Assessment

Look:
- Does the patient appear weak?
- Has the patient lost weight?
- Are there signs of weight loss?
- Does the patient appear dehydrated?
- Does the patient appear in distress?

Listen:
- Quantity & quality of bowel movements (e.g., change in frequency, consistency, pain upon defecation)
- Blood, mucus, or pus in stool
- Fever
- Abdominal pain or cramping
- Increased fatigue
- Upper abdominal, nausea, or vomiting
- Bleeding/irritated rectum

Recognize:
- Serum chemistry/hematology abnormalities
- Increase in infectious related adverse events
- New signs of bowel perforation (e.g., pain, tenderness, tachycardia)

Grading Toxicity

Diarhoea (increased frequency, loose, large volume, or liquidity stools)

Red Flags:
- Fever
- Sharp abdominal pain
- Severe abdominal pain
- Gradually increasing fever
- Increased heart rate

Management (including Anticipatory Guidance)

Overall Strategy:
- Rule out infectious, non-infectious, disease-related etiologies
- Assess patient & family understanding of recommendations and rationale
- Identify barriers to adherence

Advisory Treatment:
- IM/IV broad-spectrum antibiotics
- Administer antifungal agents
- Gastroenterology consult
- Consult infectious disease

ADLs = activities of daily living; po = by mouth

Diarhoea (increased frequency, loose, large volume, or liquidity stools)

Grading Toxicity

Grade 1 (Mild)
- Increase of 4–6 stools/day over baseline
- Mild increase in ostomy output compared with baseline
- Limiting instrumental ADLs

Grade 2 (Moderate)
- Increase of 4–6 stools/day over baseline
- Moderate increase in ostomy output compared with baseline
- Limiting instrumental ADLs

Grade 3 (Severe)
- Increase of >7 stools/day over baseline
- Incontinence

Grade 4 (Potentially Life-Threatening)
- Life-threatening (e.g., peritonitis, bleeding, ischemic colitis, sepsis, pneumonia)

Grade 5 (Death)
- Urgent intervention required

Colitis (inflammation of the intestinal lining)

Grade 1 (Mild)
- Asymptomatic; clinical or diagnostic observation only; intervention not indicated

Grade 2 (Moderate)
- Abdominal pain; bloated or mucous in stool

Grade 3 (Severe)
- Severe abdominal pain; peritoneal signs; medical intervention indicated

Grade 4 (Potentially Life-Threatening)
- Life-threatening (e.g., hemorrhagic colitis), urgent intervention indicated

Grade 5 (Death)
- Urgent intervention required

Overall Strategy:
- Rule out infectious, non-infectious, disease-related etiologies
- Assess patient & family understanding of recommendations and rationale
- Identify barriers to adherence

Grade 1 (Mild)
- May continue immunotherapy
- Consider tapering immunotherapy/slow taper
- Consider antimicrobial prophylaxis
- Institute bland diet; decrease fiber, uncooked fruits/vegetables, red meats, fats, dairy, oil, caffeine, alcohol
- Assure adequate hydration

Grade 2 (Moderate)
- Send stool sample for C difficile testing, culture, and ova and parasites
- Depending on institutional availability, consider fecal leukocytes/qPCR
- Consider gastroenterology consult (forflix sigmoidoscopy or colonoscopy)
- Consider abdominal/pelvic CT (w/ contrast)
- Immunosuppression to be withheld until Grade 1 or patient’s baseline (plasmapheresis, immunoblock)
- Consider anti-diarrhoeics: Imodium® (loperamide) or Lomotil® (diphenoxylate/atropine)
- If fever or loose GI symptoms persist >4 days:
  - Oral steroids* to be started (0.5 mg/kg/day or equivalent)
  - After control of symptoms, a 2–3-week steroid* taper will be initiated
  - If no response to corticosteroids* in 4 days, treat as steroid* refractory (see specific recommendations under Grades 3/4)
  - Immunosuppression to be discontinued if Grade 2 symptoms persist >14 days (plasmapheresis) or >7 days (purulence, rectorrhema, or for inability to reduce steroid* dose to ≤1.5 mg (plasmapheresis) or ≤12.5 mg prednisone or equivalent (plasmapheresis, rectorrhema) within 12 weeks

Grade 3 (Severe)
- Dose of steroids* to be increased (renal side effect)
- IV methylprednisolone 1 mg/kg/day for 3–7 days then followed by high-dose oral prednisone 1–2 mg/kg/day or equivalent
- Steroid* taper to include IV to oral transition
- Hospitalization
- GI consultation
- Assess for perianal signs, perforation (NPO & abdominal x-ray, surgical consult prn)
- Use caution with analgesics (opioids) and anti-diarrheal medications
- Steroid* taper to induce IV to oral transition

Steroid* induction,
- If not responsive within 72 hours to high-dose IV steroids:
- IV methylprednisolone 1 mg/kg/day for 3–7 days then followed by high-dose oral prednisone 1–2 mg/kg/day or equivalent
- Avoid with bowel perforation or sepsis
- PPI (lubiprostone) testing not required in this setting
- Delaying infliximab infusion may have life-threatening consequences
- Steroid* induction
- If not responsive within 72 hours to high-dose IV steroids:
- IV methylprednisolone 1 mg/kg/day for 3–7 days then followed by high-dose oral prednisone 1–2 mg/kg/day or equivalent
- Avoid with bowel perforation or sepsis
- PPI (lubiprostone) testing not required in this setting
- Delaying infliximab infusion may have life-threatening consequences

Grade 4 (Severe or Life-Threatening)
- Onset:
  - Steroid-mediated immunosuppression
  - Immunologic
  - Gastrointestinal Toxicity:
    - Severe abdominal pain; peritoneal signs; medical intervention indicated
    - Severe increase in ostomy output
    - Hospitalization indicated
    - Consider anti-diarrhoeics: Imodium® or Lomotil®
    - Consider abdominal/pelvic CT (w/ contrast)
    - Steroids* taper to include IV to oral transition
    - Hospitalization
    - GI consultation
    - Assess for perianal signs, perforation (NPO & abdominal x-ray, surgical consult prn)
    - Use caution with analgesics (opioids) and anti-diarrheal medications
    - Steroid* taper to induce IV to oral transition

*Administering Corticosteroids:

Steroid taper instructions/calculator as a guide but not an absolute
- Taper should consider patient’s current symptom profile
- Close follow-up in person or by phone, based on individual need & symptomatology
- Steroids cause indigestion; provide antacid therapy daily as gastric ulcer prevention while on steroids (e.g., proton pump inhibitor or H2 blocker if prednisone dosage ≥2 mg/kg/day)
- Review steroid medication side effects: mood changes (angry, reactive, hyperaware, euphoric, manic), increased appetite, interrupted sleep, oral thrush, fluid retention
- Be alert to recurring symptoms as steroids taper down & report them (taper may need to be adjusted)
- Very strict with acute symptoms: clear liquids; very bland, low fiber and low residue (SBAR diet)
- May require complete gut rest
- Advance diet slowly as steroids are tapered,* reduced to low doses and assess for loose or liquid stool for several days or longer
- Steroids* to be tapered slowly over at least 4 weeks
- Steroid* taper (taper 1 dose over next 4 weeks)
- Moderate persistent or relapsed symptoms with steroid* taper
- Consider gastroenterology consult for possible relapsing hospitalization
- IV steroids* to be started at 1 mg/kg/day
- Steroids* taper to include IV to oral transition
- Consider loperamide: 2 capsules at the onset & 1 with each diarrhea stool thereafter, with a maximum of 6 per day
- Steroid* taper to include IV to oral transition
- Consider diphenoxylate/atropine 1 tablets per day
- Simethicone-containing products when necessary

Long-term high-dose steroids
- Consider antimicrobial prophylaxis
- Consider additional antiinflammatory and antihistamine coverage
- Avoid anti-diarrheal medication or other laxatives
- If extended steroid use, use for corticosteroids; initiate calcium and vitamin D supplements

Implementations:
- Compare baseline assessment; grade & document bowel frequency and stool consistency, complete a bowel chart stool chart
- Early intervention with lab work and office visit if colitis symptoms are suspected
- Diarrhea and colitis may occur together or separately

RE D FLAGS:
- Rapid change in gastrointestinal function, decreased appetite
- Blaoting, nausea
- More frequent stools, constancy change from loose to liquid
- Persistent abdominal pain
- Fever

ADLs = activities of daily living; NPO = nothing by mouth; PI D = programmed cell death protein-1; po = by mouth

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