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■ Curso Pre-congreso GE Pediátrica 2010

# Model for IBD Care. A Guideline for Consistent Reliable Care

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Diagnostic and therapeutic interventions are appropriate and recommended for a very large percentage of children and adolescents with Crohn's disease and ulcerative colitis.<sup>1</sup>

# ■ Complete Diagnostic and Initial Evaluation:

- Complete blood cell count (CBC), erythrocyte sedimentation rate (ESR), and serum albumin
- Esophagogastroduodenoscopy with biopsy and colonoscopy with biopsy
- Imaging of the small intestine (upper gastrointestinal [GI] and small bowel series; or computed tomography [CT] scan with oral and intravenous [IV] contrast; or magnetic resonance imaging [MRI] with contrast enhancement; or capsule endoscopy)<sup>2</sup>
- Other studies as indicated

*Extent of Disease:* documentation of disease location (esophagus, stomach, duodenum, jejunum, ileum, right colon, transverse colon, left colon, rectum, perineum)

*Crohn's Disease Phenotype:* based on the Montreal classification (non-stricturing, non-penetrating; penetrating; or stricturing)

*Severity:* Physician Global Assessment (quiescent, mild, moderate, severe)

*Visit frequency:* it is recommended that each patient be examined and evaluated at least once every 6 months (≤ 200 days)

# ■ Treatment with 5-ASA:

When using the following medications, recommended doses are as follows:

- 1. Mesalamine 80 (60-100) mg/kg/day up to 4.8 g/day for active colitis
- 2. Mesalamine at least 30 (30-100) mg/kg/day up to 4.8 g/day for maintenance of quiescent or inactive colonic disease
- 3. Sulfasalazine 70 (50-80) mg/kg/day up to 4 g/day for active colitis
- 4. Sulfasalazine at least 25 (25-80) mg/kg/day up to 4 g/day for maintenance of quiescent or inactive colonic disease

#### ■ Treatment with Prednisone:

- 1. Prednisone is indicated for induction of remission. Long-term treatment with prednisone can induce significant adverse effects and has not been shown to be effective for maintenance of remission.
- 2. To induce remission the oral dose of prednisone is 1 mg/kg/d, rounding up to the

<sup>1</sup> The guidance in this document does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

<sup>2</sup> In patients with left-sided ulcerative colitis (distal to the splenic flexure) in whom the terminal ileum is normal on colonoscopy, not performing small bowel imaging and/or esophagogastroduodenoscopy is also consistent with the ImproveCareNow Model of Care.

#### ■ Nutritional and Growth Assessment:

Status	Definition
Nutritional status at risk	Weight percentile changed lower by one isobar or Weight stable (no gain) or 1% to 9% loss (involuntary) Body mass index <10th percentile for age (adjust for prednisone treatment)
Nutritional failure	Weight percentile changed lower by two isobars or Weight loss ≥ 10% Body mass index <3rd percentile for age (adjust for prednisone treatment)
Nutritional status satisfactory	Not at risk or failure
Growth status at risk	Height percentile changed lower by one isobar or Height percentile <10th percentile for age or Height velocity <10th percentile for age
Growth failure	Height percentile changed lower by two isobars or Height percentile <3rd percentile for age or Height velocity <3rd percentile for age
<b>Growth satisfactory</b>	Not at risk or failure

nearest 5 mg, up to 40 to 60 mg per day, for 1 to 4 weeks.

- 3. Taper prednisone and discontinue it within 16 weeks after treatment has been initiated.
  - a. Prednisone resistance is defined as an inadequate improvement after 2 to 4 weeks of treatment.
  - b. Prednisone dependence is present when a patient, who initially improves in response to such treatment, develops a recurrence when the dose is being tapered or within 6 months after prednisone is discontinued.

# ■ Treatment with Thiopurines:

- 1. Prior to initiation of a thiopurine, determine thiopurine methyltransferase (TPMT) genotype or phenotype.
- 2. Choose a starting dose of azathioprine or 6-mercaptopurine (6MP) based on TPMT. Should TPMT activity be:
  - a. absent or very low, do not use a thiopurine.
  - b. intermediate, start azathioprine at 1.0 to 1.5 mg/kg/day or 6MP 0.5 to 0.75 mg/kg/day.
  - c. normal to high, start azathioprine at 2.0 to 3.0 mg/kg/day or 6MP 1.0 to 1.5 mg/kg/day.
- 3. For a maintenance dose of thiopurine use either at least the starting dose as defined above, or base the dose on blood concentrations of thiopurine metabolites or evidence of toxicity.
- 4. Monitor CBC and alanine aminotransferase (ALT) for evidence of toxicity.
- 5. For patients treated with a thiopurine, when disease is moderately or severely active it is recommended that the 6-TGN level be measured (if not done in the previous 90 days).

#### ■ Treatment with Methotrexate:

- 1. For induction of remission the recommended dose of methotrexate is 15 mg/m² (up to 25 mg/m²) intramuscularly (IM), subcutaneously (SO) or orally once a week.
- 2. For maintenance of remission the recommended dose of methotrexate is 10 to 15 mg/m $^2$  (up to 15 to 25 mg/m $^2$ ) IM, subcutaneous or oral once a week.
- 3. Folic acid supplementation is recommended in a dose of 400 μg or 1 mg per day.
- 4. Monitor CBC and ALT for evidence of toxicity.

# ■ Treatment with Infliximab:

- 1. It is recommended that a skin test (PPD) and/or a chest radiograph for tuberculosis be obtained before initiation of infliximab therapy.
- 2. For induction of remission it is recommended that infliximab 5 mg/kg IV (or rounding

- up to the nearest 100 mg) be used as an initial dose, with repeated doses of 5 mg/kg IV 2 and 6 weeks later (0, 2, 6 weeks).
- 3. For initial maintenance of remission it is recommended that infliximab 5 mg/kg IV (or rounding up to the nearest 100 mg) be given every 8 weeks.
- 4. For patients treated with infliximab, when disease is moderately or severely active it is recommended that the infliximab trough level be measured (if not done in the previous 180 days).

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