

**PRT Questions from first review of: *Project Sonar (PS)*, submitted by the Illinois Gastroenterology Group and SonarMD, LLC**

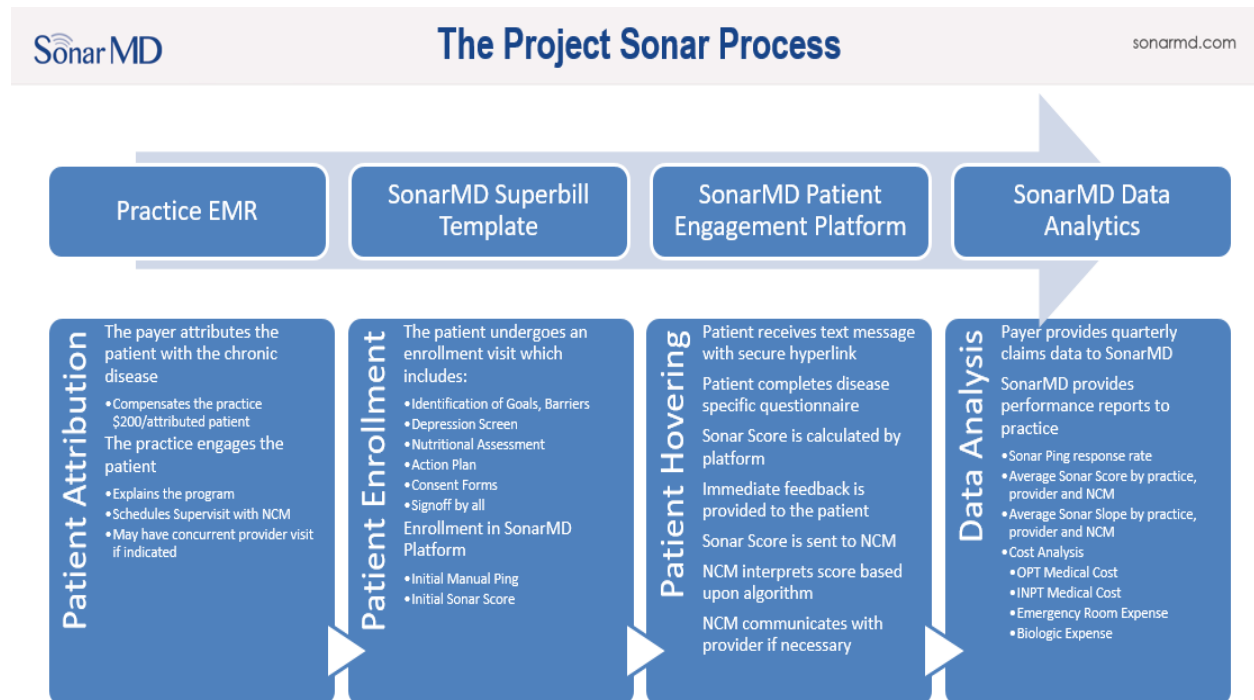
**Questions for Submitter**

- Please provide a more in-depth description regarding the intervention. How might Project Sonar be experienced by an individual patient and his or her care team?**

Thank you for your question. Project Sonar incorporate the following key actions from a patient engagement standpoint:

- The patient is identified by the payer, based on claims data and disease criteria
- The payer notifies SonarMD and the practice about the patient being a candidate for the program via an attribution list
- The practice engages the patient to discuss the program and schedule the initial intake (Supervisit) and enrollment visits
- The practice communicates to the referring PCP that the patient is enrolled in the SonarMD program
- The patient is provided with information to facilitate communication with the care team, both during and after office hours
- Appropriate consents signed

This diagram below provides an overview of the patient experience.



- 1) Patient Attribution
  - a) The payer attributes the patient with the chronic disease
  - b) The practice engages the patient
    - i) Explains the program
    - ii) Schedules Supervisit with nurse care manager (NCM)
    - iii) May have concurrent provider visit if indicated
- 2) Patient Enrollment
  - a) The patient undergoes an enrollment visit which includes:
    - i) Identification of Goals, Barriers
    - ii) Depression Screen
    - iii) Nutritional Assessment
    - iv) Action Plan
    - v) Consent Forms
    - vi) Signoff by all
  - b) Enrollment in SonarMD Platform
    - i) Initial Manual Ping
    - ii) Initial Sonar Score
- 3) Patient Hovering
  - a) Patient receives a “ping” text message with secure hyperlink on first business day of each month
    - i) If patient does not respond, a second ping is sent out one week later
    - ii) If patient still does not respond, they are contacted by phone
    - iii) Patient completes disease specific questionnaire
  - b) Sonar Score is calculated by platform
  - c) Immediate feedback is provided to the patient
  - d) Sonar Score is sent to NCM

- e) NCM interprets score based upon algorithm
- f) NCM communicates with provider if necessary

#### 4) Data Analysis

- a) Payer provides quarterly claims data to SonarMD
- b) SonarMD provides performance reports to practice
  - i) Sonar Ping response rate
  - ii) Average Sonar Score by practice, provider and NCM
  - iii) Average Sonar Slope by practice, provider and NCM
  - iv) Cost Analysis
    - (1) OPT Medical Cost
    - (2) INPT Medical Cost
    - (3) Emergency Room Expense
    - (4) Biologic Expense

## 2. Are patients generally only “touched” once per month with a survey? Is there any follow-up for “non-pingers”?

Patients are touched a minimum of once per month. Those whose score indicates a problem are ‘touched’ more often, whether in-person, via phone, or survey. Although the initial “touch” is via the web-based survey, all patients are contacted. Overall, we have a sustained 80% response rate to the SonarMD software. Non-responders are contacted by phone.

The process is as follows:

- The Ping is sent on the first business day of the month at 10AM in the time zone of the patient
- Patients are listed as “nonresponder” on the SonarMD desktop and monitored by the NCMs until they respond
- If the patient has not responded in one week, a second ping is automatically sent on day seven (7).
- Patients who have not responded to the second ping are now updated in the Nonresponder tab for the NCM to contact
- The NCM calls the patient via telephone, which is repeated every 1-2 days until the patient is contacted. Answers to the questionnaire are obtained via phone and manually entered by the NCM into the SonarMD system

- 3. Project Sonar has been tested with the commercially insured population, which is different (e.g. age distribution) than the Medicare population. Is there evidence that Project Sonar can engage patients and is successful across different patient demographics, including the Medicare population?**

Yes, there is evidence that Project Sonar can engage patients across different demographics, including the Medicare population. The 21 Gastroenterology (GI) practices have enrolled Inflammatory Bowel Disease patients on the platform regardless of the payor or age of the patient. Over 20% of the patients enrolled to date are Medicare.

- 4. Please further clarify how the Sonar Score is calculated and the thresholds that determine a need for further intervention.**

The Sonar Score for IBD is calculated from a subset of questions derived from the Crohn's Disease Activity Index, a well-established index of disease activity for IBD<sup>1</sup>. The subset of questions selected are those that a patient can answer on their own without the assistance or presence of a health professional, as shown below:

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<sup>1</sup> Best WR, Bectel JM, Singleton JW, Kern F; Development of a Crohn's disease activity index. *Gastroenterology* 1976; 70: 439-44.

**IGG CD CDAI Calculator** X

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**Sonar Score** 04/14/2014

**For the last seven days please describe each of the following:**

Number of loose stools per day:  0  1  2  3  4  5+

Abdominal pain or cramps:  None  Mild  Moderat  Severe

General Well Being:  Generally Well  Slightly Under  Poor  Very Poor  Terrible

Select all the symptoms you have had below:

Arthritis or Joint Pain  Eye Pain  Painful Skin Rash or Bumps  Fever over 100 Degrees

Are you on any drugs for diarrhea

**Total**

The Sonar Score is calculated as the sum of the values on each of the questions. Their relative score ratings are shown in the table below:

<b>Sonar Score</b>	
<b>Question</b>	<b>Metric</b>
Number of loose stools per day	0,1,2,3,4,5
Abdominal Pain or Cramps	0,5,10,15
General Well Being	0,7,14,21,28
Individual Items	
Arthritis or Joint Pain	0,20
Eye Pain	0,20
Painful Skin Rash or Bumps	0,20
Fever over 100 degrees	0,20
Use of drugs for diarrhea	0,30
<b>Sonar Score</b>	<b>Sum of all</b>

The score is deemed worthy of a response by the NCM if the raw score is over 40. When this occurs, the patient and score turns red on the NCM desktop.

In addition to raw scores, the slope of the scores over the last three sessions is calculated. If this exceeds 20, the score turns red as well. This allows the physician and NCM to avoid missing trends in patients whose raw scores might be below the raw score threshold.

**5. With commercial payors, Project Sonar has focused on Crohn's Disease. Are you proposing a model that includes only Crohn's Disease or are you proposing a model that expands to other chronic illnesses?**

We are proposing a model that expands to address conditions in addition to Crohn's Disease. We believe that the patient characteristics in the CD population which we have uncovered can be advanced and expanded to other high beta chronic diseases. We define high beta diseases as those that are high cost per patient with high variability in cost per year and high potential to avoid unnecessary Emergency Department (ED) and inpatient (IP) admissions. Ulcerative Colitis and Irritable Bowel Syndrome have already been placed in production. Development is in place for End Stage Liver Disease, COPD and periods in Diabetes. Other examples of high beta conditions include chronic inflammatory diseases such as rheumatoid arthritis and systemic lupus erythematosus, heart failure, renal failure and other conditions.

**6. To what degree will there be coordination with primary care providers?**

Coordination with the patient's primary care providers (PCPs) is critical. The platform is designed to feed information to any of the providers involved in the care of the patient. Critical to the management of the patient is a recognition of and establishing whom is the responsible provider, and how the patient is co-managed by the PCP and specialist. This is determined during the Supervisit and initial enrollment, and reinforced by the NCM on a regular basis.

**7. Can you provide the biopsychosocial risk assessment tool?**

The biopsychosocial risk assessment tool shown below has been developed based on multiple sources including the American Gastroenterological Association's Crohn's Disease Care Pathway. The risk assessment tool addresses three categories of risk: Disease Burden, Inflammation Burden and Comorbidity Burden. It is shown in in the figure on the next page.

**Step 1**  
Disease Burden Risk Assessment

	Low Risk	High Risk
Age at Diagnosis:	<input type="radio"/> Over 30	<input checked="" type="radio"/> Under 30
Anatomic Involvement:	<input checked="" type="radio"/> Limited	<input type="radio"/> Extensive
Perianal Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Severe Rectal Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Deep Ulcers:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Strictureing:	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Penetrating Disease:	<input checked="" type="radio"/> No	<input type="radio"/> Yes

Overall Risk: Low

**Step 2**  
Inflammation Burden Risk Assessment

Symptoms	Lab Abnormalities
<input type="checkbox"/> Fever	<input type="checkbox"/> Low Hb
<input checked="" type="checkbox"/> Abdominal Pain	<input type="checkbox"/> Leukocytosis
<input type="checkbox"/> GI Bleeding	<input type="checkbox"/> Elevated CRP
<input type="checkbox"/> Localized Tenderness	<input checked="" type="checkbox"/> Decreased Albumin
<input type="checkbox"/> Weight Loss	<input type="checkbox"/> Elevated ESR
<input checked="" type="checkbox"/> Joint Pains	<input type="checkbox"/> Elevated FCP
<input type="checkbox"/> Cutaneous Signs	

Overall Risk: High

**Step 3**  
Comorbidity Burden Risk Assessment

Comorbidity
<input type="checkbox"/> Infections <i>Examples: C Diff, CMV</i>
<input type="checkbox"/> Strictureing/Remodeling <i>Examples: Abnormal Imaging, Obstructive Symptoms, Weight Loss</i>
<input type="checkbox"/> Symptoms from Prior Surgery <i>Examples: Bile Acid Diarrhea, Bacterial Overgrowth, Steatorrhea</i>
<input type="checkbox"/> Adverse Medical Reaction <i>Examples: Recent addition of new drug; drug holiday</i>
<input type="checkbox"/> Abnormal Abscess/Fistula <i>Examples: Pain, Fistula, Drainage, Fever</i>
<input type="checkbox"/> Perianal Abscess/Fistula <i>Examples: Pain, Fistula, Drainage, Fever</i>

Overall Risk: Low

The biological risk assessment is combined with a depression risk using the PHQ-2:

**Depression Screen PHQ-2**

During the past two weeks, how often have you been bothered by any of the following problems:

	Not at all	Several Days	More than half the days	Nearly Every Day
1) Feeling little interest or pleasure in doing things:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Feeling down, depressed or hopeless:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**Action Plan**  3 A score of 3 indicates a 90% likelihood of depression

We are piloting the implementation of the Hospital Anxiety and Depression Score (HADS) and the CDC Healthy Days Core Measures.

**8. Please explain your risk adjustment methodology more fully. Also explain how it relates to shared savings/losses.**

The risk adjustment is based upon clinical characteristics and how each one influences the cost of care. The following metrics are used in our risk assessment:

- Age
- Sex
- Disease Phenotype as determined by ICD-10 Code
- PHQ-2 rating
- The 26 individual metrics from the AGA Crohn’s Disease Care Pathway
- Sonar Ping response rate

For each item, a relative value derived from the performance of multiple linear regressions of the item against the Crohn's related cost of care is then factored in. The following illustrates this calculation methodology. We anticipate further refinement with larger populations.

Descriptive Statistics					
Variable	Sum	Mean	Uncorrected		
			SS	Variance	Std Dev
Intercept	83	1	83	0	0
age	3613	43.53012	171889	178.22774	13.3502
ageatdx	865	10.42169	19419	126.88099	11.26415
male	33	0.39759	33	0.24243	0.49238
yrs_sincedx	2748	33.10843	107224	198.07346	14.07386
corisk_abcess	4	0.04819	4	0.04643	0.21548
corisk_advrx	2	0.0241	2	0.0238	0.15428
corisk_assessed	105	1.26506	177	0.53864	0.73392
corisk_inf	3	0.03614	3	0.03526	0.18778
corisk_metricbased	37	0.44578	85	0.83544	0.91402
corisk_perianal	6	0.07229	6	0.06788	0.26054
corisk_priorsg	8	0.09639	8	0.08816	0.29691
corisk_structuring	14	0.16867	14	0.14193	0.37674
dzburden_anatomic	26	0.31325	26	0.21775	0.46664
dzburden_penetratingdz	12	0.14458	12	0.12518	0.35381
dzburden_perianal	12	0.14458	12	0.12518	0.35381
dzburden_rectaldz	6	0.07229	6	0.06788	0.26054
dzburden_structuring	15	0.18072	15	0.14987	0.38713
dzburden_ulcers	13	0.15663	13	0.13371	0.36566
inflrisk_abdominalpain	32	0.38554	32	0.23979	0.48968
inflrisk_albumin	5	0.06024	5	0.0573	0.23938
inflrisk_crp	12	0.14458	12	0.12518	0.35381
inflrisk_cutaneous	2	0.0241	2	0.0238	0.15428
inflrisk_esr	3	0.03614	3	0.03526	0.18778
inflrisk_fcp	0	0	0	0	0
inflrisk_fever	1	0.01205	1	0.01205	0.10976
inflrisk_gibleed	7	0.08434	7	0.07817	0.27958

Use of this methodology is complimentary to assessment of the patient using Hierarchical Condition Categories (HCC) and related tools.

Providers are rated on 1) patient participation / engagement 2), their patient's risk adjusted average sonar scores, and 3) medical, facility, hospital, pharmaceutical and total costs of care for their patients compared to the medical group, geographic (MSA) and national data.

Performance is measured on a quarterly basis, and is reflected in distribution of shared savings on a quarterly and yearly basis.



**9. How is the target price determined? Is target price based on the total cost of care or is it specific to Crohn’s Disease spending?**

We have calculated the target cost in both ways. At present, our data suggests use of the Crohn’s specific target. We have identified ICD-10 codes that are specific to Crohn’s disease as well as other ICD-10 codes for Crohn’s related conditions, which is factored into calculation of the target price.

**10. Will the target price be adjusted over time? If so, what is the frequency and method of adjustment?**

We anticipate that the target price will be adjusted over time, based on continual comparison of the study group against a control group.

Data from Health Care Service Corporation / BCBS IL was made available after the PFPM proposal was submitted. The results differ from the data presented in the PTAC proposal as they reflect completed claims 90 days post service and compare the study group against an age/sex/risk matched control group.

Metrics	Trending Pre to Post			
	Ping	Matched Ping	Non Ping	Matched Non Ping
Age & Gender Factor	2.8%	3.1%	2.0%	4.1%
Admissions Per 1000	0.0%	100.0%	57.1%	137.5%
Days Per 1000	0.0%	172.0%	96.2%	102.7%
ALOS	0.0%	36.0%	24.8%	-14.7%
Admission Allowed PMPM	-11.5%	186.4%	123.1%	176.7%
ER Allowed PMPM	-2.8%	93.0%	-8.1%	69.4%
Outpatient Allowed PMPM	1.2%	49.7%	13.2%	30.9%
<b>Total Medical Allowed PMPM</b>	<b>14.2%</b>	<b>44.5%</b>	<b>31.9%</b>	<b>41.4%</b>
<b>Total Medical Allowed PMPM (Excluded Infused Bio)</b>	<b>-1.3%</b>	<b>69.8%</b>	<b>31.3%</b>	<b>50.8%</b>

The results are very favorable and show:

- **There were no Crohn’s admissions in the study group among the actively responding (pinging) patients.**
- **Total Medical Allowed cost minus biologics FELL by 1.3% in the pinger study group whereas it rose by 69.8% in the matched control group.**

These types of analyses will be required to calculate target prices for a bidirectional risk model, recognizing that the target prices may fluctuate over time based on costs that are not under our control (e.g. Medicare physician, outpatient prospective payment, and clinical laboratory fee schedules, pharmaceutical average sales price calculations, etc.).

**11. Provide additional detail on how Project Sonar will improve or maintain quality. Will any other patient reported outcomes (besides PHQ 2) be included?**

Our goal is to continuously use the science behind the risk assessment to determine the most valuable quality metrics going forward. Our research has identified that serum albumin in CD patients is the most powerful driver of variation in cost. Ping response rate is a predictable driver of cost and can be used as a major metric of quality. We recognize the limitations of the PHQ-2 and are testing implementing the HADS and CDC Healthy Days.

**12. Can you provide an overall estimate of savings to Medicare for different levels of enrollment?**

Our savings are calculated and normalized based on Medicare rates. We believe that the cost savings achieved through reduction in ED visits and IP admissions, along with improved medication adherence, better care coordination, and moving infusion services from hospital outpatient to non-facility office settings appropriately reflect the savings that would be achieved in Medicare beneficiaries.

**13. Is the technology described in this proposal proprietary? If so, is it your plan that it remain proprietary?**

The SonarMD platform is currently proprietary. The platform questions could be replicated by others and could be incorporated into an EHR. However, the true proprietary value of Project Sonar lies not with the IT platform, but in the chronic care management algorithms, the clinical decision support (hovering) tools, and the predictive analytics which will guide patient engagement based on the metrics that we collect.

**Questions for Submitter**

- 1. Over 20% of the patients enrolled in Project Sonar to date are Medicare beneficiaries. How many patients are enrolled in Project Sonar to date (what is the denominator)? Is Medicare currently participating in Project Sonar in some way (e.g. a pilot) or are the Medicare beneficiaries enrolled in Project Sonar in Medicare Advantage or beneficiaries for whom Medicare is a secondary payor?**

Subsequent to submission of the proposal to PTAC in December 2016, enrolled patients have continued to increase. The majority of new enrollees are commercial, as BCBS IL has expanded this program throughout Illinois effective January 1, 2017. As of February 3, 2017, there are 674 patients in the SonarMD Database, 50 of whom are Medicare beneficiaries. At present, beneficiaries in original Medicare or Medicare Advantage are not participating in Project Sonar *as a pilot*.

- 2. Please clarify what is meant by “patient engagement.” Is it the same as ping response rate?**

Patient Engagement means that each patient is communicated with on at least a monthly basis, and a survey completed. The ping response rate refers to the use of the digital platform for this function and hovers around 78% overall. The remaining 20% of patients are engaged via phone or in person at the time of an encounter such as an infusion, procedure or office visit.

- 3. Is the level of patient engagement and distribution of pingers versus nonpingers for Medicare beneficiaries similar to other patients enrolled in Project Sonar?**

The ping response rate for patients over 65 is 65.44%, compared to 78% in commercial patients. Attempts to engage patients are performed on an at least monthly basis. If the patient is unable or unwilling to use the SonarMD online platform, the patient is contacted via telephone.

- 4. How will information be transmitted to the primary care physician? What kind of information will be shared with the primary care physician?**

At present, the primary care physician (PCP) receives faxed notes when there is an intervention. These notes address changes in patient status and the resulting management decisions. As the SonarMD platform is web-based, there is no reason that a PCPs could not access the exact same data that the specialist accesses. As the Sonar Scores are pushed into the EMR as lab data, these can easily be pushed to the PCP.

**5. What are the incentives for primary care physicians’ involvement? Are primary care physicians eligible for shared savings or at risk for shared losses?**

In the pilot with BCBS IL, the structure did not incorporate PCP financial involvement. Project Sonar was based on the concept of a specialist assuming responsibility for the management of the patient with a complex condition that could or would not be managed by the PCP. Thus, as PCP are involved in a manner similar to the typical PCP/specialist communication. It was determined that, at present, they would not be financially eligible for shared savings or at risk for shared losses. As Project Sonar collects data on patients and physicians, we envision having sufficient data in subsequent years that would allow all healthcare professionals participating at the group level to see their performance, that this data could be shared with the referring PCPs, and that PCPs could use the performance data to specify which specialist to refer the patient to. If the specialist is clinically and financially integrated with a PCP group, that model would lend itself to the specialist and PCP being eligible for shared savings and at risk for shared losses.

**6. Is it your intent that the IT platform, chronic care management algorithms, clinical decision support tools, and predictive analytics remain proprietary?**

As noted in our previous responses, at present the SonarMD platform is proprietary. That being said, the platform could be replicated by others and does not need to remain proprietary. However, the true value of Project Sonar is in the chronic care management algorithms, the clinical decision support (hovering) tools, and the predictive analytics which guide patient management based on the metrics and data collected. As these have intellectual property value, they will remain proprietary.

**7. In response to our initial set of questions, you indicate that you have calculated target cost in two ways: (1) based on total cost of care and (2) based on costs specific to Crohn’s Disease. Please clarify whether the data in your proposal and the Health Care Service Corporation / BCBS IL data in your response are based on total cost of care or Crohn’s-related cost of care.**

The HCSC/BCBS IL data, which was submitted previously to the PTAC and copied below, reflects the Total Cost of Care.

	Trending Pre to Post			
Metrics	Ping	Matched Ping	Non Ping	Matched Non Ping
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**8. The proposal outlines an upside risk revenue share model. How are shared losses distributed?**

To date, we have not had incurred any shared losses. If the total cost of care exceeds the target amount, losses would be distributed to the specialist medical group operating under a TIN. There are two models for distributing shared losses. At the Illinois Gastroenterology Group, the model requires the losses to be shared equally amongst the physicians in the group. We see this evolving into a model where the specialist group would determine which physicians / healthcare professionals were responsible for the management of the patients. The group as a whole would share some portion of the losses, and the individual physicians managing the patient would have responsibility for their percentage of the losses.

**9. In response to our initial set of questions, you indicate that you have identified ICD-10 codes specific to Crohn's disease and for Crohn's related conditions. What related conditions are included?**

The following list of diagnoses was used in our initial analysis. At the time, our study period involved a period which included the use of ICD-9 and ICD-10. The conditions listed below were determined by our physician panel to be potentially referable to Crohn's Disease based upon symptoms or complications. In the interests of responding rapidly to the PTAC's questions, we have not provided the ICD-10 codes. If provision of ICD-10 codes is required, we will provide such in a subsequent communication

**Gastrointestinal symptoms referable to Crohn's**

Symptoms concerning nutrition metabolism and development

Anorexia

Abnormal weight gain

Abnormal loss of weight and underweight

Loss of weight

Underweight

Symptoms involving digestive system

Nausea and vomiting

Bilious emesis

Heartburn

Dysphagia

Dysphagia, oral phase

Dysphagia, oropharyngeal phase

Dysphagia, pharyngeal phase

Dysphagia, pharyngoesophageal phase

Other dysphagia

Visible peristalsis

Abnormal bowel sounds  
Incontinence of feces  
Full incontinence of feces  
Incomplete defecation  
Fecal smearing  
Fecal urgency  
Abnormal feces  
Other symptoms involving digestive system  
Other symptoms involving abdomen and pelvis  
Abdominal pain  
Abdominal pain, left upper quadrant  
Abdominal pain, periumbilic  
Abdominal pain, epigastric  
Abdominal or pelvic swelling mass or lump  
Abdominal or pelvic swelling, mass, or lump, left upper quadrant  
Abdominal or pelvic swelling, mass, or lump, left lower quadrant  
Abdominal or pelvic swelling, mass, or lump, epigastric  
Abdominal or pelvic swelling, mass, or lump, generalized  
Abdominal or pelvic swelling, mass, or lump, other specified site  
Abdominal rigidity  
Abdominal rigidity, unspecified site  
Abdominal rigidity, right upper quadrant  
Abdominal rigidity, left upper quadrant  
Abdominal rigidity, right lower quadrant  
Abdominal rigidity, left lower quadrant  
Abdominal rigidity, periumbilic  
Abdominal rigidity, epigastric  
Abdominal rigidity, generalized  
Abdominal rigidity, other specified site  
Abdominal tenderness  
Abdominal tenderness, unspecified site  
Abdominal tenderness, right upper quadrant  
Abdominal tenderness, left upper quadrant  
Abdominal tenderness, right lower quadrant  
Abdominal tenderness, left lower quadrant  
Abdominal tenderness, periumbilic  
Abdominal tenderness, epigastric  
Abdominal tenderness, generalized  
Abdominal tenderness, other specified site  
Colic  
Other symptoms involving abdomen and pelvis

### **Other Lower Digestive System Conditions**

Intestinal obstruction without mention of hernia  
Intussusception  
Volvulus  
Impaction of intestine  
Impaction of intestine, unspecified  
Gallstone ileus  
Fecal impaction  
Other impaction of intestine  
Other specified intestinal obstruction  
Diverticula of intestine  
Diverticula of small intestine  
Diverticulosis of small intestine (without mention of hemorrhage)  
Diverticulitis of small intestine (without mention of hemorrhage)  
Diverticulosis of small intestine with hemorrhage  
Diverticulitis of small intestine with hemorrhage  
Diverticula of colon  
Diverticulitis of colon (without mention of hemorrhage)  
Diverticulosis of colon with hemorrhage  
Diverticulitis of colon with hemorrhage  
Other postoperative functional disorders  
Functional diarrhea  
Anal spasm  
Megacolon, other than Hirschsprung's  
Other specified functional disorders of intestine  
Neurogenic bowel  
Unspecified functional disorder of intestine  
Peritonitis and retroperitoneal infections  
Peritonitis in infectious diseases classified elsewhere  
Pneumococcal peritonitis  
Other suppurative peritonitis  
Peritonitis (acute) generalized  
Spontaneous bacterial peritonitis  
Other suppurative peritonitis  
Retroperitoneal infections  
Psoas muscle abscess  
Other retroperitoneal abscess  
Other retroperitoneal infections  
Other specified peritonitis  
Choleperitonitis  
Other specified peritonitis  
Unspecified peritonitis  
Other disorders of intestine

Rectal prolapse  
Stenosis of rectum and anus  
Hemorrhage of rectum and anus  
Other specified disorders of rectum and anus  
Ulcer of anus and rectum  
Anal sphincter tear (healed) (old)  
Dysplasia of anus  
Abscess of intestine  
Colostomy and enterostomy complications  
Colostomy and enterostomy complication, unspecified  
Infection of colostomy or enterostomy  
Mechanical complication of colostomy and enterostomy  
Complications of intestinal pouch  
Pouchitis  
Other complications of intestinal pouch  
Other specified disorders of intestine  
Perforation of intestine  
Angiodysplasia of intestine (without mention of hemorrhage)  
Angiodysplasia of intestine with hemorrhage  
Dieulafoy lesion (hemorrhagic) of intestine convert  
Vomiting of fecal matter

### **Upper Digestive System (Esophagus Stomach and Duodenum) Conditions**

Diseases of esophagus  
Achalasia and cardiospasm  
Esophagitis  
Esophagitis, unspecified  
Acute esophagitis  
Eosinophilic esophagitis  
Other esophagitis  
Ulcer of esophagus  
Ulcer of esophagus without bleeding  
Ulcer of esophagus with bleeding  
Stricture and stenosis of esophagus  
Perforation of esophagus  
Dyskinesia of esophagus  
Diverticulum of esophagus, acquired  
Gastroesophageal laceration-hemorrhage syndrome  
Other specified disorders of esophagus  
Esophageal hemorrhage  
Esophageal leukoplakia  
Tracheoesophageal fistula



Barrett's esophagus  
Infection of esophagostomy  
Other specified disorders of esophagus  
Unspecified disorder of esophagus  
Gastritis and duodenitis  
Acute gastritis  
Acute gastritis, without mention of hemorrhage  
Acute gastritis, with hemorrhage  
Atrophic gastritis  
Atrophic gastritis, with hemorrhage  
Gastric mucosal hypertrophy  
Gastric mucosal hypertrophy, without mention of hemorrhage  
Gastric mucosal hypertrophy, with hemorrhage  
Other specified gastritis  
Other specified gastritis, with hemorrhage  
Unspecified gastritis and gastroduodenitis  
Unspecified gastritis and gastroduodenitis, with hemorrhage  
Duodenitis  
Duodenitis, with hemorrhage  
Eosinophilic gastritis  
Eosinophilic gastritis, without mention of hemorrhage  
Eosinophilic gastritis, with hemorrhage  
Other disorders of stomach and duodenum  
Acquired hypertrophic pyloric stenosis  
Gastric diverticulum  
Chronic duodenal ileus  
Gastroptosis  
Hourglass stricture or stenosis of stomach  
Other specified disorders of stomach and duodenum  
Pylorospasm  
Angiodysplasia of stomach and duodenum without mention of hemorrhage  
Angiodysplasia of stomach and duodenum with hemorrhage  
Dieulafoy lesion (hemorrhagic) of stomach and duodenum  
Other specified disorders of stomach and duodenum  
Unspecified disorder of stomach and duodenum

**Malnutrition Related**

Other severe protein-calorie malnutrition  
Malnutrition of Mild Degree  
Arrested development following protein-calorie malnutrition  
Other protein-calorie malnutrition

Vitamin A deficiency  
Vitamin B deficiency  
Vitamin C deficiency  
Vitamin D deficiency  
Unspecified nutritional deficiency

**Anemia**

Iron deficiency anemias  
Iron deficiency anemia secondary to inadequate dietary iron intake  
Other specified iron deficiency anemias

Other deficiency anemias  
Folate-deficiency anemia  
Other specified megaloblastic anemias not elsewhere classified  
Protein-deficiency anemia  
Anemia associated with other specified nutritional deficiency  
Unspecified deficiency anemia

**Miscellaneous Conditions related to Crohn's disease**

Osteoporosis  
Osteopenia  
Erythema Nodosum  
Pyoderma, unspecified  
Pyoderma gangrenosum  
Other pyoderma  
Acute and subacute iridocyclitis  
Acute and subacute iridocyclitis, unspecified  
Primary iridocyclitis  
Recurrent iridocyclitis  
Secondary iridocyclitis, noninfectious  
Chronic iridocyclitis  
Chronic iridocyclitis, unspecified  
Chronic iridocyclitis in diseases classified elsewhere  
Certain types of iridocyclitis  
Scleritis and episcleritis  
Episcleritis periodica fugax  
Nodular episcleritis  
Other scleritis and episcleritis

**10. In the proposal, you indicate that you normalized commercial data to Medicare payments and saw a 9.87% net savings equal to \$1,000 savings per patient per year. Do you anticipate that level of savings to Medicare regardless of levels of enrollment?**

Our net savings was driven by declines in inpatient hospital admissions and Emergency Room visits, despite an increase in pharmaceutical costs due to improved adherence. This data was not adjusted for patient risk or co-morbidities. We anticipate the same level of savings could be realized by Medicare beneficiaries, adjusted for patient risk and co-morbidities. We caution that certain costs, such as part B or part D drugs, the OPPS fee schedule, or advancements in clinical and/or diagnostic evaluation and management, are not in our control and could impact the level of savings to Medicare in future years.

**11. In the proposal you indicate that quality reporting will be based upon mutually agreed upon measures, including MIPS and Project Sonar derived measures. The upside risk revenue share model is based on (1) number of patients followed, (2) ping response rate, and (3) risk adjusted cost of care. By how much will quality be improved? Do you have specific benchmarks or targets?**

We define value as follows:

$$\text{VALUE} = \frac{\text{Population Outcome} + \text{Population Service}}{\text{Population Cost}}$$

Population Outcome can be further defined as equivalent to quality. Our objectives of outcome include:

- Decline in Hospitalization Rate and its maintenance. We lowered this by 53%. We do not have a hospital admission in our Pinger Group.
- Decline in Emergency Room Utilization and its maintenance. We lowered this by 57%
- Decline in lost time from work. While this needs to be assessed, we recognize that this is a soft cost which is not applicable to the Medicare program.

The metrics needed to accomplish these outcomes are driven by the analytics behind cost and risk assessment. As stated in our proposal and in our response to question 8 from the initial (previous) set of questions from the PTAC, we have analyzed the relationship between our risk assessments and the Crohn's-related cost of care. Multiple linear regressions have been used to create a relative strength of our risk metrics, which is incorporated into the algorithms used for patient management. The relative value of the metrics drives management decisions over time. The most significant example is the use of serum albumin, which we found to be the most powerful driver of the variation in cost. Learning from the data generated and analyzed, we obtain serum albumin levels on a quarterly basis on Crohn's Disease patients managed under Project Sonar. Our data has revealed a rising albumin slope in pinging patients and a falling

slope in non-pinging patients. We are looking at other metrics such as fecal Calprotectin and serum C-Reactive Protein to determine whether these are predictive biomarkers which can be used by the physician and beneficiary to proactively identify those patients at risk and to intervene early in order to avoid complications and otherwise potentially preventable ED visits and inpatient admissions. We will continue to analyze the data and refine our predictive tools over time. This same exercise can be used in other chronic conditions.