A).
1c.4.5. **Grade assigned to the recommendation with definition of the grade**:

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.

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

American College of Rheumatology 2010 recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Grossman JM, Gordon R, Ranganath VK, Deal C, Caplan L, Chen W, Curtis JR, Furst DE, McMahon M, Patkar NM, Volkmann E, Saag KG. Arthritis Care Res (Hoboken). 2010 Nov;62(11):1515-26.

1c.4.2. **URL** (*if available online*): http://onlinelibrary.wiley.com/doi/10.1002/acr.20295/pdf

1c.4.3. **Identify guideline number and/or page number**: p.1521

1c.4.4. **Quote verbatim, the specific guideline recommendation**:

Table 2. Recommendations on counseling for lifestyle modification and assessment of patients starting glucocorticoids at any dose with an anticipated duration >3 months: Baseline dual x-ray absorptiometry (level of evidence C)
Table 3. Recommended monitoring for patients receiving prevalent glucocorticoid therapy for a duration of >3 months: Serial bone mineral density testing (level of evidence C)

1c.4.5. **Grade assigned to the recommendation with definition of the grade**:

Level C.

The strength of evidence was graded using the methods reported by the American College of Cardiology (Hunt SA et al, Circulation, 2005;112:e154–235) as follows: 1) Level A: data derived from multiple RCTs or a meta-analysis, 2) level B: data derived from a single RCT or nonrandomized study, and 3) level C: data derived from consensus, expert opinion, or case series.

Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes☐ NoX

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)* Yes☐ NoX *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*):

1c.6.2. **URL** (*if available online*):

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

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☐ NoX

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: Click here to enter date range

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*)

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*)

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) across studies 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*)

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

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**.

BRIDGES to Excellence®
IBD CARE RECOGNITION™
Version 1.1

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.

BRIDGES to Excellence®
IBD CARE RECOGNITION™
Version 1.1

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