Assessment Question: Possible Acceleration of Neoplastic Growth

- **Based on the pharmacologic activity and findings in animals, GATTEX has the potential to cause hyperplastic changes including neoplasia. In patients at increased risk for malignancy or those with active non-gastrointestinal malignancy, the clinical decision to continue GATTEX should be made based on risk-benefit considerations. GATTEX should be discontinued in patients with active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic).**

  A. True
  B. False

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Assessment Question: Intestinal Obstruction

- **Intestinal obstruction has been reported in clinical studies. Which of the following statements regarding obstruction is *true:***

  A. Patients with symptoms suggestive of these conditions should be permanently discontinued from GATTEX.

  B. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued while the patient is clinically managed. GATTEX may be restarted when the obstructive presentation resolves, if clinically indicated.

  C. GATTEX should be discontinued if mucosal hypertrophy at a stoma is observed.

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Assessment Question: Gallbladder, Biliary Tract, and Pancreatic Disease

- **Biliary disease (cholecystitis, cholangitis, cholelithiasis) and pancreatic disease (pancreatitis) have been reported in clinical studies. What is the recommended schedule for assessments for bilirubin, alkaline phosphatase, lipase and amylase?**

A. Within 6 months following initiation of GATTEX, and every 6 months thereafter.

B. Within 6 months prior to starting GATTEX, and subsequently at least every 6 months while on GATTEX, or more frequently if needed. Imaging is recommended if there are clinically meaningful changes in biliary or pancreatic functional markers.

C. At the time GATTEX is started (within 2 weeks), and then annually. Imaging is recommended for a possible obstruction if there are clinically meaningful elevations biliary or pancreatic functional markers.

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Assessment Question:
Enhanced Growth of Colorectal Polyps

- **Colorectal polyps were identified during the clinical studies in adults. In adults, colonoscopy should be done according to which of the following schedules:**

  A. Colonoscopy (or alternate imaging) of the entire colon with removal of polyps at the end of 1 year of GATTEX therapy, and subsequently every 5 years.

  B. Colonoscopy (or alternate imaging) of the entire colon with removal of polyps within 6 months prior to starting GATTEX, subsequently every 5 years.

  C. Colonoscopy (or alternate imaging) of the entire colon with removal of polyps within 6 months prior to starting GATTEX. A follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of treatment. If no polyp is found, subsequent colonoscopies should be done every 5 years or more often as needed. If a polyp is found, adherence to current polyp follow-up guidelines is recommended.

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Assessment Question:
Enhanced Growth of Colorectal Polyps

- **In children and adolescents, colonoscopy should be done according to which of the following schedules:**

  A. Colonoscopy (or alternate imaging) of the entire colon with removal of polyps within 6 months prior to starting GATTEX, and subsequently every 5 years.

  B. Perform fecal blood testing prior to initiating treatment. Colonoscopy/sigmoidoscopy is required if there is unexplained blood in the stool. Perform subsequent fecal occult blood testing annually while receiving GATTEX. Colonoscopy/sigmoidoscopy is recommended for all children and adolescents after 1 year of treatment, every 5 years thereafter while on continuous treatment with GATTEX, and if they have new or unexplained gastrointestinal bleeding.

  C. No colonoscopy is required for children and adolescents. Only fecal occult blood testing is required prior to initiating treatment with GATTEX and annually thereafter.

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Assessment Question: Fluid Overload

- **Fluid overload and congestive heart failure have been observed in clinical studies, which were deemed to be related to enhanced fluid absorption associated with GATTEX. What is the recommended management for patients regarding fluid overload?**

  A. Patients should be monitored with regard to fluid overload, especially during initiation of therapy.

  B. If fluid overload occurs, parenteral support should be adjusted and the need for continued GATTEX treatment should be reassessed.

  C. If significant cardiac deterioration develops while on GATTEX, the need for continued GATTEX treatment should be reassessed.

  D. All of the above.

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Assessment Question: Increased Absorption of Concomitant Oral Medication

- **GATTEX may increase absorption of concomitant oral medications. Altered mental status in association with GATTEX has been observed in patients on benzodiazepines in clinical studies. Which of the following statements is *true*?**

  A. Patient on concomitant oral drugs requiring titration or with a narrow therapeutic index may require dose adjustment while on GATTEX.

  B. Oral medications requiring titration or that have a narrow therapeutic index should be discontinued prior to starting GATTEX.

  C. No dose adjustment considerations are needed, but patients on oral medications should be monitored carefully.

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