

ImproveCareNow Case Report Form

Registration/Diagnosis Data:

The following data are collected at the time the patient is first seen during Ambulatory (outpatient) visits only for the ImproveCARENow Network (not subsequent visits).

Site ID: _____

Patient ID: _____

Date of Registration: ____-____-____

Patient Birth-date: ____-____-____

Date of Diagnosis: ____-____-____

Date of diagnosis not available but:

- Less than 4 months
More than 4 months

Patient's Diagnosis:

- Crohn's Disease
Ulcerative Colitis
Indeterminate Colitis

Gender (check one):

- Male
Female

Ethnicity (check one)

- Hispanic
Non-Hispanic
Not Assessed/Collected

Race (check all that apply)

- American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White
Other: (specify): _____
Not Assessed/Collected

Parent's Education

- Mother
Did not graduate high school
Graduated high school/GED
Some College
Graduated college
Attended graduate school
Unknown
Father
Did not graduate high school
Graduated high school/GED
Some College
Graduated college
Attended graduate school
Unknown

Health Insurance

- Medicaid
Commercial
Both Medicaid and Commercial
No Insurance
Don't know

Recent Height from at least 6 months prior to this visit (to the nearest tenth) _____.____ cm/in
Not Assessed

Date the height was measured ____-____-____

Recent Past Weight from 4 months prior to this visit (to the nearest tenth) _____.____ kg/lb
Not Assessed

Date the weight was measured ____-____-____

Extent of Disease: Crohn's Disease/Indeterminate Colitis Patients Only (select one for each category):

- Macroscopic Lower GI Disease
None
Ileal only
Colonic only
Ileocolonic
Not Assessed
Don't know
Macroscopic Upper GI Disease proximal to the ligament of Treitz
Yes
No
Not Assessed
Don't know
Macroscopic Upper GI Disease distal to the ligament of Treitz
Yes
No
Not Assessed
Don't know

What is the Crohn's Disease Phenotype? (select one):

- Inflammatory, non-penetrating, non-stricturing
Stricturing only
Penetrating only
Both stricturing and penetrating
Don't know

Perianal Phenotype

- Yes
No
Don't know

Extent of Disease: Ulcerative Colitis patients only

- Ulcerative Proctitis (rectum only)
Left sided Ulcerative Colitis (distal to the splenic flexure only)
Extensive Ulcerative Colitis (extends proximal to the splenic flexure)
Pancolitis (the entire colon)
Not Assessed completely (colonoscopy incomplete)
Don't know

Ulcerative Colitis Behavior: Has the patient ever had severe disease (defined as PUCAI >=65 or severe disease determined by PGA) as an inpatient or outpatient?

- Yes
No
Don't know

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Visit Data

Site ID: _____

Patient ID: _____

Date of Assessment: ____-____-_____

Location of assessment

In-person Telehealth (video and audio) Phone (audio only)

Assessment

Since the last visit documented in the registry, were there any visits that were not captured? (select one)

Yes No Don't know If YES, How many? _____

Current visit data entered by: _____

Primary attending gastroenterologist: _____

Secondary Provider: _____

Diagnosis/Colectomy/Ostomy

What is the patient's current diagnosis? (select one)

Crohn's Disease Ulcerative Colitis Indeterminate Colitis

Has the patient had a colectomy? (If yes, and the patient's diagnosis is UC, the patient should be deactivated) (select one)

Yes No Don't know

Date of Colectomy ____ / ____ / _____

Does the patient currently have an ileostomy or a colostomy?

(Select one): Yes No Don't know

Symptoms

In the following set of questions, describe the symptoms on the worst day in the last 7 days.

General well-being related to IBD (select one):

Well/Normal Fair Poor Don't know/Not assessed

Limitations in daily activities related to IBD (select one):

None Occasional Frequent Don't know/Not assessed

Abdominal pain due to IBD (select one):

None Mild Moderate to Severe

Don't know/Not assessed

Stools

In the following set of questions, describe the stools on the worst day in the last 7 days.

Total number of stools per day (enter 0 if none):

____.____ Not assessed

Most stools were (select one):

Formed Partially formed Liquid

Don't know/ Not assessed

Number of liquid watery stools per day (enter 0 if none):

____.____ Not assessed

Did the patient report bloody stools? (select one)

Yes No Don't know/ Not assessed

If blood was present, the typical amount was (select one)

Small amount in <50% of stools Large amount

Small amount in >50% of stools Not available/assessed

Nocturnal diarrhea (select one):

Yes No Not available/assessed

Extraintestinal Manifestations

Fever 38.5°C (101.3 degrees F) for 3 of last 7 days? (select one)

Yes No Not available/assessed

Definite arthritis? (select one) Yes No Not

available/assessed

Uveitis? (select one) Yes No Not available/assessed

Erythema nodosum? (select one) Yes No Not

available/assessed

Pyoderma gangrenosum? (select one) Yes No Not

available/assessed

Exam

Abdominal Exam (select one)

No tenderness, no mass

Mild tenderness or questionable mass without tenderness

Moderate to severe tenderness, involuntary guarding, definite mass

Don't Know

Not Assessed

Perirectal disease at current exam (select one)

Normal or asymptomatic tag, non-draining fistula without tenderness, no deep fissuring or abscess

Mildly inflamed skin tag(s), 1 to 2 indolent fistulas with scant drainage (NO tenderness, deep fissure, or abscess)

Severely inflamed skin tag(s), active fistula with drainage, tenderness, abscess or deep fissure

Don't Know

Not Assessed

Current Height: _____ cm/in

Current Weight: _____ kg/lb

For patients less than 18 years old, have height, weight and BMI been plotted on a growth chart (select one)?

Yes No Don't know

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Disease Assessment

Physician's Global Assessment of current disease status (select one):

- Quiescent Mild Moderate Severe
Don't know/Not assessed

Extent of Disease: Crohn's Disease/Indeterminate Colitis patients only (select one for each category)

Macroscopic Lower GI Disease

- None Ileal only
Colonic only Ileocolonic
Not Assessed Don't know

Macroscopic Upper GI Disease proximal to the ligament of Treitz

- Yes No
Not Assessed Don't know

Macroscopic Upper GI Disease distal to the ligament of Treitz

- Yes No
Not Assessed Don't know

For CD/IC patients only

Current Crohn's Disease Phenotype (select one):

- Inflammatory, non-penetrating, non-stricturing
Stricturing
Penetrating only
Both stricturing and penetrating
Don't know

Perianal Phenotype (select one):

- Yes No Don't know

Ulcerative Colitis patients only

Extent of Disease (select one):

- Ulcerative Proctitis (rectum only)
Left sided Ulcerative Colitis
Extensive Ulcerative Colitis
Pancolitis (the entire colon)
Not assessed completely
Don't know

Ulcerative Colitis Behavior: Has the patient ever had severe disease?

- Yes No Don't know

Nutritional and Growth Status

Nutritional Status (select one):

- Satisfactory At risk In failure Not Assessed

For patients less than 18 years old: Growth Status (select one):

- Satisfactory At risk In failure Not Assessed

Since the previous visit, has the patient been in continuous remission? (select one):

- Yes No Don't know

Since the last visit, has the patient had a serious infection? (Note: A serious infection is one that requires hospitalization or IV therapy)

- Yes No Don't know

If Yes, indicate infection:

Psychosocial Risks

Are there psychosocial factors that are felt to significantly impact the patient's medical care?

- Yes No Don't know

Laboratory Analysis

Was a blood sample drawn for laboratory analysis? (select one)

- Yes No Don't know

Date of Lab Sample:

C-Reactive Protein (CRP)

- Not Done Done on same date as above
Done on different date than above

Date of sample:

Result Outside Quantifiable Range

If result is outside the quantifiable range, select one

- Above level of quantification Below level of quantification

Lab (select one): Lab Corp Quest In-house Other

Hematocrit:

- Not Done Done on same date as above
Done on different date than above

Date of sample:

Result

Erythrocyte Sedimentation Rate (ESR):

- Not Done Done on same date as above
Done on different date than above

Date of sample:

Result Outside Quantifiable

If result is outside the quantifiable range, select one

- Above level of quantification Below level of quantification

Albumin:

- Not Done Done on same date as above
Done on different date than above

Date of sample:

Result

Was a stool sample drawn for laboratory analysis? (select one)

- Yes No Don't know

Date of Stool Lab Sample:

Fecal Calprotectin

- Not Done Done on same date as above
Done on different date than above

Date of sample:

Result Outside Quantifiable Range

If result is outside the quantifiable range, select one

- Above level of quantification Below level of quantification

Lab (select one): Lab Corp Quest In-house Other

Lactoferrin

- Not Done Done on same date as above
Done on different date than above

Date of sample:

Numerical Result Outside Quantifiable Range (OR) Negative Positive

If result is outside the quantifiable range, select one

- Above level of quantification Below level of quantification

Lab (select one): Lab Corp Quest In-house Other

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Medications

Is the patient currently taking any non-biologic prescription medications for IBD? (select one)

- Yes No Don't know

Aminosalicylates

Is the patient taking any oral aminosalicylates?

- Yes No

- Mesazaline (oral) Dose mg/day
Sulfasalazine Dose mg/day
Pentasa Dose mg/day
Asacol Dose mg/day
Apriso Dose mg/day
Lialda Dose mg/day
Colazal Dose mg/day
Delzicol Dose mg/day
Salofalk Dose mg/day

Rectal Therapy

Is the patient taking any rectal therapy?

- Yes No

- Rowasa Dose mg/day
Canasa Dose mg/day
Mesalazine Dose mg/day
Hydrocortisone enema/suppository Dose mg/day

Corticosteroids

Is the patient taking any corticosteroids?

- Yes No

- Prednisone Dose mg/day
Budesonide Dose mg/day
Methylprednisolone Dose mg/day

Immunomodulators

Is the patient taking any immunomodulators?

- Yes No

- 6MP Dose mg/day
Azathioprine Dose mg/day
Allopurinol Dose mg/day
Tofacitinib Dose mg/wk
Methotrexate Dose mg/wk
Methotrexate Route (select one):
Subcutaneous PO IM Don't know
Folic Acid Dose mg/day

Other Immune Suppressants

Is the patient taking cyclosporine, tacrolimus or sirolimus?

- Yes No

- Cyclosporine Dose mg/day
Tacrolimus Dose mg/day
Sirolimus Dose mg/day

Antibiotics for IBD

Is the patient taking any antibiotics for IBD?

- Yes No

- Cipro Dose mg/day
Flagyl Dose mg/day
Rifaximin Dose mg/day

Enteral Nutrition

Is the patient currently taking the following?

An enteral caloric intake supplement? (select one)

- Yes No Don't know

Enteral nutrition as primary therapy? (select one)

- Yes No Don't know

Other Medication

Other prescription medications for IBD (per site discretion)

Rx: Dose/Unit/Interval

Rx: Dose/Unit/Interval

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Biologics Information

Infliximab

- Remicade Dose, Treatment Period, Dosing Interval, Induction
Remsima Dose, Treatment Period, Dosing Interval, Induction
Inflectra Dose, Treatment Period, Dosing Interval, Induction
Renflexis/Flixabi Dose, Treatment Period, Dosing Interval, Induction
Ixifi Dose, Treatment Period, Dosing Interval, Induction

Cerolizumab

- Cimzia Dose, Treatment Period, Dosing Interval, Induction

Adalimumab

- Humira Dose, Treatment Period, Dosing Interval, Induction
Amjevita/Solymbic Dose, Treatment Period, Dosing Interval, Induction
Cyltezo Dose, Treatment Period, Dosing Interval, Induction
Imraldi Dose, Treatment Period, Dosing Interval, Induction

Natalizumab

- Tysabri Dose, Treatment Period, Dosing Interval, Induction

Golimimumab

- Simponi Dose, Treatment Period, Dosing Interval, Induction

Ustekinumab

- Stelara Dose, Treatment Period, Dosing Interval, Induction

Vedolizumab

- Entyvio Dose, Treatment Period, Dosing Interval, Induction

TPMT

Has the TPMT been measured? (select one)

- Yes No

TPMT Genotype: (select one)

- Normal Heterozygous
Homozygous Recessive Not Done

TPMT Genotype Date: - - - - -

TPMT Phenotype (enzyme activity):

- Normal/High Intermediate Low Not Done

TPMT Phenotype Date: - - - - -

6MP/AZA

Has the patient had 6MP metabolites measured more recently than the test indicated above? (select one)

- Yes No Don't know

If Yes, most recent measurement date: - - - - -

Most recent 6-TGN level: _____

- Outside Quantifiable Range
If result is outside the quantifiable range, select one
Above level of quantification Below level of quantification

Most recent 6-MMPN: _____

- Outside Quantifiable Range
If result is outside the quantifiable range, select one
Above level of quantification Below level of quantification

Therapy

Infliximab Patients only

Has the patient had infliximab trough level measured more recently than the test above? (select one)

- Yes No Don't know

If yes infliximab trough level: _____

If result is outside the quantifiable range, select one:

- Below level of quantification Above level of quantification

Date of infliximab trough level measurement: - - - - -

Infliximab trough lab?

- LabCorp Prometheus Mayo ARUP

Has the patient had infliximab antibody levels measured more recently than the test above? (select one)

- Yes No Don't know

Infliximab antibody level: _____

If result is outside the quantifiable range, select one:

- Below level of quantification Above level of quantification

Date of Infliximab antibody level measurement: - - - - -

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Adalimumab Patients only

Has the patient had adalimumab trough level measured more recently than the test above? (select one)
 Yes No Don't know

If yes adalimumab trough level: _____

If result is outside the quantifiable range, select one:
 Below level of quantification Above level of quantification

Date of adalimumab trough level measurement:
____-____-____

Adalimumab trough lab?

LabCorp Prometheus Mayo ARUP

Has the patient had adalimumab antibody levels measured more recently than the test above? (select one)
 Yes No Don't know

Adalimumab antibody level: _____

If result is outside the quantifiable range, select one:
 Below level of quantification Above level of quantification

Date of adalimumab antibody level measurement:
____-____-____

Ustekinumab Patients only

Has the patient had ustekinumab trough level measured more recently than the test above? (select one)
 Yes No Don't know

If yes ustekinumab trough level: _____

If result is outside the quantifiable range, select one:
 Below level of quantification Above level of quantification

Date of ustekinumab trough level measurement:
____-____-____

Ustekinumab trough lab?

LabCorp Prometheus Mayo ARUP

Has the patient had ustekinumab antibody levels measured more recently than the test above? (select one)
 Yes No Don't know

Ustekinumab antibody level: _____

If result is outside the quantifiable range, select one:
 Below level of quantification Above level of quantification

Date of ustekinumab antibody level measurement:
____-____-____

Vedolizumab Patients only

Has the patient had vedolizumab trough level measured more recently than the test above? (select one)
 Yes No Don't know

If yes vedolizumab trough level: _____

If result is outside the quantifiable range, select one:
 Below level of quantification Above level of quantification

Date of vedolizumab trough level measurement:
____-____-____

Vedolizumab trough lab?

LabCorp Prometheus Mayo ARUP

Has the patient had vedolizumab antibody levels measured more recently than the test above? (select one)
 Yes No Don't know

Vedolizumab antibody level: _____

If result is outside the quantifiable range, select one:
 Below level of quantification Above level of quantification

Date of vedolizumab antibody level measurement:
____-____-____

Endoscopy/ Imaging

Since the last visit, has the patient had an esophagogastroduodenoscopy (EGD)? (select one)
 Yes No Don't know

Date of esophagogastroduodenoscopy (EGD):
____-____-____

Since the last visit, has the patient had a colonoscopy? (select one)
 Yes No Don't know

Date of colonoscopy:
____-____-____

Since the last visit, has the patient had a Magnetic Resonance Enterography (MRE) /Computed Tomography Enterography (CTE)/capsule endoscopy (select one)
 Yes No Don't know

Date of Magnetic Resonance Enterography (MRE) /Computed Tomography Enterography (CTE)/capsule endoscopy:
____-____-____

Activation Status

Status: Activated Deactivated Removed

Date of status change: ____-____-____

Reason for deactivation of this patient:

- Transferred to an adult gastroenterologist
- Transferred to another pediatric gastroenterology practice
- Transferred to another physician who is not a gastroenterologist
- Colectomy for ulcerative colitis
- Moved to another city
- Lost to follow-up
- Death
- Other, specify: _____

Reason for removal:

- Data Entry Error Thought to never have had IBD
- Withdraw of consent Other, specify: _____

Hospitalization Data

Date of admission: ____-____-____

Discharge Date: ____-____-____

Is hospitalization IBD related? Yes No Not Sure

Was intra-abdominal GI surgery performed during the admission?

Yes No Not Sure

Comments:
